ODESA NATIONAL MEDICAL UNIVERSITY

DEPARTMENT OF ORGANIZATION AND ECONOMICS OF PHARMACY
WITH POST-DIPLOMA SPECIALIZATION

# A TEXT BOOK OF
# PHARMACEUTICAL AND MEDICAL COMMODITY SCIENCE

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The lectures reveal the system of knowledge about pharmaceutical and medical commodity science. The publication provides information on the range, classification and coding of goods, the main aspects of commodity analysis of pharmacy products, regulatory documentation, packaging, labeling, storage and transportation of finished medicines and medical devices.
The course of lectures is built as a textbook that can be used in the training of specialists of the master's degree in specialty 226 "Pharmacy. Industrial Pharmacy"

| | Content | P.P |
|---|---|---|
| 1 | Fundamentals of commodity science. Normative documentation in the pharmaceutical industry. | 5 |
| 2 | Classification and coding of goods. | 16 |
| 3 | Packaging, labeling of finished medicines. Closures. | 29 |
| 4 | Commodity analysis of rubber products and patient care items | 41 |
| 5 | Commodity analysis of suture materials and puncture needles. | 50 |
| 6 | Eye optics. Commodity analysis devices and means for research, correction and protection of the organs of vision. | 58 |
| 7 | Commodity analysis of related products pharmacy assortment products | 68 |
| 8 | Acceptance of goods at the pharmacy warehouse. | 80 |
| 9 | Prevention of circulation of falsified medicinal products in Ukraine. | 89 |
| 10 | Commodity analysis medical devices for diagnosis and treatment. | 98 |
| Total: | | 116 |

# INTRODUCTION

Lecture notes on pharmaceutical and medical commodity science contains theoretical training material for independent work. The publication provides information on the range, classification and coding of goods, the main aspects of commodity analysis, regulatory documentation, packaging, labeling, storage and transportation of finished medicines and medical devices. At the beginning of each topic its relevance is substantiated.

Lecture notes are intended for students of international faculty in specialty 226 "Pharmacy, Industrial Pharmacy" qualification Master of Pharmacy.

## THEME № 1. FUNDAMENTALS OF COMMODITY SCIENCE. NORMATIVE DOCUMENTATION IN THE PHARMACEUTICAL INDUSTRY.

In economics goods are products that can be utilized to satisfy some human needs and that has exchange value. A commodity is a basic good used in commerce that is interchangeable with other commodities of the same type. Commodities are most often used as inputs in the production of other goods or services. Some traditional examples of commodities include grains, gold, beef, oil, and natural gas. More recently, the definition has expanded to include financial products, such as foreign currencies and indexes.

Consumer goods are products that people buy and do not use to make other things that are then sold. They are also called final goods because when somebody buys them, they have reached their final destination.

Consumer goods are the end result of manufacturing and production. All the food and drink that we purchase in the supermarket, all medicines and medical things that we purchase in the pharmacy, for example, are consumer goods.

Consumers are people or other entities that buy goods or services. Consumers do not sell what they bought – they 'consume' them.

Consumer goods vs. capital goods

Goods are products. We exchange money, for example, for goods and services.

Capital goods are things that businesses buy to make other things. These type of goods last a long time, i.e., they are durable. Pharmaceutical machinery, vehicles, and computers, for example, are capital goods.


*Consumer goods*

We do not buy consumer goods to make something else that we aim to sell. These goods satisfy personal needs and not the needs required for the production of other products.

*Durable and non-durable goods*

Durable goods are things that last a long time. Medical instruments and devices (glucometers, tonometer's, thermometers), refrigerators, for example, are durable goods. We do not buy them every week or every month.

Non-durable

We all buy food and drink on a regular basis. We buy bread, for example, usually at least once a week. Bread is a non-durable good. Medical preparations, dressings, things for personal hygiene, and food, for example, are non-durable goods.

If something is non-durable, it means that it does not last for a long time.

Three types of consumer goods:

Consumer goods are classified into three categories:

– Durable goods.

– Non-durable goods.

– Services – the non-physical, intangible part of a nation's economy. We cannot touch, see, or handle services. Education, transportation, and banking, for example, are services. We cannot touch banking, nor can we weigh it or measure its length.

**Product Standardization**

Product standardization is the process of setting generally uniform characteristics for a particular good or service. Product standardization provided by different businesses operating in technology-based industries can be useful for consumers since it permits competition among the various suppliers.

Standardization and certification have undergone a continuous development in recent years, closely related to the development of the specific legislation.

The term "standard" has been used related to characteristics (dimensions, forms, physical or chemical properties, etc) of products as well as related to the conditions for safety at work or to the skills of employers and good behavior of people. The significance of the term "standard" used to be: a generally accepted document that provides rules, guidelines or characteristics for activities or their results, whatever the provider of the document is (tradition, a manufacturer, a governmental authority or a standardization association).

The first standards appeared during the Industrial Revolution with the need to make interchangeable part and dealt with sizes for screws, nuts bolts and other threaded fasteners, then pipe sizes or shoe size. In the late 19th century safety standards appeared, prepared by governmental authorities in United States of America and England. At the beginning of the 20th century standardization organizations have been formed.

In the late years, in order to avoid misunderstanding, the international standards organizations made efforts to establish a clear terminology making the difference between the rules depending the provider, as:

- normative document = ‘document (any medium with information recorded on or in it ) providing rules, guidelines or characteristics for activities or their results; it covers standards, technical specifications, codes of practice and regulations’;

- technical specification = ‘document prescribing technical requirements to be fulfilled by a product, process or service; it may be a standard, a part of a standard or independent of a standard’;

- code of practice = ‘document that recommends practices or procedures for the design, manufacture, installation, maintenance or utilization of equipment, structures or products; it may be a standard, a part of a standard or independent of a standard’;

- regulation = ‘document providing binding legislative rules, adopted by an authority’;

- standard = ‘document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context’.

Standards have public availability and should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

Standardization consists in activity of ‘establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context’. In particular, the activity consists of the processes of formulating, issuing and implementing standards. Usually the standardization is a process based on consensus of the interested parties forming the standardization organization.

The subject of standardization can be any topic to be standardized, meaning any material, component, equipment, system, interface, protocol, procedure, function, method or activity; the phrase ‘a product, a process or a service’ is usually used. Standardization can cover different fields: engineering, pharmacy practice, transport, agriculture; quantities and units.

Objectives and application

Standardization may have one or more specific aims, to make a product, process or service fit for its purpose, comprising but not restricted to:

- variety control or variety reduction, meaning the selection of the optimum number of sizes or types of products, processes or services to meet prevailing needs;
- usability;
- compatibility, suitability of products, processes or services for use together under specific conditions, without causing unacceptable interactions;
- interchangeability or the ability of one product, process or service to be used in place of another to fulfill the same requirements; it may be “functional interchangeability”, or “dimensional interchangeability”;
- health;

- safety = freedom from unacceptable risk of harm;
- protection of the environment;
- product protection against climatic or other adverse conditions during its use, transport or storage;
- mutual understanding, achievement of an easier communication, facilitation of processes and tasks; economic performance; trade.

A standard is used by companies or authorities as references in order to:

- prove, towards the customers, a certain level of quality /the performances of a product;
- ensure compatibility, allowing the new product to be used by the consumers in connection with others owned product; ensure interchangeability;
- improve efficiency to handle people, their interactions, cases, modernization, bureaucratization, homogenization, and centralization of society (in social sciences, when establishing criteria for diagnosing mental disease);
- enable organizations to focus their attention on delivering excellence in customer service, whilst providing recognition of success through a third party organization;
- demonstrate the compliance with the regulations.

Standardization improves the suitability of products, processes and services for their intended purposes, prevents the barriers to trade and facilitates the technological cooperation. In European Union, it is considered that standardization can make an important contribution to the development of sustainable industrial policy, unlock the potential of innovative markets and strengthen the position of European economy by capitalizing more efficiently on its knowledge basis.

*Levels of Standards*

The geographical, political or economic extent of involvement in standardization process leads to the levels of standardization given in Table 1. Each level is coordinated by a standardization organization, gathering interested parties from the relevant region: individual manufacturers and users/ consumers or professional organizations, trade-unions, representative of research institutes or testing laboratories, public authorities, certification bodies etc.

Table 1: Levels of standards

| | | | |
|---|---|---|---|
| Regional | - opened to relevant **bodies** from countries from only one geographical, political or economic area of the world;<br>- In every continent there are at least 2 regional organisations.' | **CEN** (European Committee for Standardisation), | EN xxx:abcd |
| | | **CENELEC** (European Committee for Electrotechnical Standardisation), | CEI xxx:abcd |
| | | *'ARSO -ORAN* ***(African Regional Organization for Standardisation),'*** | ARS xx |
| | | **COPANT** (Pan American Standards Commission), | **NORMA COPANT xxxx-abcd**<br>**COPANT-ISO/IEC xxx**<br>**GUÍA COPANT-ISO/IEC xxx** |
| National standardisation | - takes place at the level of one specific country<br>***- one organisation/ country'*** | **AFNOR** (Association Française de Normalisation) | NF xxx:abcd<br>NF EN xxx:abcd |
| | | **BSI** (British Standards Institution - BSI Group- Great Britain) | BS xxx:abcd<br>BS EN xxx:abcd |
| Provincial standadization | - take place on a branch or sectoral basis (e.g. ministries), at local levels, at association and company levels in industry and inindividual factories, workshops and offices | - branch standards and company standards | OHSAS xxxx: abcd<br>X ST (or TS) xxxx:abcd<br>(where X = name of company or association; ST = code for the document/ technical specification) |

ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. ISO is a non-governmental organization, including 163 countries national standardization organizations (one member per country), with a Central Secretariat in Geneva, Switzerland. Other international organizations, governmental and non-governmental, in liaison with ISO also take part in the process of elaboration of new standards. ISO has developed over 19,000 International Standards. Over 1,000 new ISO standards are published every year.

CEN (The European Committee for Standardization [CEN, French: Comité Européen de Normalization]) is the major provider of European Standards and technical specifications and the only European organization recognized, according to European Directive 98/34/EC, for the planning, drafting and adoption of European Standards in all areas of economic activity, with the exception of electrotechnology (CENELEC) and telecommunication (ETSI). CEN is a non-profit organization, created in 1975. CEN National Members are the National Standards Bodies (NSB) of the 27 European Union countries, Croatia and Turkey plus three countries of the European Free Trade Association (Iceland, Norway and Switzerland). There is one member per country. The CEN Members have voting rights in the General Assembly and Administrative Board of CEN and provide delegations to the Technical Board, which defines the work program.

In order to avoid barriers to trade caused by deferring national standards in the different member states of the EU, the European Directive 98/34/EC stipulates a mutual obligation of the CEN National Members to implement European Standards as national standards and to withdraw any conflicting national standards, as well as a procedure to inform both the other member states and the Commission in advance when a new national standard is planned to be adopted.

CEN has signed the 'Vienna Agreement with the International ISO through which common European and international standards can be developed in parallel. More than 30% of the European Standards adopted by CEN are identical to international standards. In addition, a number of ENs developed by CEN is closely linked to ISO standards.

In general, each country or economy has a single recognized National Standards Body, which is the sole member in ISO, as well as in CEN. A National Standards Body may be either public or private sector organizations, or combinations of the two. The national standardization includes a process of adoption of international or regional standards, as well as a process of development of new, specific standards.

Types of Standards and Other Normative Documents

Each standard is identified by a code composed by groups of letters specific to the standards organization (see table 1) and a unique numeric index, followed by the year of approval.

The normative documents can be classified taking into account:

- the level of standardization (see above);
- the process of standardization;
- the content, the subject of standardization;
- the way of implementation.

Depending on the process of standardization, the documents established by the international standards organizations (ISO, CEI) as well as by CEN are delivered as:

- *Standard* – document issued when the process of standardization respects all the established rules;

- *Publicly Available Specification* (eg. ISO/PAS) - a document representing the consensus of a working group, which have been approved by the simple majority of the members of the Technical Committee; usually, it is a consultative document, giving more solutions;

- *Technical Specification* (e.g. ISO/TS) - a pre-standard, submitted to a simplified vote procedure in a Technical Committee which contains technical requirements for innovative technology or various alternatives which need to coexist in anticipation of future harmonization;

- *Technical Report* (e.g. ISO/TR 10017) - a document that has not the content of a standard, prepared when it is considered urgent to give additional information or advise on a subject and submitted to a simplified vote procedure in a Technical Committee;

- *Guide* - a document providing rules, orientation, advice or recommendations relating to European standardization (e.g.: information or guidance on matters of conformity assessment in relation to the standardization activities).

Following the subject of standardization, the standards can be classified, for example, in:

- *Basic standard* = standard that has a wide-ranging coverage or contains general provisions for one particular field; it may be used as a standard for direct application or as a basis for other standards (e.g. EN 420 containing general requirements for protective gloves).
- *Terminology standard* = standard that is concerned with terms, usually accompanied by their definitions, and sometimes by explanatory notes, illustrations, examples, etc (e.g.: EN 1005-1 and EN 1005-2 containing terms and definition on human physical performance related to safety of machinery, CEN ISO/TR 11610:2004 containing vocabulary on protective clothing or EN 60743: 2001/ IEC 60743: 2001 on terminology for tools, equipment and devices designed for live working).
- *Testing standard* = standard that is concerned with test methods (mechanical, electrical, chemical ergonomic or practical testing, specific to groups of products, to materials or on human subjects), sometimes supplemented with other provisions related to testing, such as sampling, use of statistical methods (ISO 2859-1, ISO 2859-2, ISO/TR 10017), sequence of tests.
- *Product standard* = standard that specifies requirements to be fulfilled by a product or a group of products, to establish its fitness for purpose; it may include in addition, directly or by reference, aspects such as terminology, sampling, testing, packaging and labeling and, sometimes, processing requirements; a product standard can be either complete or not, respectively it specifies all or only a part of the necessary requirements (e.g.: EN ISO 11612 regarding protective clothing against flames and heat)..
- *Process standard* = standard that specifies requirements to be fulfilled by a process, to establish its fitness for purpose (e.g.: OHSAS 18001 on occupational health and safety management systems).
- *Service standard* = standard that specifies requirements to be fulfilled by a service, to establish its fitness for purpose (e.g.: service standards prepared in fields such as transport, insurance, banking, trading).
- *Safety standards* = a standard concerned with freedom from unacceptable risk of harm; it can be a standard dealing with evaluation of risks (e.g. EN ISO 12100 on risk assessment and risk reduction of machinery, PAS 1010 – draft document on psychosocial risk management) or a product standard containing safety requirements, such as those mentioned above;
-*Environmental standard* = a policy guideline that regulates the effect of human activity upon the environment; it may specify a desired state (e.g. lake pH should be between 6.5 and 7.5) or limit alterations (e.g. no more than 50% of natural forest may be damaged).
- *Interface standard* = standard that specifies requirements concerned with the compatibility of products or systems at their points of interconnection.

- *Standard on data to be provided* = standard that contains a list of characteristics for which values or other data are to be stated for specifying the product, process or service (e.g.: data to be stated by suppliers in the information file).

**Regulatory framework for medical devices and personal protective equipment in the EU.**

Medical devices within the EU are currently regulated by the following Directives:

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (hereafter referred to as AIMDD)

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (hereafter referred to as MDD)

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (hereafter referred to as IVDD)

Medical devices can also already be placed on the EU market if they comply with the following new Regulations which entered into force in May 2017:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April

2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC6 (hereafter referred to as MDR, fully applicable as from 26 May 2021)

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU7 (hereafter referred to as IVDR, fully applicable as from 26 May 2022)

The temporal scope and the conditions of applicability of the relevant legal requirements to devices, from the AIMDD, the MDD and the IVDD (hereafter referred to as Directives) to the MDR and the IVDR (hereafter referred to as new Regulations on medical devices), are governed by specific transitional provisions.

On the other hand, personal protective equipment within the EU is currently regulated

by Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (hereafter referred to as PPER).

In order to lawfully place on the EU market medical devices under the scope of the Directives or the new Regulations, as well as personal protective equipment under the scope of the PPER, these products must be CE-marked10 with the EC or EU declaration of conformity signed and issued by the manufacturer.

In the EC or EU declaration of conformity, manufacturers must declare that their products comply with the applicable EU legislative act(s) and requirements. There are however no obligations in the EU legal framework to separately draw up declarations of compliance with national legislation, as well as with national, European or international standards.

The Directives and the new Regulations on medical devices, and the PPER, in line with the main pieces of the EU legislation concerning the internal market for goods, lay down essential safety and performance requirements and health and safety requirements, respectively, but do not prescribe any specific mandatory technical solutions for the manufacturing and design of the products. Therefore, the manufacturer can choose which technical solution(s) to use to comply with these legal requirements. Manufacturers can use those offered in harmonized European standards or in other standards or technical specifications, or can come up with their own technical solution(s). The use of harmonized European standards is a voluntary means to comply with the legal requirements. On the contrary, where a manufacturer chooses not to follow a harmonized European standard, it must demonstrate that the alternative technical solution applied is adequate to ensure compliance of the product with the applicable legal requirements. The manufacturer must also prepare and maintain the relevant technical documentation for the product, in support to the compliance claimed in the EC or EU declaration of conformity. Such technical documentation has to be kept and made available to national competent authorities upon their request.

For medical devices, manufacturers outside the EU must designate a single authorized representative in the EU. Information on the authorized representative must be available at least on the EC or EU declaration of conformity, on the certificate where applicable, and on the labelling of the device.

For certain medical devices and personal protective equipment, the manufacturer needs to involve a notified body in the prescribed conformity assessment procedure(s). Once the notified body assesses the compliance of the product with the relevant requirements of the applicable EU legislation, it will issue the appropriate certificate (as for example an EC or EU type-examination certificate, a design-examination certificate or a quality management system certificate). Such product must be CE-marked followed by the 4-digits identification number (NB xxxx) of the notified body. Conformity assessment procedures can include audits of manufacturers and/or critical suppliers/subcontractors, testing or review of technical documentation (such as test reports, manufacturer’s risk assessment and/or management process, drawings and clinical data) in support of compliance of the product with the applicable legal requirements.

Only documents which are explicitly referred to in the applicable EU legislation (namely the EC or EU declaration of conformity and, where needed, certificates issued according to the relevant conformity assessment procedures) may be drawn up and used for the purpose of lawfully placing a product on the EU market. Therefore, any other document is not valid for such a purpose. In practice there are several examples of documents which have no legal status according to the applicable EU legislation, for instance the so-called "certificate of compliance", "attestation of compliance", "certificate of conformity", "certificate of notification", "certificate of registration", "documentation review" or similar, which do not comply with the requirements of an EC or EU declaration of conformity issued by the manufacturer or a certificate issued by a notified body. Those "other documents" with no legal status according to the applicable EU legislation are issued by different kinds of entities, for instance non-notified conformity/certification bodies but also bodies notified under other EU legislative acts, or testing houses or laboratories, or even authorized representatives, etc. Even if such documents may include some elements of a declaration of conformity or a certificate, they are usually voluntary statements that manufacturers request from third parties but do not provide any legal basis to place products on the EU market.

These statements may address different issues such as compliance with legislation or standards, appropriateness of the technical documentation and so on, but do not constitute "declarations of conformity" (because valid declarations of conformity can only be issued by manufacturers) nor "certificates" (because valid certificates can only be issued by notified bodies designated for the specific legislative act) within the meaning of the applicable EU legislation.

These voluntary statements may be included in the technical documentation as supporting documents to provide evidence of compliance with certain applicable requirements. However, they can never replace the EC or EU declaration of conformity issued by the manufacturer, or the certificate(s) issued by notified bodies, as prescribed by the applicable EU legislation.

A valid EC or EU declaration of conformity must be drafted and signed by the manufacturer, and include as a minimum:

- ✓ the identification and description of the product;
- ✓ the EU legislative act(s) to which conformity is claimed;
- ✓ the name and address of the manufacturer, and/or of the authorised representative, where applicable;
- ✓ a statement that the declaration is issued under the sole responsibility of the manufacturer;
- ✓ the conformity assessment procedure(s) applied;

- ✓ references to the relevant harmonized European standard(s) or common specification(s) used, where applicable;
- ✓ the name and the 4-digits identification number (NB xxxx) of the notified body and reference to the certificate(s) issued, where applicable;
- ✓ date of issue of the declaration, identification and signature of the manufacturer.

*The main characteristics of a valid certificate*

There are two types of certificates that can be issued by a notified body under the applicable EU legislation, in view of placing medical devices or personal protective equipment on the EU market: product certificates and quality management system certificates. The first certifies that the product complies with the relevant requirements (after the notified body has reviewed the relevant technical documentation and/or has performed the relevant tests). The latter certifies the quality management system of the manufacturer for a defined product range (either in its entirety or in aspects limited to production or product quality assurance).

A valid certificate under the applicable EU legislation (as for example an EC or EU type-examination certificate, a design-examination certificate or a quality management system certificate) is issued by a notified body after the successful completion of the conformity assessment procedure applicable to the product. Notified bodies are designated by the relevant national authorities to perform specific conformity assessment procedure(s) and thus to issue the related certificate(s), for specific types of products or quality management systems under different EU legislative acts. Only those notified bodies listed in the Commission's NANDO information system: https://ec.europa.eu/growth/tools-databases/nando/ are entitled to issue valid certificates, within their scope and competences:

- List of notified bodies for the AIMDD: https://ec.europa.eu/growth/tools databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8
- List of notified bodies for the MDD: https://ec.europa.eu/growth/tools databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13
- List of notified bodies for the IVDD: https://ec.europa.eu/growth/tools databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20
- List of notified bodies for the MDR: https://ec.europa.eu/growth/tools databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
- List of notified bodies for the IVDR: https://ec.europa.eu/growth/tools databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

- List of notified bodies for the PPER: https://ec.europa.eu/growth/tools databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501

Every certificate issued by a notified body prior to placing medical devices or personal protective equipment on the EU market must specify the conformity assessment procedure applied, and may include references to the test reports if applicable and other relevant technical documents, as well as to the harmonized European standards used if it is the case. The name and the 4-digits identification number (NB xxxx) of the notified body must be clearly indicated on the certificate.

*Principles of affixing the CE marking.*

"A minimum height of 5 mm is required to ensure that it is legible. However, according to the several pieces of legislation (*220) the minimum dimension of the CE marking may be waived for small devices or components."

For medical devices, the involvement of a notified body is required for the conformity assessment procedures applicable to class III, IIa and IIb devices, as in the case of respiratory patient ventilators, as well as for class I devices supplied in sterile condition or with measuring functions. For other class I devices, as in the case of medical face masks (often referred to as type I, II or IIR masks16), gloves and overalls when supplied in non-sterile condition, the intervention of a notified body is not required, and manufacturers are entitled to carry out the applicable conformity assessment procedure under their sole responsibility ("self-assessment").

For in vitro diagnostic medical devices, under the IVDD, notified body intervention is required for devices intended for self-testing, i.e. devices intended by the manufacturer to be used by lay persons in a home environment17. It is also required for devices listed in Annex II of the IVDD. Under the IVDR, notified bodies are involved in conformity assessment of class B, C and D devices, as well as class A sterile device.

For products under the scope of the PPER, a notified body is required for the conformity assessment procedures applicable to risk categories II and III equipment. In particular, respiratory protection face masks used in the COVID-19 context (often referred to as FFP2 or FFP3 masks18) are products falling in category III and as such a notified body must be systematically involved in the conformity assessment procedures prior to placing these products on the EU market.

CE 0086

## THEME № 2. CLASSIFICATION AND CODING OF GOODS.

The important concept at work with the information is classification of objects.

*Classification* is a method of distribution of objects (subjects, the phenomena, processes, concepts) to classes according to the certain attribute. The object is understood as any subjects, processes, and the phenomenon of material or non-material property. The system of classification allows to group objects and to allocate to the certain classes which will be characterized by a number of the common properties. Classification of objects is a procedure of grouping at the qualitative level, directed to allocation of homogeneous properties.

With reference to the information as to object of classification the allocated classes are named as information objects. Properties of the information object are defined by the information parameters named essential elements. Essential elements are represented as the numerical data, for example, weight, cost, year, or attributes, and for example, color, mark of machine, a surname. Essential element is a logically indivisible information element describing certain property of object, processes, the phenomenon, etc. Except for revealing the common properties of information object classification is necessary for the development of rules (algorithms) and procedures of processing of the information submitted by set of essential elements.

At any classification it is desirable, that the following requirements were observed:

- Completeness of scope of objects of considered area;
- Un-ambiguity of essential elements
- An opportunity of inclusion of new objects.
- The qualifier is the systematized arch of names and codes of classification groupings.

At classification concepts a classification attribute and the value of a classification attribute which allow for establishing similarity or distinction of objects are widely used. The approach to classification with association of these two concepts in one, is named as an attribute of classification. The attribute of classification also has a synonym, i.e. the basis of division.

Three methods of classification of objects are developed:

- Hierarchical
- Facet (facet is a group of headings which all define a certain method of classification. That is, a facet is a way in which a resource can be classified; for example, classified by color, classified by geography, classified by subject, etc.)
- Descriptor (Descriptor system is a semi-hierarchical system with several descriptors for describing the state of goods and other objects of nature; Descriptor subsets should be selected for the study goals.

*Hierarchical system of classification.*

The hierarchical system of classification is created by the following method:

- The initial set of elements makes 0-1 level and shares depending on the chosen classification attribute on classes (grouping) which form the 1st level.
- Each class of the 1st level according to a classification attribute shares on subclasses which form the 2nd level;
- Each class of the 2nd level similarly shares on groups which form the 3rd level, etc.

Taking into account rigid enough procedure of the construction of structure of classification, it is necessary to determine its purpose before the beginning of work, i.e. what properties objects united in classes should possess. These properties are accepted further for attribute of classification.

Remember –in hierarchical system of classification the special attention should be given to a choice of classification attribute. In hierarchical system of classification each object at any level should be related to one class which is characterized by concrete value of the chosen classification attribute.

Advantages of hierarchical system of classification:

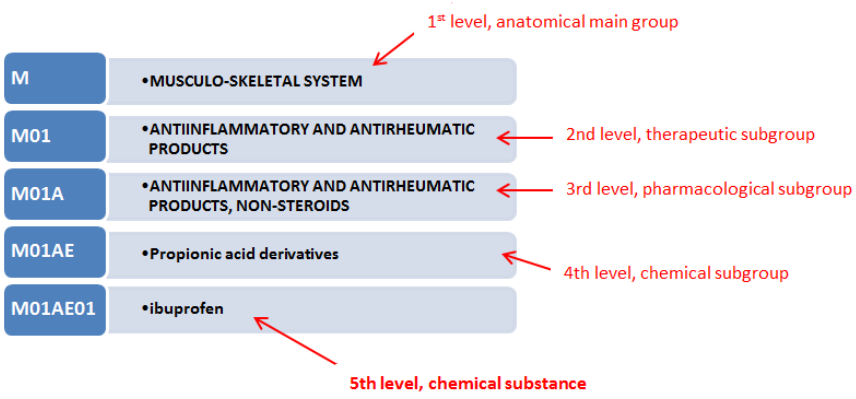
Simplicity of construction;

Use of independent classification attributes in various branches of hierarchical system .

Lacks of hierarchical system:

Rigid structure which leads to the complexity of modification as it necessary to redistribute all classification groupings;

Impossibility to group objects on beforehand not stipulated combinations of attributes




The hierarchical classification: Anatomical Therapeutic Chemical Classification System (ATC)

*Faceted classification*

Faceted classification means breaking subjects into standard component parts, or facets. Faceted method of classification is based on parallel division of subjects by classification attributes.

Faceted method of classification allows for removing or adding new classification attributes (facets), thus it possess more flexible structure.

Product classification is to automatically divide products into a set of categories or classes. The classification of goods according to the Foreign Economic Activity Commodity Nomenclature of the Customs Union (hereinafter referred to as the FEACN of the CU) is one of the most relevant issues for participants of the foreign economic activity (hereinafter referred to as the FEA).

The accuracy of the classification of goods is of great importance for better objectivity of customs statistics of the foreign trade, used in the course of development of the customs policy of the Member States of the Customs Union, and for adoption of specific measures for its implementation during customs clearance and control of goods and vehicles.

Participants of the FEA shall determine, on their own, the code of goods crossing the customs border.

In case of incorrect classification of goods during their declaration, the classification code shall be determined by the customs authority.

*Criteria and rules of classification*

1. Criteria of classification – a property or characteristic of an object (product) that forms the basis of its classification (purpose, type of material, structure, construction, manufacturing process, finishing etc.). The classification of goods is based on criteria, such as the raw materials in use, chemical composition, application etc.

2. There are six rules of classification of goods – these are Fundamental Rules of Interpretation of the FEACN (hereinafter referred to as the FRI of the FEACN).

Creation of the commodity nomenclature used today in the international practice of the FEA is preceded by a long history.

For the purpose of state regulation of export and import of goods in the Customs Union, the international classifier – Foreign Economic Activity Commodity Nomenclature of the Customs Union (FEACN of the CU) – is used.

It is based on the experience in international trade and provisions of the International Convention on the Harmonized Commodity Description and Coding System. Thus, the FEACN of the CU is based on the nomenclature of the Harmonized Commodity Description and Coding System and the Combined Nomenclature of the European Community.

The first six digits of the product code correspond to the HS nomenclature, the seventh and eighth digits – to the Combined Nomenclature of the European Community, the ninth digit – to the

FEACN of the CIS. The tenth digit of the product code is designed for detailing of goods at the national level.

The Harmonized Commodity Description and Coding System, also known as the Harmonized System (HS) of tariff nomenclature is an internationally standardized system of names and numbers to classify traded products. It came into effect in 1988 and has since been developed and maintained by the World Customs Organization (WCO) (formerly the Customs Co-operation Council), an independent intergovernmental organization based in Brussels, Belgium, with over 200 member countries.

*Harmonized system* – a commodity nomenclature that includes commodity items and sub-items, relevant digit codes divided into groups and sections based on certain criteria, notes and fundamental rules of interpretation of the Harmonized System.

The basic principle of the Harmonized System consists in mandatory comparability of national and international data on foreign trade of any country.

The basic provisions of the Convention define the following: certain countries or groups of countries acceded thereto may, based on the Harmonized System, develop their commodity nomenclature and customs tariffs with a better level of detail of commodity sub-items in complementary structural elements in addition to a six-digit code specified in the nomenclature of the Harmonized System.

The classification scheme of the Harmonized System meets the following three conditions:

goods are divided into groups so that goods within each group have one common criterion. All parts of the classification are independent and can be subdivided;

goods can be only classified at a time based on one main criterion;

goods shall be first classified based on more general criteria, and then – based on more detailed (specific) criteria.

Thus, development of the Harmonized System was part of general conditions designed to facilitate international trade procedures, overcome tariff and non-tariff barriers, standardize international trade documents and get the opportunity to exchange data in soft form.

Today there are more than 170 countries that develop their customs tariffs and commodity nomenclatures based on the Harmonized Commodity Description and Coding System.

Thus, the Harmonized System is the first international nomenclature that takes into account the requirements of foreign trade statistics.

Together with creation of the nomenclature of the Harmonized System, the International Convention as to application thereof has being developed in parallel.

The contracting parties shall take the following commitments under the Convention:

- use all commodity items and sub-items of the Harmonized System and their respective codes without any additions and alterations;
- follow the basic rules of classification for interpretation of the Harmonized System, all notes; do not change the volume of sections and groups of the Harmonized System;
- comply with the coding procedure specified in the Harmonized System;
- publish their statistics on import and export of goods;
- have the right, for the purpose of the national nomenclature of customs tariffs or statistical nomenclature, to create subsections for classification of goods using more characters compared to the Harmonized System (provided that they are added to a six-digit code specified in the Harmonized System).

The commodity group includes the first two digits, the commodity item – four digits, sub-item – six digits and sub-sub-item – ten digits.

Ukrainian Goods nomenclature of foreign trade activities actually is the classifier of the goods - the systematized list of goods, allowing finding a place to each goods and after that to assign to it the certain code of the goods. Coding (classification) of the goods is made according to Goods nomenclature of foreign trade activities and is a technique allowing to present the classified goods in the form of the group of the signs established by the given classifier. The goods code is to be indicated in the cargo customs declaration.

System of Coding

Common concept:

The System of Coding is applied to replacement of name of object(code) worth a view to maintain the convenient and more effective processing of the information

System of Coding is the set of rules of a code designation of objects

The code is constructed on the basis of the alphabet consisting of letters, figures and symbols. The code is characterized by:

The length – a number of positions in a code

Structure – the order of an arrangement in a code of the symbols used for a designation of a classification attribute.

Coding is the procedure of assignment to object of a code designation. There are two groups of the methods used in system coding form:

The classification system of coding focused on carrying out the preliminary classification of object either on the basis of hierarchical system or on the basis of facet systems;

The registration system of coding which is not demanding preliminary classification of objects.

Consecutive coding is used for hierarchical system classification structure. The essence of the method consists in the following: the code of the senior grouping of the 1st level then a code of grouping of the 2nd level then a code of grouping of the 3rd level, etc., first enters the name. The result is the code combination where each category contains the information on specificity of the allocated group at each level of hierarchical structure. The consecutive system of coding possesses the same merits and demerits as the hierarchical system of classification.

Two systems of coding are widely used: *UPC and EAN systems.*

The Universal Product Code (UPC) (UPC code) is a barcode symbology that is widely used in the United States, Canada, Europe, Australia, New Zealand, and other countries for tracking trade items in stores.

UPC (technically refers to UPC-A) consists of 12 numeric digits that are uniquely assigned to each trade item.

The International Article Number (also known as European Article Number or EAN) is a standard describing a barcode symbology and numbering system used in global trade to identify a specific retail product type, in a specific packaging configuration, from a specific manufacturer. The standard has been subsumed in the Global Trade Item Number standard from the GS1 organization; the same numbers can be referred to as GTINs and can be encoded in other barcode symbologies defined by GS1. EAN barcodes are used worldwide for lookup at retail point of sale, but can also be used as numbers for other purposes such as wholesale ordering or accounting.

The most commonly used EAN standard is the thirteen-digit EAN-13, a superset of the original 12-digit Universal Product Code (UPC-A) standard developed in 1970 by George J. Laurer. An EAN-13 number includes a 3-digit GS1 prefix (indicating country of registration or special type of product). A prefix with a first digit of "0" indicates a 12-digit UPC-A code follows. A prefix with first two digits of "45" or "49" indicates a Japanese Article Number (JAN) follows.

The less commonly used 8-digit EAN-8 barcode was introduced for use on small packages, where EAN-13 would be too large.

A typical EAN-13 bar code looks something like this:



COMPONENTS OF AN EAN-13 BARCODE

An EAN-13 bar code is divided into four areas: 1) The number system, 2) The manufacturer code, 3) the product code, and 4) the check digit. Normally the first number system digit is printed just to the left of the bar code, the second number system digit is printed as the first character of the group of six numbers on the left-hand side below the bar code, the manufacturer code is the next five digits on the left-hand side below the bar code, the product code product code is the first five digits on the right-hand side below the bar code, and the check digit is the last digit on the right-hand side below the bar code.

Number System: The number system consists of two digits (sometimes three digits) which identify the country (or economic region) numbering authority which assigned the manufacturer code. Any number system which starts with the digit 0 is a UPC-A bar code. The valid number system codes are presented in the following table:

| | |
|---|---|
| 0 | USA / Canada |
| 1 | USA |
| 30–37 | France & Monaco |
| 380 | Bulgaria |
| 383 | Slovenia |
| 385 | Croatia |
| 387 | Bosnia & Herzegovina |
| 389 | Montenegro |
| 390 | Kosovo |
| 40–44 | Germany |

| | |
|---|---|
| 45 | Japan |
| 46 | Russia |
| 470 | Kyrgyzstan |
| 471 | Taiwan |
| 474 | Estonia |
| 475 | Latvia |
| 476 | Azerbaijan |
| 477 | Lithuania |
| 478 | Uzbekistan |
| 479 | Sri Lanka |
| 480 | Philippines |
| 481 | Belarus |
| 482 | Ukraine |
| 483 | Turkmenistan |
| 484 | Moldava |
| 485 | Armenia |
| 486 | Georgia |
| 487 | Kazakhstan |
| 488 | Tajikaistan |
| 489 | Hong Kong |
| 49 | Japan |
| 50 | United Kingdom |
| 520, 521 | Greece |
| 528 | Lebanon |

| | |
|---|---|
| 529 | Cyprus |

Does the barcode number always indicate the country of origin of a product?

No, it doesn't. The 3-digit prefix code indicates which numbering organization has allocated the bank of numbers to the company. For example, a company may have its headquarters in South Africa. The EAN organization in South Africa has the code "600", but all the products of the company may be manufactured in England. The English-made products would still have the "600" prefix code. The prefix code is a way to have 70-plus EAN member organizations issuing numbers without having to worry about duplicate numbers.

Manufacturer Code: The manufacturer code is a unique code assigned to each manufacturer by the numbering authority indicated by the number system code. All products produced by a given company will use the same manufacturer code.

EAN uses fixed-length 5-digit manufacturer codes.

Product Code: The product code is a unique code assigned by the manufacturer. Unlike the manufacturer code, which must be assigned by the UCC, the manufacturer is free to assign product codes to each of their products without consulting any other organization. Since the UCC will already have guaranteed that the manufacturer code is unique, the manufacturer need only make sure that they do not repeat their own product codes.

Check Digit: The check digit is an additional digit used to verify that a bar code has been scanned correctly. Since a scan can produce incorrect data due to inconsistent scanning speed, print imperfections, or a host of other problems, it is useful to verify that the rest of the data in the bar code has been correctly interpreted. The check digit is calculated based on the rest of the digits of the bar code. Normally, if the check digit is the same as the value of the check digit based on the data that has been scanned, there is a high level of confidence that the bar code was scanned correctly. The method of calculating the check digit will be discussed later in this page.

The steps for calculating the check digit are as follows:

Consider the right-most digit of the message to be in an "odd" position, and assign odd/even to each character moving from right to left.

Sum the digits in all odd positions, and multiply the result by 3.

Sum the digits in all even positions.

Sum the totals calculated in steps 2 and 3.

The check digit is the number which, when added to the totals calculated in step 4, result in a number evenly divisible by 10.

If the sum calculated in step 4 is evenly disivisible by 10, the check digit is "0" (not 10).

| Barcode | 0 | 0 | 7 | 5 | 6 | 7 | 8 | 1 | 6 | 4 | 1 | 2 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Position | E | O | E | O | E | O | E | O | E | O | E | O |
| Weighting | 1 | 3 | 1 | 3 | 1 | 3 | 1 | 3 | 1 | 3 | 1 | 3 |
| Calculation | 0 * 1 | 0 * 3 | 7 * 1 | 5 * 3 | 6 * 1 | 7 * 3 | 8 * 1 | 1 * 3 | 6 * 1 | 4 * 3 | 1 * 1 | 2 * 3 |
| Weighted Sum | 0 | 0 | 7 | 15 | 6 | 21 | 8 | 3 | 6 | 12 | 1 | 6 |

This is easier to understand with an example. Let's calculate the checksum digit for the bar code 0075678164125. Actually, we know the checksum digit is the last digit in the bar code, "5". This means the "message" itself of the bar code is really 007567816412 (we just dropped the last character of the bar code). This represents a number system of "00", a manufacturer code of "75678" and a product code of "16412". Thus, we must calculate a check digit for the message 007567816412. Summing up the weighted sum for each digit, we get 0 + 0 + 7 + 15 + 6 + 21 + 8 + 3 + 6 + 12 + 1 + 6 = 85. This is the checksum value. However, there is only one checksum digit. The checksum digit is the value which must be added to the checksum value in order to make it even divisible by 10. In this case, the next number following 85 which is evenly divisible by 10 is the number 90. We must add 5 to 85 to get 90, therefore our check digit is "5". We subsequently append the original bar code message (007567816412) with our newly calculated check digit (5), to arrive at the final value of 0075678164125.

Comparing this with our original bar code, we find that our calculated check digit is in fact the same as the check digit that we found on the bar code. Our calculation, therefore, is correct.

There are two general classes of barcodes: one-dimensional (1D or linear) and two-dimensional (2D). They are used in different types of applications, and in some cases are scanned using different types of technology. The difference between 1D and 2D barcode scanning relies on the layout and amount of data that can be stored in each, but both can be used effectively in a variety of automatic identification applications.

1D Barcode Scanning:

Linear or 1D barcodes, like the UPC code commonly found on consumer goods, use a series of variable-width lines and spaces to encode data — what most people probably think of when they hear "barcode." Linear barcodes hold just a few dozen characters, and generally get physically longer as more data is added. Because of this, users typically limit their barcodes to 8-15 characters

Barcode scanners read 1D barcodes horizontally. 1D laser barcode scanners are the most commonly used scanners, and typically come in a "gun" model. These scanners do not need to be in direct contact with the 1D barcode to work properly, but typically need to be within a range of 4 to 24 inches to scan.

1D barcodes are dependent on database connectivity to be meaningful. If you scan a UPC code, for instance, the characters in the barcode have to relate to an item in a pricing database to be useful. These barcode systems are a necessity for large retailers, and can help increase inventory accuracy and save time.

2D Barcode Scanning:

2D barcodes, like Data Matrix, QR Code or PDF417, use patterns of squares, hexagons, dots, and other shapes to encode data. Because of their structure, 2D barcodes can hold more data than 1D codes (up to 2000 characters), while still appearing physically smaller. The data is encoded based on both the vertical and horizontal arrangement of the pattern, thus it is read in two dimensions.

A 2D barcode doesn't just encode alphanumeric information. These codes can also contain images, website addresses, voice, and other types of binary data. That means you can make use of the information whether you are connected to a database or not. A large amount of information can travel with an item labeled with a 2D barcode.

2D barcode scanners are typically used to read 2D barcodes, although some 2D barcodes, like the commonly-recognized QR code, can be read with certain smartphone apps. 2D barcode scanners can read from over 3 feet away and are available in the common "gun" style, as well as cordless, countertop, and mounted styles. Some 2D barcode scanners are also compatible with 1D barcodes, giving the user more flexibility in how they are used.

A data matrix is a 2D matrix code, capable of encoding very large amounts of data in a compact space. It's used in a variety of capacities, including aerospace uses, component labeling, defense, mail, and printed media.

Specifications: A data matrix is capable of encoding up to 2,335 alphanumeric characters, or up to 3,116 numerical characters. It's composed of several blocks of black and white cells, that come in either a square pattern or a rectangular

one. It can also encode symbols of various sizes, both large and small. Along the edges of each data matrix code is a quiet zone.

Advantages: A data matrix code is designed to be read even when it's up to 40% damaged, due to a built in error correction system. It's also capable of encoding either letters or numerical data.

Disadvantages: Even though it can read a lot of characters, far more than most 1D barcodes, it still has an overall character limit, and so is impractical for sending longer messages.

The most popular application for Data Matrix is marking small items, due to its ability to encode a large amount of data in a small amount of space.

Typically, Data matrix codes are the better choice when it comes to asset tracking, identification and data-driven applications. However, because they are read by 2D imaging scanners or vision systems, they are typically used in warehousing rather than for consumer applications.

A Maxi Code is a two-dimensional matrix, fixed size code that was originally developed for use by UPS in tracking and shipping packages, as it can be scanned quickly on a conveyor belt. It's similar to a 1D barcode, but uses dots instead of bars.

Specifications: A Maxi Code is exactly one inch squared, with a bullseye in the middle of it. Around the bullseye are a series of hexagonal dots. It can encode up to 93 characters of data. It also includes an error correction code, so that the code can be read even if it becomes damaged. It has several fields, wherein are encoded the postal code (either a United States zip code or an international code), country code, and service code.

Advantages: The Maxi Code can be scanned quickly and accurately, even on a fast moving conveyor belt. It can also encode both letters and numbers.

Disadvantages: A Maxi Code is only able to encode up to 93 characters of data, which makes it useless for larger amounts of information.

An Aztec code is so named because of the finder code in the center, which somewhat resembles the aerial view of an Aztec pyramid. The Aztec is a 2D matrix code, typically used for airline tickets and other travel documents, as well as car registration documents. It can also be used in hospitals for patient identification, or to identify medication, samples, or other items related to a particular patient.

Specifications: Unlike most other 2D matrix codes, an Aztec code doesn't require a quiet zone around the edge. Therefore, it's potentially able to store more data in a smaller space. The finder pattern is in the very center of the Aztec code, with the other data encoded around it in concentric square rings.

Advantages: The Aztec code uses its space more efficiently than other matrix codes. The size can also vary, allowing it potentially to hold vast amounts of information.

Disadvantages: The Aztec code doesn't support Kana or Kanji characters, as QR codes do.

A QR (Quick Read) code is a 2D matrix code designed for use in the labeling and identifying of automotive parts. It's gained immense popularity through commercial use, due to its ability to be scanned and read by smartphones. Advertisers can include their code on almost anything, either printed or digital, and smartphone users can scan it to decode the message, often giving them a special offer or discount.

Specifications: A QR code can be either very simple or very complex, and can vary in size. It's a square shape that includes both black and white cells. The top two corners and the bottom left corner each contain a small finder pattern, displayed as a square within a square.

Advantages: It can be read very quickly and has an enormous storage capacity, making it superior to UPC bar codes in just about every way. It can encode both numeric and alphanumeric characters, as well as binary characters and even Chinese logographic characters.

Disadvantages: It has a high storage capacity, as well as error correction for damaged codes, but it's a tradeoff between the two. The higher the error correction, the lower the storage capacity. Also, since it can contain executable files, there's a risk of putting your device's contents at risk if you're not careful. The risk is low, however.

**THEME № 3 PACKAGING, LABELING OF FINISHED MEDICINES. CLOSURES.**

Finished Product is means a Licensed Product in a finished pharmaceutical dosage form that is suitable for commercial sale following Regulatory Approval thereof. It is the medicinal product that has undergone all stages of production, including packaging in its final container. The specifications for release of the finished product must comply with the regulations. The specifications of the finished product at manufacture may be different from those of the medicinal product at expiry.

Bulk product is any product that has completed all the processing stages up to, but not including, final packaging.

Pharmaceutical packaging (or drug packaging) is the packages and the packaging processes for pharmaceutical preparations. It involves all of the operations from production through drug distribution channels to the end consumer.

Primary packaging is the packaging in direct contact with the product itself and is sometimes referred to as consumer or retail packaging. The

main purpose of primary packaging is to protect and/or preserve, contain and inform the consumer. Typical containers are ampoules, vials, bottles, etc.

Secondary packaging component means a packaging component that is not and will not be in direct contact with the dosage form (boxes.).

Tertiary packaging facilitates the protection, handling and transportation of a series of sales units or secondary packaging in order to group everything into unit loads during transit. This type of packaging is rarely seen by the consumer.

*Functions of packaging*

1.Containment

The containment of the product is the most fundamental function of packaging for medicinal products. The design of high-quality packaging must take into account both the needs of the product and of the manufacturing and distribution system. This requires the packaging:

- ✓ not to leak, nor allow diffusion and permeation of the product;
- ✓ to be strong enough to hold the contents when subjected to normal handling;
- ✓ not to be altered by the ingredients of the formulation in its final dosage form.

2. Protection

The packaging must protect the product against all adverse external influences that may affect its quality or potency, such as:

- ✓ light
- ✓ moisture
- ✓ oxygen
- ✓ biological contamination
- ✓ mechanical damage.

The compatibility of the packaging with the active pharmaceutical ingredients is very important in maintaining the integrity of the product.

3. Stability. Information on stability is given in the guidelines for stability testing of pharmaceutical products containing well-established drug substances in conventional dosage forms.

For primary packaging, it is necessary to know the possible interactions between the container and the contents. Normally, product/ component stability and compatibility are confirmed during the primary research and development stage.

While excluding the effect of external factors on the product, the packaging itself should not interact with it so as to introduce unacceptable changes. There are numerous possibilities of interactions between (primary) packaging materials and pharmaceutical products, such as:

- ✓ the release of chemicals from components of the packaging materials;
- ✓ the release of visible and/or subvisible particles;
- ✓ the absorption or adsorption of pharmaceutical components by the packaging materials;
- ✓ chemical reactions between the pharmaceutical product and the packaging materials;
- ✓ the degradation of packaging components in contact with the pharmaceutical products;
- ✓ the influence of the manufacturing process (e.g. sterilization) on the container.

The active pharmaceutical ingredients should remain within their specification limits over the shelf-life of the pharmaceutical product. The question of whether a packaging will provide the required protection for the pharmaceutical product and the required stability over a certain time period can only be answered by means of real-time stability studies. Such studies must evaluate the changes in the quality of the product, in contact with its packaging, during a period equivalent to its intended shelf-life.

In addition, packaging must meet the following requirements:

- ✓ it must preserve the physical properties of all dosage forms and protect them against damage or breakage;
- ✓ it must not alter the identity of the product;
- ✓ it must preserve the characteristic properties of the product, so that the latter complies with its specifications;
- ✓ it must protect the product against undesirable or adulterating chemical, biological or physical entities.

*Storage.* Packaging materials should be stored in accordance with GMP for storage areas. The characteristics of the active pharmaceutical ingredients will determine whether different packaging will be needed. For example, the packaging requirements of medicinal products kept at temperatures between 2 and 8°C may differ from those of products intended for tropical countries or light-sensitive products. If the contents are sterile, sterility must be maintained, including that of any unused

remaining product. The shelf-life and utilization period are always determined in relation to storage conditions and the stability of the active pharmaceutical ingredient.

Normal storage conditions are defined as “storage in dry, well-ventilated premises at temperatures of 15–25°C or, depending on climatic conditions, up to 30°C. Extraneous odours, other indications of contamination, and intense light have to be excluded”

*Containers*

A container for pharmaceutical use is an article which holds or is intended to contain and protect a drug and is or may be in direct contact with it. The closure is a part of the container. The container and its closure must not interact physically or chemically with the substance within in any way that would alter its quality. The following terms include general requirements for the permeability of containers:

• Well-closed containers must protect the contents from extraneous matter or from loss of the substance under normal conditions of handling, shipment or storage.

• Tightly closed containers must protect the contents from extraneous matter, from loss of the substance, and from efflorescence, deliquescence or evaporation under normal conditions of handling, shipment or storage. If the container is intended to be opened on several occasions, it must be designed to be airtight after reclosure.

• Hermetically closed containers must protect the contents from extraneous matter and from loss of the substance, and be impervious to air or any other gas under normal conditions of handling, shipment or storage.

Substances and dosage forms requiring protection from light should be maintained in a light-resistant container that — either by reason of the inherent properties of the material of which it is composed, or because a special coating has been applied to it — shields the contents from the effects of light. Alternatively, the container may be placed inside a suitable light-resistant (opaque) covering and/or stored in a dark place.

Containers for pharmaceuticals

Ampoule. A container sealed by fusion and to be opened exclusively by breaking. The contents are intended for use on one occasion only.

Bag. A container consisting of surfaces, whether or not with a flat bottom, made of flexible material, closed at the bottom and at the sides by sealing; the top may be closed by fusion of the material, depending on the intended use.

Blister. A multi-dose container consisting of two layers, of which one is shaped to contain the individual doses. Strips are excluded.

Bottle. A container with a more or less pronounced neck and usually a flat bottom.

Cartridge. A container, usually cylindrical, suitable for liquid or solid pharmaceutical dosage forms; generally, for use in a specially designed apparatus (e.g. a prefilled syringe).

Gas cylinder. A container, usually cylindrical, suitable for compressed, liquefied or dissolved gas, fitted with a device to regulate the spontaneous outflow of gas at atmospheric pressure and room temperature.

Injection needle. A hollow needle with a locking device intended for the administration of liquid pharmaceutical dosage forms.

Injection syringe. A cylindrical device with a cannula-like nozzle, with or without a fixed needle and a movable piston, used for the administration, usually parenteral, of an accurately measured quantity of a liquid pharmaceutical form. The syringe may be prefilled, and can be for single-dose or multi-dose use.

Pressurized container. A container suitable for compressed, liquefied or dissolved gas fitted with a device that, after its actuation, produces a controlled spontaneous release of the contents at atmospheric pressure and room temperature.

Single-dose container. A container for single doses of solid, semi-solid or liquid preparations.

Strip. A multi-dose container consisting of two layers, usually provided with perforations, suitable for containing single doses of solid or semi-solid preparations. Blisters are excluded.

Tube. A container for multi-dose semi-solid pharmaceutical forms consisting of collapsible material; the contents are released via a nozzle by squeezing the package.

Vial. A small container for parenteral medicinal products, with a stopper and overseal; the contents are removed after piercing the stopper. Both single-dose and multi-dose types exist.

*Labels*

All finished drug products should be identified by labelling, as required by the national legislation, bearing at least the following information:

- ✓ the name of the drug product;
- ✓ a list of the active ingredients (if applicable, with the International Nonproprietary Names (INNs)), showing the amount of each present, and a statement of the net contents, e.g. number of dosage units, mass or volume;
- ✓ the batch number assigned by the manufacturer;
- ✓ the expiry date in an uncoded form;
- ✓ any special storage conditions or handling precautions that may be necessary;
- ✓ the directions for use, and any warnings and precautions that may be necessary;

- ✓ the name and address of the manufacturer or the company or person responsible for placing the product on the market.

*Presentation and information*

Packaging is also an essential source of information on medicinal products. Such information is provided by labels and package inserts for patients.

The information provided to the patient may include the following:

- ✓ the name of the patient;
- ✓ the identification number for dispensing records;
- ✓ the name, strength, quantity and physical description or identification of the medicinal product;
- ✓ directions for use and cautionary statements, if applicable;
- ✓ the storage instructions;
- ✓ the date of dispensing and period of use (related to the expiry date);
- ✓ the name and address of the dispenser.

Labels

Throughout manufacturing, a succession of specific outer labels are applied to the container of the medicinal product. The level of processing is indicated by the following words:

- ✓ quarantine
- ✓ storage
- ✓ distribution.

Specifications for labels for finished drug products are defined in the WHO guidelines on GMP for pharmaceutical products.

Written labels on the packaging:

• Permit the identification of each active ingredient by means of its INN, and also give the dosage form and the trade name/trademark. All information concerning the medicinal product, as required by national legislation, must be stated on the packaging.

• Preserve the stability of the medicinal product by giving advice on its storage:

After the stability of the product has been evaluated, one of the following recommendations as to storage conditions can be prominently indicated on the label:

- ✓ store under normal storage conditions;
- ✓ store between 2 and 8 °C (under refrigeration, no freezing);
- ✓ store below 8 °C (under refrigeration);
- ✓ store between -5 and -20 °C (in a freezer);
- ✓ store below -18 °C (in a deep freezer).

• Permit the follow-up of a specific medicinal product by means of the batch number on the labels. It must be possible to follow the route of distribution of a product from the manufacturing process to its administration to the patient with the aim of locating and identifying products that are of potential risk (e.g. blood products, blood-derived products).

• Mask the real identity of the medicinal product in clinical studies. This is extremely important in clinical trials in determining the real efficacy of a medicinal product in blinded studies. If the identity is masked by a code, it must be possible to disclose it at any time in a medical emergency.

National legislation must be followed with regard to the information provided to the patient, as well as the record-keeping and packaging instructions.

*Repacking, relabeling and dispensing*

In some countries, it is common practice not to dispense drugs in the original packaging, but rather in a personalized manner to each patient. This applies specially to solid oral dosage forms, and involves the "repacking" and "relabeling" of drugs in small quantities. Different drugs may even be included in "customized" medication packages, also referred to as "patient med packs". The quantities of drugs supplied in this way are usually enough only for a short period of time, i.e. to provide drugs for immediate use. It should be remembered, however, that data obtained in stability studies undertaken by the manufacturer are no longer valid for drugs removed from the original package.

Where repacking and relabeling are necessary, the WHO guidelines on GMP for pharmaceutical products should be followed to avoid any mix-up or contamination of the product, which could place the patients' safety at risk.

Package inserts for patients (patient information leaflets)

Product information must help patients and other users to understand the medication. The patient package insert, together with the label, provides the patient with key information concerning the proper use of the product, potential adverse drug reactions and interactions, storage conditions and the expiry date. In OTC medicinal products, the package insert, together with the label, may constitute the only pharmaceutical advice that the patient receives.

Compliance. Packaging and labelling may help to reinforce the instructions given by the physician or the pharmacist, and improve compliance with drug therapy. In this respect, packaging becomes a compliance aid.

The design of pharmaceutical packaging should be such that the product can easily be administered in a safe manner to the patient. If the patient feels at ease with the packaging and route

of administration, the design of the packaging may become a key factor in increasing compliance. This is also an important factor in clinical trials.

Protection of patients. Packaging must not only increase compliance through its design, but must also protect the patient and indicate the integrity of the product.

Packaging equipped with a tamper-evident device protects against incidental and accidental poisoning. To protect children, several child-resistant closures have been developed.

Detection of counterfeiting. The Forty-first World Health Assembly, after reviewing the report of the Executive Board on the implementation of WHO's revised drug strategy, requested: ". . . governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations".

Several documents show that counterfeit pharmaceutical products are in wide circulation. In November 1985, during the WHO Conference of Experts on the Rational Use of Drugs in Nairobi, Kenya, concern was expressed regarding the extent to which counterfeit pharmaceutical products were in circulation in developing countries (10). In view of the importance of this issue, a text has been drafted to provide model provisions to deal with counterfeit drugs.

The design of the packaging must therefore contribute to preventing tampering with, or the counterfeiting of, certain medicinal products. Such tamper-evident containers can allow the visual inspection of the medicinal product before use, and this may serve as a first stage in detecting counterfeit drugs.

## Packaging materials and closures

In accordance with the methods of use and administration of medicinal products, packaging materials, closures and containers vary a great deal and have to meet a wide variety of different requirements.

All the routes used for systemic access have demanding requirements, which often can only be met by complex structured and formulated medicinal products. This is particularly true of the new medicinal products that are now appearing, such as those administered via transdermal delivery systems.

To ensure the efficacy of a product during its total shelf-life, pharmaceuticals must be regarded as a combination of the medicinal product itself and the packaging.

### Types of material glass

For a large number of pharmaceuticals, including medicinal products for oral and local administration, glass containers are usually the first choice (e.g. bottles for tablets, injection syringes

for unit- or multidose administration). Different types of glass may be necessary, depending on the characteristics and the intended use of the medicinal products concerned.

Manufacturers should arrange with their suppliers to obtain the appropriate type of glass container for the intended use. Suppliers should provide the raw and packaging materials in conformity with industrial norms. Classifications of types of glass are given in the European and United States pharmacopoeias, whereas no such classification exists in the Japanese pharmacopoeia.

Glass can be tested for light transmission and hydrolytic resistance. In the Japanese pharmacopoeia, such tests are described only for glass containers for injection, whereas in the European and United States pharmacopoeias they are given for all types of glass containers.

Classification of Glass

Glass containers are classified into Type I glass, Type II glass, Type III glass and Type IV glass based on their degree of chemical/hydrolytic resistance to water attack.

1) Type I glass containers (Borosilicate glass / Neutral glass)

This is a type of glass container that contains 80% silica, 10% boric oxide, small amount of sodium oxide and aluminium oxide. It is chemically inert and possess high hydrolytic resistant due to the presence of boric oxide. It has the lowest coefficient of expansion and so has high thermal shock properties.

Uses of Type I glass containers

Type I glass is suitable as packaging material for most preparations whether parenteral or non-parenteral.

They can also be used to contain strong acids and alkalis

2) Type II glass containers (soda-lime-silica glass/ treated soda-lime glass/ De alkalized soda lime glass)

This is a modified type of Type III glass container with a high hydrolytic resistance resulting from suitable treatment of the inner surface of a type III glass with sulfur. This is done to remove leachable oxides and thus prevents blooming/weathering from bottles. Type II glass has lower melting point when compared to Type I glass and so easier to mould.

Uses of Type II glass containers

They are suitable for most acidic and neutral aqueous preparations whether parenteral or non-parenteral.

3) Type III glass containers (Regular soda lime glass)

This is an untreated soda lime glass with average chemical resistance. It contains 75% silica, 15% sodium oxide, 10% calcium oxide, small amounts of aluminium oxide, magnesium oxide, and potassium oxide.

Uses of Type III glass containers

They are used as packaging material for parenteral products or powders for parenteral use ONLY WHERE there is suitable stability test data indicating that Type III glass is satisfactory.

They used in packaging non-aqueous preparations and powders for parenteral use with the exception of freeze-dried preparations.

It is also used in packaging non-parenteral preparations.

4) Type IV glass containers (Type NP glass/ Non-parenteral glass or General purpose soda-lime glass)

This type of glass container has low hydrolytic resistance. This type of glass containers are not used for products that need to be autoclaved as it will increase erosion reaction rate of the glass container.

Uses of type IV glass containers

It is used to store topical products and oral dosage forms

*Plastics*

Some containers are now being made of plastics; the main use is for bags for parenteral solutions. Plastic containers have several advantages compared with glass containers:

- ✓ they are unbreakable
- ✓ they are collapsible
- ✓ they are light.

The European, Japanese and United States pharmacopoeias all describe materials of the same type, but there are considerable differences in the classification and presentation.

As far as tests are concerned, the three pharmacopoeias are extremely difficult to compare. The European pharmacopoeia is the most detailed and requires tests in relation to the use and routes of administration of the medicinal product. Moreover, the same concept is extended to bulk containers for active ingredients.

*Metal*

Metal containers are used solely for medicinal products for no parenteral administration. They include tubes, packs made from foil or blisters, cans, and aerosol and gas cylinders. Aluminium and stainless steel are the metals of choice for both primary and secondary packaging for medicinal products. They have certain advantages and provide excellent tamper-evident containers.

Since metal is strong, impermeable to gases and shatterproof, it is the ideal packaging material for pressurized containers. Descriptions and tests can be found in the norms and standards of the ISO; these have been established in collaboration with manufacturers. Requirements are not given in pharmacopoeias; the suitability of a particular material for a container is normally established by conducting stability studies in which the material is in contact with the drug in question.

## Closures

Closures are devices and techniques used to close or seal container such as a bottle, jug, jar, tube, can, etc. Closures can be a cap, cover, lid, plug, etc.

Purpose of closures

Many containers and packages require a means of closing. It can be a separate device or seal or sometimes an integral latch or lock. Depending on the contents and container, closures have several functions:

- ✓ Keep the container closed and the contents contained for the specified shelf life until time of opening
- ✓ Provide a barrier to dirt, oxygen, moisture, etc. Control of permeation is critical to many types of products: foods, chemicals, etc.
- ✓ Keep the product secure from undesired premature opening
- ✓ Provide a means of reclosing or reusing the container
- ✓ Assist in dispensing and use of product
- ✓ Allow reasonable ease to open the container by the intended user.

Closures used for the purpose of covering drug containers after the filling process should be as inert as possible. They should not give rise to undesired interactions between the contents and the outside environment, and should provide a complete seal. Besides their protective function, closures must also allow the easy and safe administration of the drug.

Depending on the application, closures may have to be pierced with a needle for intravenous sets. Such closures are made from elastomeric materials (rubbers), while those that cannot be pierced are generally made from plastics such as polyethylene or polypropylene.

Depending on the type of container, closures may have different shapes and sizes, e.g. stoppers for infusion or injection bottles or plungers for prefilled syringes. A special design of stopper may also be required for some pharmaceutical production processes such as lyophilization.

Closures, as primary packaging components, are of critical importance and must be carefully selected. They are an essential component of the container and, as such, an integral part of the drug preparation.

A container type which does not require a removable closure at the time of administration is usually preferred since such a container/ closure system avoids, or at least minimizes, the risk of biological and other contamination as well as tampering.

For parenteral preparations, the combination of glass containers and elastomeric closures, usually secured by an aluminum cap, is widely used. Typical examples are infusion bottles, injection vials and prefilled syringes. The rubber closures used within such a system must be carefully selected in accordance with the intended purpose. Most often, improper rubber closures are the cause of incompatibility between the packaging and the drug.

Rubber closures

Rubber consists of several ingredients, one of which is elastomer.

Modern rubber compounds used in packaging pharmaceuticals contain only a limited number of ingredients, which are very difficult to extract. Closures made from such materials generally do not pose any problems, and can be used in contact with a large number of drug preparations.

Rubber closures for pharmaceutical use must meet the relevant requirements of the most important pharmacopoeias (the European, Japanese and United States pharmacopoeias). International standards have also been established (ISO 8871). It should be emphasized that the requirements of pharmacopoeias and standards must be seen as minimal requirements. The suitability of a rubber closure for a given application can only be established by means of stability studies.

*Caps or overseals*

Caps or overseals are used to secure the rubber closure to the container in order to maintain the integrity of the seal under normal conditions of transport, handling and storage during the intended shelf-life of the product. Such caps are usually made of aluminum and can be equipped with a plastic top to facilitate opening. Caps also provide evidence of tampering: once opened or removed they cannot be repositioned. This is especially true for caps with a plastic top.

*Special types of closure*

Demographic trends are causing new problems for packaging designers. Thus while child-resistant closures safeguard children against drug intoxication, opening such packaging may prove difficult for the increasing number of elderly persons in the population.

Child-resistant closures. Tragic accidents involving the drug intoxication of children has led to new legislation making it difficult for drug packaging to be opened by young children, while allowing adults easy access. Such packaging is designated as child-resistant.0

The ISO has published an internationally agreed standard test procedure for reclosable child-resistant packaging (16). In Europe several norms have been introduced, which complement the ISO standard.

The European Committee for Standardization (CEN) has defined a child-resistant package as one "which makes it difficult for young children to gain access to the contents, but which is not too difficult for adults to use properly in accordance with the requirement of this European standard" The three most common reclosable child-resistant types of closure are the "press–turn", the "squeeze–turn" and a combination lock.

To determine whether a packaging is child-resistant, it must be subjected to the ISO test procedure for reclosable child-resistant packaging.

Most designs that are child-resistant require two hands to open the closure. Such packaging can cause problems for elderly people, and can even lead to the deliberate purchase of drugs with packaging that is not child-resistant; alternatively, the child-resistant closure may not be replaced on the container. An optional "elderly adult test" has been inserted in the ISO standard to deal with this problem.

## THEME № 4. COMMODITY ANALYSIS OF RUBBER PRODUCTS AND PATIENT CARE ITEMS.

The medical industry is highly equipped with rubber products. The rubber products which are used in hospitals are wide and varied. Rubber is used to make various objects like surgical gloves, tubes, stoppers, condoms, breathing bags, cushioning or supporting materials, prosthetics, implants and catheters. Types of rubber used in making medical products

### *Natural and Synthetic Rubber*

Natural Rubber is an elastic substance obtained from the latex sap of trees, especially those trees which belong to the genera Hevea and Ficus. Technically speaking, natural rubber is an elastomer or an elastic hydrocarbon polymer.

*Latex* - a milky white liquid, which contains 34-37% rubber, water, protein, sugar and mineral salts. For mixing rubber latex and coagulating solution of acetic or formic acid. The resulting gel is washed with water, passed through rollers, making the plates are dried at a temperature of 45 degrees. How is Natural Rubber Made? The raw material from which natural rubber is made comes from the sap of rubber trees. The rubber plants are tapped for collecting the rubber latex. For this, an incision

is made into the bark of the rubber tree and the latex sap is collected in cups. After collecting the latex sap, the raw natural rubber is refined to convert it into a usable rubber. Initially an acid was added to the latex which used to make the sap set like a jelly.

In the year 1839, Charles Goodyear invented a more sophisticated way of making rubber stronger and more elastic. his was the process of rubber vulcanizing - heating in the presence of sulfur. Vulcanization prevents the polymer chains from moving independently. As a result, when stress is applied the vulcanized rubber deforms, but upon release of the stress, the product reverts to its original shape. The process of vulcanization makes natural rubber a more coherent substance, somewhat soft and having elasticity. The unprocessed natural rubber is sticky, deforms easily when warm, and is brittle when cold. In such a state, it cannot be used to make products having a good level of elasticity.

*Properties of Natural Rubber.*

Rubber has such characters as elasticity, toughness, impermeability, adhesiveness, and electrical resistance. All these properties of rubber make it useful as an adhesive, coating composition, a molding compound, and an electrical insulator.

Natural rubber has certain unique properties such as follows:

- ✓ Rubber is elastic as well as water-resistant.
- ✓ It is resistant to alkalis and weak acids.
- ✓ It traps air and thus it floats.
- ✓ It is a bad conductor of electricity and thus doesn't conduct electricity.

Natural rubber combines high strength (tensile and tear) with outstanding resistance to fatigue.

It has high resistance to cutting, chipping and tearing. Natural rubber forms an excellent barrier to water.

*Synthetic Rubber* is any type of artificial elastomer, invariably a polymer. It is produced in factories with the use of different catalysts. The feedstocks for synthetic rubber industry are products of the petrochemical industry.

These rubbers are divided into organic, which mainly consist of hydrocarbons or their derivatives; element organic that contain atoms of silicon, sulfur. Raw material for synthetic rubber used oil, natural gas and coal.

*Natural or synthetic rubber*- both of them in their native form are useless. After addition of chemicals, these rubbers take on properties that cannot be completed by any other known material in the world. Depending on the chemicals used, products made of rubber can be soft, resilient, and/or hard in varying degrees.

*Rubber compounds* - a composition based on natural rubber, which contain other substances necessary for the processing of natural rubber in rubber. Rubber compounds contain vulcanization accelerators, fillers, plasticizers, substances that prevent the aging of rubber/

The technological process of manufacturing medical rubber products consists of the following stages:

1. Obtaining a rubber mixture;
2. Manufacture of semi-finished products - this operation is performed for rubber heaters, ice bubbles, liners, catheters, tubes;
3. Forming or obtaining rubber products is carried out by one of the following methods:

Extrusion begins with an unvulcanized compound being fed into an extruder. Once it's inside the extruder, it gets carried forward to a dye, which is a specialized manufacturing tool used to shape the rubber. Once the compound reaches the dye, the pressure from the process forces it through the opening of the extruder. Then, the extruded product will need to be vulcanized prior to being defined "usable". Extrusion manufacturing has the advantage of being able to produce products in high volumes at a lower production cost. Some of the common rubber products produced from extrusion include probes, tubing, etc

Latex dipping occurs when thin walled molds are immersed into latex compounds and then slowly withdrawn. The thickness of the dipped product can be increased by re-dipping the product. After the dipping process occurs, the product is finished by vulcanization. The main advantage of dip molding includes being able to dip latex products with thinner walls and to create more complex shapes than extrusion. Some of the common dip molded products include rubber gloves, nipples, condoms, etc.

Compression molding is the oldest and least expensive method. With compression molding, a rubber compound is formed into a blank (chunk of rubber); the blank then gets placed into a mold cavity to be shaped. Some of the common products made with the compression molding process include hot-water bottles, enema syringes, etc.

The last most common manufacturing process is called calendaring, which works by forcing softened material into the center of counter-rotating rollers. This process works best to produce sheets or films of rubber.

*Shelf Life of Rubber Products*

Rubber products can remain in inventory for long periods of time. Shelf life, the storage period prior to part installation, varies by elastomer type. Storage conditions such as temperature, humidity, ozone, and exposure to light also affect the shelf life of rubber products. By understanding these factors and best practices, buyers can make informed decisions about sourcing elastomers and storing die cut seals, gaskets, and O-rings.

Environmental conditions such as high temperatures and high humidity can cause unwanted physical changes in rubber products. Proper storage conditions won't guarantee product quality, but they do promote storage life.

| Environmental Condition | Recommended Storage Condition |
|---|---|
| Temperature | Below 100° F (38° C) |
| Humidity | Less than 75% unless products are stored in sealed, moisture-proof bags |
| Light | Protection from direct sunlight or intense artificial light |
| Ozone | Storage rooms should not contain any ozone-generating equipment |

Recommended shelf life for natural rubber, pure gum is 3 – 5 years.

*Types of Medical rubber products*

Some popular medical rubber products are as follows:

Rubber Caps/Tabs for Medical use: Rubber caps are specially designed for medical purposes. These are caps on T-piece as the main adjunct which provides pass and injection port for infusion and transfusion sets. They are made of natural rubber and polychloroprene rubber.

Rubber Tubes for Infusion and Transfusion Set: This is a component of infusions sets, through which the medicine liquid can be added into the infusion canula. It is suitable for medicine liquid addition. Made of synthetic rubber etc.

Birth Control Products: Rubber is used to make various products which serve as effective birth control measures like condoms, diaphragms, and cervical caps.

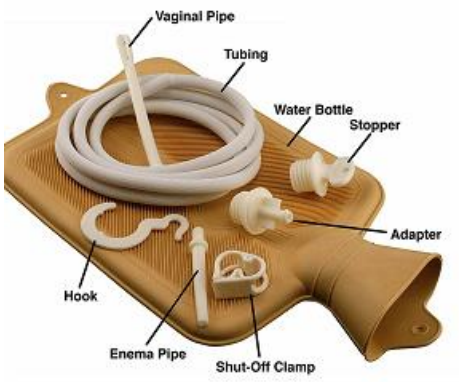
Surgical Gloves: Surgical gloves are made of various types of synthetic rubber as well as from the latex of natural rubber. These gloves are designed with some features which may not be available in normal glove. Such features are like ultra sensitivity, extra flexibility, maximum strength, greater protection, ambidextrous and can be sterilized.

*Rubber Medical Masks*: Rubber is also used to make various kinds of masks used for medical purposes. The breathing mask also known as oxygen mask are manufactured using natural rubber and silicone rubber. Such masks are specially designed to provide a tight seal without leakage and are widely used by aviators, medical researchers and other patients that require administration of 100% oxygen.

*Rubber Catheters:* Rubber is used to make medical catheters. A catheter is a flexible tube made of latex or silicone and can be inserted into the body creating a way for the passage of fluid or the entry

of a medical device. Compared to latex or natural rubber catheter, silicone rubber catheters are believed to be superior as silicone is more bio compatible, causes less cell death, and more resistant to bacterial colonization.

*Rubber Bulb Syringe*: It is syringe with a hollow rubber bulb and a cannula. The rubber bulb and the canula are provided with a check valve. The syringe is used on infants.




*Rubber bladders*: A bladder is a device made of rubber that can be used for a containing a substance. In medical industry, this is the most common product used in blood pressure monitor units. A typical blood pressure monitor features a neoprene or rubber pump bulb or a rubber bladder that a medical expert squeezes to build air pressure in the system.

This is possibly the best barrier against pathogens such as the AIDS virus (HIV). That is the reason why latex is used in condoms and surgical and medical examination gloves.

*Hot Water Bottle*

Hot Water Bottle a rubber container that is filled with hot water and used to warm a bed or a part of the body.

Produced two types: hot-water bottles A and B.

Rubber hot-water bottle of A type is designed for local warming of the body (hot-water bottle with a plug).

Rubber hot-water bottle of B type (combined) is designed for local warming of the body, rinsing and syringing (hot-water bottle with accessories).

Advantages: resistant to multiple disinfections

Suitable for multiple and prolonged use.

Safe for adults and children.

Specifications

Guaranteed shelf life: 3.5 years.

Guaranteed effective life: 2 years.

Contents: Type B kit contains a pipe, tips (pediatric, adult and uterine), a clip.

Package: Individual: polymer pack. Group (corrugated box): type A — 40 pcs., type A2, A3 — 30 pcs., type B-1, B-2, B-3 — 20 pcs.

*Rubber Esmarch Irrigator*

Purpose Mug Esmarch to cleanse the bowel, gynecological irrigator, 2 l

Esmarch rubber mug is used in medical institutions to clean the intestines before research or surgery, as well as at home as a cleansing and therapeutic enemas for constipation, intestinal slagging, as well as enemas for weight loss. In addition, the mug is used for gynecological procedures: irrigation or douching.

Mug Esmarch rubber consists of a reservoir for the liquid volume of 2 liters. A tube with a mounted clip is attached to the container. To control the movement of liquid, the tube is made of transparent medical PVC (length 140 mm). The clip allows you to control the flow rate of the solution.

The Esmarch mug set includes two tips: hard (PE) – 95x7. 4 mm and soft (PVC) - 76x7 mm. The tip can be changed by dipping the end of the tube into hot water.

Esmarch mug has no age restrictions and is suitable for all family members. The shelf life of the mugs is 3.5 years from the date of manufacture.

Designed for sanitary and hygienic purposes (syringing, rinsing). Suitable for multiple and prolonged use. Safe for adults and children.

Specifications. Esmarch irrigator has almost the same purpose as the hot-water bottle of type B, but there is one significant difference: the open top for withdrawing liquid that provides convenience of its use in health care facilities and veterinary clinics. Volume: №1 — 0.8 ± 0.1 l, № 2 — 1.5 ± 0.15 l, №3 — 2.5 ± 0.25 l.

Guaranteed shelf life: 3 years. Guaranteed effective life: 2 years.

Completeness Is supplied as a rubber cylinder with a tube, tips (pediatric, adult, uterine), and a clip.

Package / Individual: polymer pack. • Group (corrugated box): No. 1, 2, 3 — 20 pcs.

*Rubber Ice Packs*

The cooling rubber ice bag is very suitable for cold therapy. It is made of skin-friendly rubber material and provided with a leakage proof plastic cap. Cooling is immediately required if there is any injury, sprain or strain. It prevents swelling, inflammation, blood clot formation which helps in early recovery from injuries. Its use is also recommended for patients doing physiotherapy exercises and for rehabilitation of injuries. It is water-proof, light-weight, easy to store or carry.

Specifications: Are of three types: №1, №2, № 3 with relevant diameters of 150, 200 and 250 mm, airtight.

Guaranteed shelf life: 3.5 years. Guaranteed effective life: 1.5 years.

Package. Individual: polymer pack. Group (corrugated box): № 1 — 50 pcs., № 2 — 35 pcs., № 3 — 30 pcs.

*Ball syringes*

Ball syringes are used to an irrigation (irrigation) and a suction of liquid from organism cavities. Are intended for use in medical institutions and for individual use in house conditions. Can use as cleansing enemas.

There are syringes type A (with a soft tip) and type B (with a firm tip made of ebonite or plastic).

The volume of the syringe is determined by multiplying its number by 30 ml (for example, №2x30 ml-60 ml).

Large syringes are often used for enemas, medium - for rinsing the ears, small - in laboratory practice or to clean the nasal cavity from the mucus of the baby

*Irrigation Syringes*

Syringes with a firm tip (type B) gynecological are designed for irrigation (irrigation) in gynecology for medical and hygienic purposes.

*Air Cushion (Invalid Air Rings)*

This inflatable rubber invalid ring has an open center that helps distribute weight evenly and allows you to sit comfortably for extended periods of time. In addition, the inflation level can be adjusted to maximize comfort.

Air Cushion are an inflatable hollow product of annular shape. Used for the prevention of bedsores, as well as after operations on the rectum. The air rings is inflated independently, or by means of the pump. Produced by the Compression molding or the method of manual gluing of three sizes (№ 1, № 2, № 3),

*Bedpan Rubber*

A bedpan or bed pan is a receptacle used for the toileting of a bedridden patient in a health care facility, and is usually made of metal, glass, ceramic, plastic or rubber. A bedpan can be used for both urinary and fecal discharge.

*Elastic tubular rubber products.*

Tubes made of rubber and synthetic materials are used as drainage in the treatment of postoperative wounds, in devices for blood transfusion, injection and suction of fluids from the body, for connecting individual parts of devices and devices, for oxygen pillows and in laboratory practice.

In medical practice, a number of tubular products are used, namely: probes, catheters, tourniquets, exhaust tubes and others, which are made by compression molding.

Catheters are designed to drain the contents of various body cavities or to introduce water and essential body substances.

The probes are designed to enter the cavity and take their contents (samples for research). They are divided into:

The gastric probe is intended: for gastric lavage; sampling of gastric juice for its analysis. A probe that is inserted through the nose, down the throat and esophagus, and into the stomach. It can be used to give drugs, liquids, and liquid food, or used to remove substances from the stomach. Giving food through a gastric feeding tube is a type of enteral nutrition. Also called nasogastric tube and NG tube. It is a rubber or PVC tube with a length of 1 m to 1.5 m with one rounded blind end, on the side surface of which there are two oval holes facing in opposite directions.

*Medical Gloves*

Medical gloves are disposable gloves used during medical examinations and procedures to help prevent cross-contamination between caregivers and patients. Medical gloves are made of different polymers including latex, nitrile rubber, polyvinyl chloride and neoprene; they come unpowered, or powdered with cornstarch to lubricate the gloves, making them easier to put on the hands.

*Exam gloves* are made with latex, vinyl, and nitrile. Latex gloves have been the standard in medical offices for many years, and different brands and styles of them have various features. For example, some latex gloves have powder, while others do not, and some are thicker and longer than others.

*Latex gloves are* used in high-risk situations that involve infectious material. They're elastic, strong, and biodegradable too. For providing mid-range barrier protection, latex is comfortable, flexible, and fits well. However, some professionals and patients are allergic to it.

Made from polyvinyl chloride, vinyl is a low-cost option that is soft, comfortable, and latex-free. These gloves can be sufficient to wear for low-risk tasks and touching non-hazardous materials. Vinyl gloves are may also be worn for less tactile work, but keep in mind that they are usually less durable than latex gloves.

*Nitrile is* a great general purpose material that is commonly used for exams, especially on patients with latex allergies. Nitrile is a very durable and tear-resistant material that makes it good to use with sharp objects and instruments. You can wear nitrile gloves for longer periods of time, and these gloves have a long shelf life. Ultimately, they provide high barrier protection and are able to resist chemicals and punctures in ways that latex and vinyl simply can't.

Medical professionals use both powdered and unpowered gloves in their line of work. Powdered gloves became popular in the industry because they are easier to take on and off and help to lubricate the hands. The powder in powdered gloves is usually cornstarch, which does not commonly cause any irritation.

However, the powder can be problematic if the powder finds its way into open cuts and wounds on the skin. The powder can prevent natural healing of skin tissue, which is why some healthcare workers choose to wear unpowered gloves with inner coatings instead while examining certain patients.

| Material | Natural/ synthetic | Pros | Cons |
|---|---|---|---|
| Latex | Natural | Provides the best protection against viruses. Excellent sensitivity, elasticity and comfort<br>Durable | Can be highly allergenic in susceptible people<br>Hydrocarbon/petroleum-based emollients must be avoided as they weaken the rubber; water-based |

| | | | |
|---|---|---|---|
| | | | emollients are preferred when wearing latex gloves |
| Neoprene | Synthetic | Latex-free<br>High strength | Lower level of elasticity and comfort than latex<br>More expensive than latex |
| Polyisoprene | Synthetic | Latex-free<br>Similar properties to latex in terms of elasticity, comfort, sensitivity, and strength | Most expensive glove |
| Nitrile | Synthetic | Excellent strength and chemical protection | Low elasticity, comfort and sensitivity; can be composed of a mix of nitrile and latex to improve these properties |

Medical examination gloves are often made of latex or synthetic materials such as nitrile or vinyl (PVC). Vinyl gloves are less durable and provide weaker chemical protection than other glove materials, so they are not suitable for healthcare workers in direct contact with bodily excretions or those who handle chemotherapy drugs.

Examination gloves are sized in XS, S, M and L. Some brands may offer size XL. Surgical gloves are usually sized more precisely since they are worn for a much longer period of time and require exceptional dexterity. The sizes of surgical gloves are based on the measured circumference around the palm in inches, at a level slightly above the thumb's sewn. Typical sizing ranges from 5.5 to 9.0. This may result in different sizing being required if you decide to change surgical glove brands. The following is a comparison of surgical glove sizes compared to medical exam glove.

| Exam Glove Size | Surgical Glove Size |
|---|---|
| XS | 5.5 |
| S | 6.0 |
| M | 6.5 |
| | 7.0 |
| L | 7.5 |
| | 8.0 |
| XL | 8.5 |
| | 9.0 |

## THEME № 5. COMMODITY ANALYSIS OF SUTURE MATERIALS AND PUNCTURE NEEDLES.

*Basic terms and definitions*

Surgical suture materials are used in the closure of most wound types.

Breaking strength - limit of tensile strength at which suture failure occurs

Capillarity - extent to which absorbed fluid is transferred along the suture

Elasticity - measure of the ability of the material to regain its original form and length after deformation Unfriendly to bacteria

Stiffness is a suture's ability to resist stretching. This is important when tissue margins need to be closely approximated and maintained against, for example, tension caused by postoperative edema or muscle contracture

Fluid absorption - ability to take up fluid after immersion

Knot-pull tensile strength - breaking strength of knotted suture material (10-40% weaker after deformation by knot placement)

Knot strength - amount of force necessary to cause a knot to slip (related to the coefficient of static friction and plasticity of a given material)

Plasticity - measure of the ability to deform without breaking and to maintain a new form after relief of the deforming force

Memory - inherent capability of suture to return to or maintain its original gross shape (related to elasticity, plasticity, and diameter)

The choice of suture material is one of the decisive factors in how successful the overall surgical treatment is. The word suture is derived from the Latin sutura, "a sewn seam." Suture materials used for treating wounds were originally natural materials, such as animal tendons and cotton fibres. Ancient Egyptians used plant fibres, hair, tendons and wool threads, which have all been found in mummified remains.

Selection of appropriate suture material, among other factors, is of immense importance in the matter of wound healing. By the term suture, we mean the material by which two surfaces are kept in position.

The ideal suture is the smallest possible to produce uniform tensile strength, securely hold the wound for the required time for healing, then be absorbed. Suture material could be enhanced with an antibacterial agent to resist infection. It should be predictable, easy to handle, produce minimal reaction, and knot securely.

Characteristics of an ideal suture:

Physical characteristic such as, breaking strength, elasticity, capillarity and memory are used to describe of sutures.

It should be non-capillary, non-allergic, non-electrolytic and non-carcinogenic.

It should produce knots which hold securely without cutting and fraying.

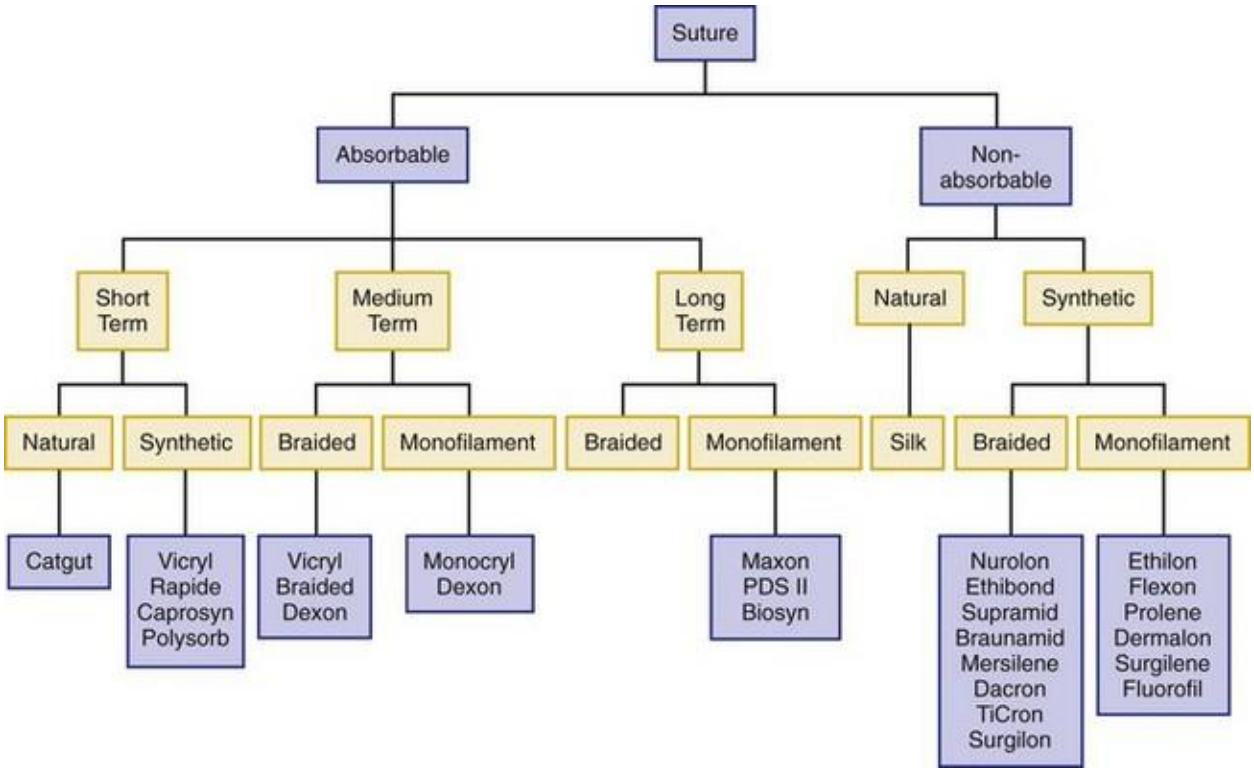
It should be resistant to infection

It should be easily sterilised without alteration of the physio-chemical properties.

It should not be expensive.

The suture can be classified according to several parameters that relate to your source material, structure and permanence in the tissues.

Classification of suture materials




Suture materials are classified as absorbable or nonabsorbable, natural or synthetic, and monofilament or multifilament, according to their composition and structure.

*Absorbable Sutures*

Absorbable sutures are broken down by the body via enzymatic reactions or hydrolysis. The time in which this absorption takes place varies between material, location of suture, and patient factors. Absorbable sutures are commonly used for deep tissues and tissues that heal rapidly; For the more commonly used absorbable sutures, complete absorption times will vary from 42 days to 200 days Absorbable sutures includ :- Polyglycolic Acid sutures, Polyglactin 910 , Catgut, Poliglecaprone 25 and Polydioxanone sutures.

*Non-Absorbable Sutures*

Non-absorbable sutures are used to provide long-term tissue support, remaining walled-off by the body's inflammatory processes (until removed manually if required).

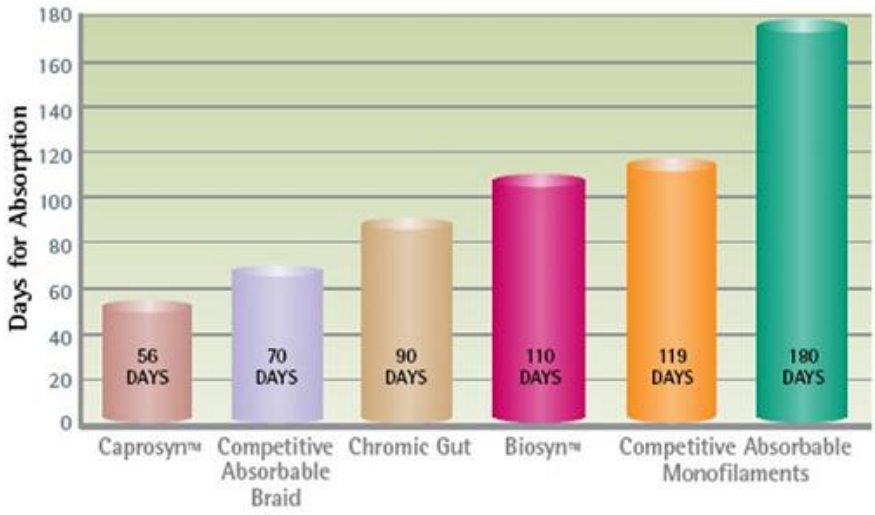
Uses include for tissues that heal slowly, such as fascia or tendons, closure of abdominal wall, or vascular anastomoses, etc.

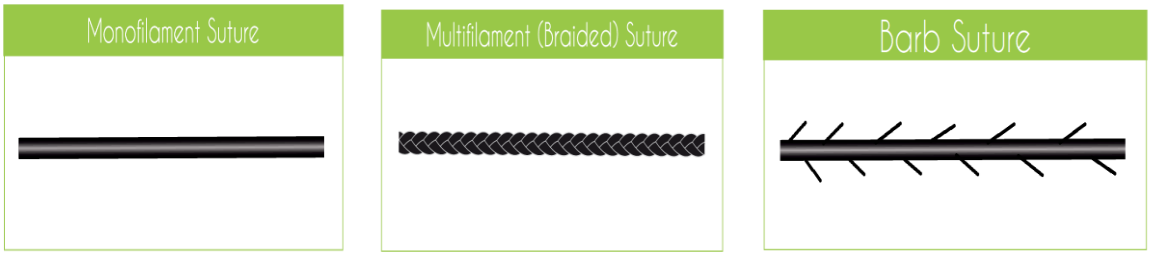
Natural absorbable sutures derived from mammalian collagen undergo enzymatic degradation whereas synthetic polymers undergo hydrolysis.

Non-Absorbable sutures include: - Polypropylene sutures, Nylon (poylamide), Polyester, PVDF, silk and stainless steel sutures.

Sutures can also be classified on the basis of material structure

Monofilament sutures (or braided) are single filaments (as their name implies) with less surface area than a multifilament (braided or twisted suture)




Monofilament sutures have higher memory which demands more handling care. They typically require more knots to ensure security, but tend to fracture less then multifilament suture, they pass through tissues more easily and cause a less inflammatory reaction than their multifilament counterparts. Monofilament sutures has lower resistance when passed through tissues. They are favored in vascular and microvascular surgery where ease of tying down sutures is crucial.

*Barb sutures are monofilament sutures* that have barbs or projections on the surface that can penetrate the tissues and hold them without necessitating the need for knots.

Monofilament sutures include: - Polypropylene sutures, Catgut, Nylon, PVDF, Stainless steel, Poliglecaprone and Polydioxanone sutures.

Multifilament (braided) sutures are more pliable; they hold knots more securely, have less memory and easier handling by the surgeon.

Multifilament sutures possesses higher tensile strength and flexibility

However, multifilament sutures also cause more friction through tissue and have increased capillarity and surface area, increasing their proclivity to inflammation and infection.

Multifilament sutures can be coated (like silicon, wax, PTFE, polycaprolactone, calcium stearate etc.) to make them slide through tissues more easily and have properties more similar to a monofilament suture. They can also be coated with antibiotics to make them more infection resistant. However, they

are more expensive than traditional sutures. Multifilament or braided sutures include:- PGA sutures, Polyglactin 910, silk and polyester sutures.

*Natural and synthetic materials*

Suture material is composed of either natural or synthetic materials. The most common natural suture materials are silk, which is nonabsorbable, and surgicalor chromic gut, which is absorbable and composed of proteins that degrade by proteolysis. Compared with synthetic suture material, natural sutures have a higher inflammatory reaction in tissue and an uneven distribution of strength along the length of the suture. Synthetic sutures are typically copolymers that degrade by hydrolysis. Their inflammatory reaction in tissue tends to be low.

| **List of some of the common suture material:** | | |
|---|---|---|
| **Generic Name** | Brand Name | Absorbability |
| **Chromic Gut** | Chromic Gut | Absorbable (10-15 days) |
| **Nylon** | Ethilon | Nonabsorbable |
| **Nylon** | Dermalon | Nonabsorbable |
| **Polydioxanone** | PDS | Absorbable (180 days) |
| **Polyester** | Ethibond | Nonabsorbable |
| **Polyglactin 910** | Vicryl | Absorbable (60 days) |
| **Polyglactin 910** | Vicryl Rapide | Absorbable (42 days) |
| **Polypropylene** | Surgilene | Nonabsorbable |
| **Polypropylene** | Prolene | Nonabsorbable |
| **Silk** | Silk | Nonabsorbable |
| **Stainless steel** | Stainless steel | No |
| | | |

*Suture material designation systems*

Surgical Sutures material and ligatures are available in a number of sizes. Sutures are classified into different sizes based on the diameter of the thread.

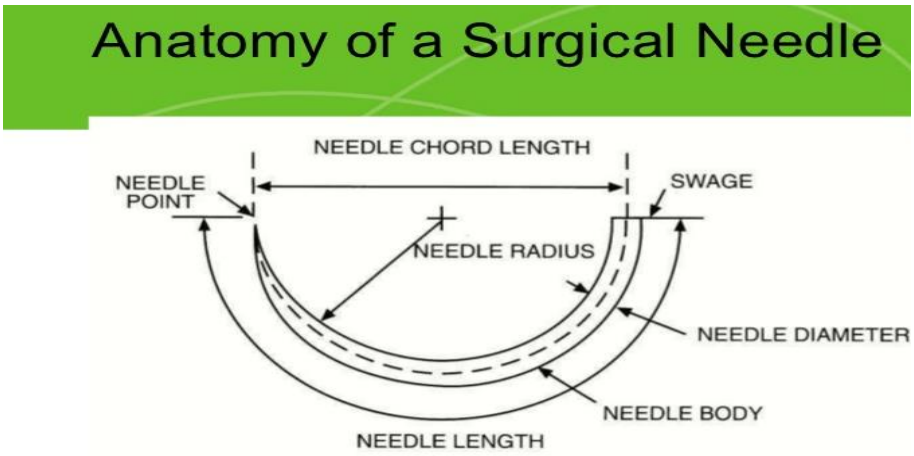
United States Pharmacopeia's classification of sutures into various sizes is widely accepted across the world.

However, certain European countries use the Metric system of classification of sutures based on the suture size. Higher the diameter of the suture, better the tensile strength. This classification helps manufacturers across the world in adopting uniform standards and also helps surgeons in selecting and ordering the right size of suture required for a particular procedure.

The suture packaging contains information on the thread diameter in both measurement systems.

On the USP scale, the thread number corresponds to its diameter and is determined by zeros. The more zeros, the smaller the diameter of the thread and the lower its tensile strength (thread 4-0 or 0000 is thinner than thread 2-0 or 00). In this system, the conditional dimensions of the threads are denoted by fractional numbers. Exam according to the EP (Metric) system, the size of the thread in

numerical terms is indicated as follows: 1, 2, 3, 4, 5, 6 and to find out the diameter of the thread in millimeters, you need to divide the size by 10.




The larger the number, the finer the suture.

Example: 2/0, 5/0 or 2-0, 5-0, this name is read as "two zeros", "five zeros", etc.

*Surgical Needles*

The surgical needle allows the placement of the suture within the tissue, carrying the material through with minimal residual trauma.

The ideal surgical needle should be rigid enough to resist distortion, yet flexible enough to bend before breaking, be as slim as possible to minimise trauma, sharp enough to penetrate tissue with minimal resistance, and be stable within a needle holder to permit accurate placement.

Basic Needle Design all surgical needles needles have three basic components:

1) Eye (or swage) 2) Body 3) Point.

The needle shape vary in their curvature and are described as the proportion of a circle completed – the ¼, ⅜, ½, and ⅝ are the most common curvatures used. Different curvatures are required depending on the access to the area to suture.

There are two types of needles (Tappered or Rounded and Cutting):

- Tapered needles are used inside the body such as on bowel, fascia, or muscle where the tissue is more easily pierced.
- Cutting needles are used for skin and very tough tissue such as bone and tendon.

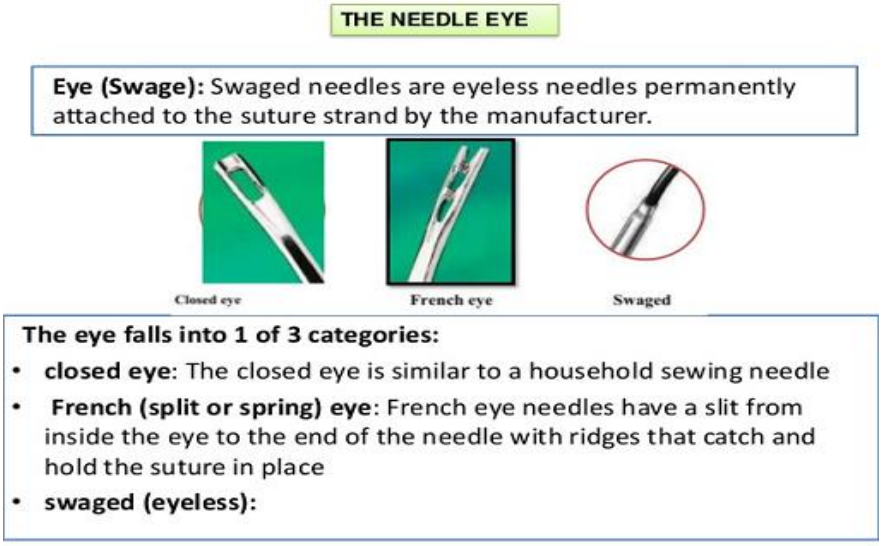
*Eye*

The eye of the surgical needle falls into the following three general categories:

1. Eyed needles, in which the needle must be threaded with the suture strand, and two strands of suture must be pulled through the tissue

2. Spring, or French, eyed needles, in which the suture is placed or snapped through the spring

3. Eyeless needles, a needle-suture combination in which a needle is swaged (permanently attached) onto one or both ends of the suture material




Almost all needles nowadays are atraumatic. A hole or channel is formed in the butt end of the needle and the suture is swaged or inserted into it. The suture will follow the needle's path without causing any further tissue damage and is therefore called 'atraumatic'. Old fashioned needles had an eye and were threaded with a loop of suture.

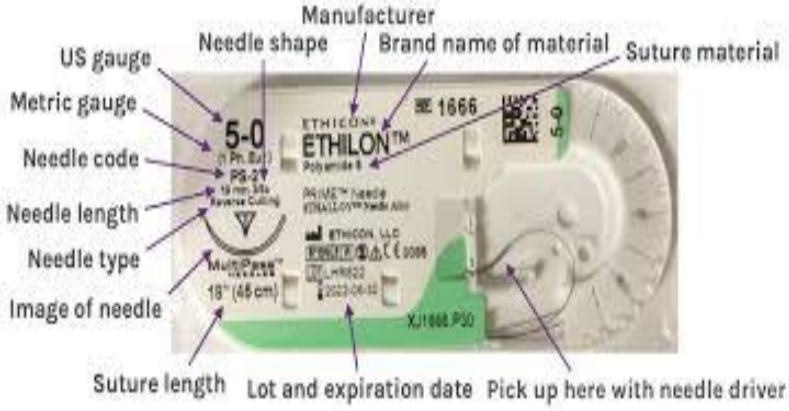
Needles are identified by means of a combination of letters and numbers, as recommended by the Technical Committee of the Registered Association of Surgical Suture Material Manufacturers. The first letter denotes the needle shape; the second letter denotes the needle type. If a third or fourth letter follows, this refers to particular features of the needle. The number after the letters denotes the length of the needle in mm when straightened.

Typically, on packages, a symbol is provided that shows a cross section of the needle tip

| EXPLANATION OF THE SURGICAL NEEDLE CODE | |
|---|---|
| NEEDLE SHAPE | |
| D = 3/8 circle | F = 5/8 circle |
| G = straight needle | H = 1/2 circle |

| | |
|---|---|
| K = semi-curve | L = spoon needle |
| V = 1/4 circle | |
| NEEDLE TYPE | |
| R = round-bodied needle | S = reverse-cutting needle |
| SPECIAL FEATURES: | |
| A = asymptotic | K = taper cutting |
| L = lancet point | M = micro point |
| N = blunt, round-bodied needle | |
| S = slim point | |
| SP = spatula needle | T = trocar point |
| X = extra strong | F = fine needle |

*Suture Packaging, Storage, and Selection*




For packaging, the suture material is sealed in a primary inner packet, which may or may not contain fluid; placed inside a dry outer peel-back packet then it is sterilized. This method permits easy dispensing onto the sterile field. Various forms of foil, plastic, and special paper are used for the inner and outer packets.

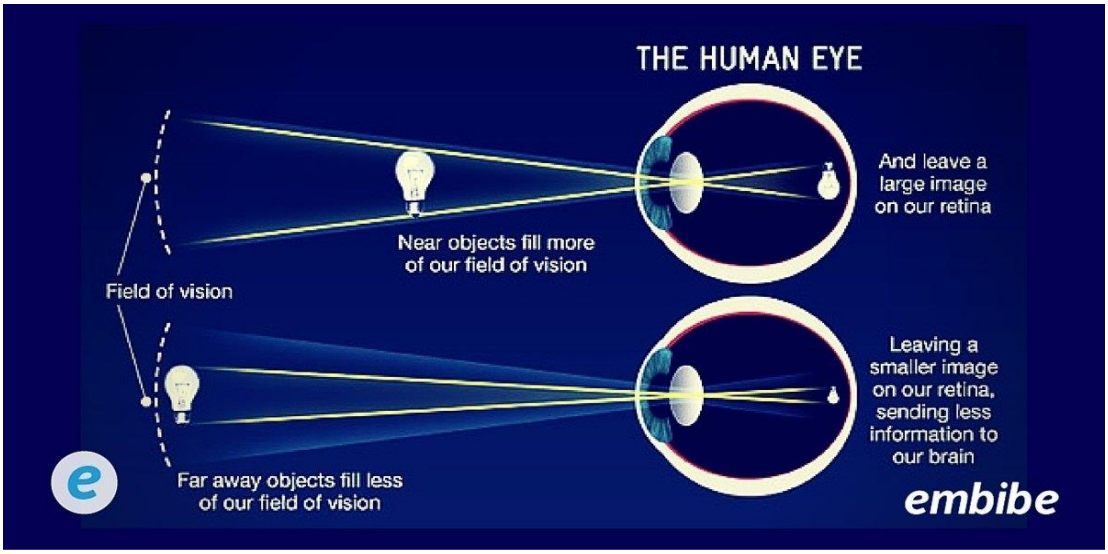
Each primary suture packet is self-contained, and its sterility for each patient is ensured as long as the integrity of the packet is maintained. Some suture packets have expiration dates that relate to stability and sterility. Packages should be stored in moisture-proof and dust-proof containers in units of one size and type.

Suture without needles are packaged as multiple strands and in reels for delivery as free ties. Suture with swaged needles can be packaged as single stitches or as multipacks containing several of the same sutures commonly used for the planned procedure. Multipacks may be permanently swaged

needles that require being cut for tying or control-release (pop-off) for easy needle detachment. Some sutures may be double-armed, with a needle at each end of the strand. Double-armed sutures are most commonly used for vascular procedures such as anastomoses and vessel repairs.

## THEME №6. EYE OPTICS. COMMODITY ANALYSIS DEVICES AND MEANS FOR RESEARCH, CORRECTION AND PROTECTION OF THE ORGANS OF VISION.

- Anatomy of the eye
- Refraction in the Eye
- Refractive Errors
- Types of Lenses for Vision Correction
- Eye-glasses Prescription
- Eyeglasses for Vision Correction
- Types of Contact Lenses
- The Contact Lens Prescription
- Contact Lens Care Systems & Solutions
- Ophthalmic Diagnostic Instruments and Devices




The eye sits in a protective bony socket called the orbit. Six extraocular muscles in the orbit are attached to the eye. These muscles move the eye up and down and side to side, and rotate the eye.

The extraocular muscles are attached to the white part of the eye called the sclera. This is a strong layer of tissue that covers nearly the entire surface of the eyeball.

The surface of the eye and the inner surface of the eyelids are covered with a clear membrane called the conjunctiva.

Light is focused into the eye through the clear, dome-shaped front portion of the eye called the cornea. Behind the cornea is a fluid-filled space called the anterior chamber. The fluid is called aqueous humor. The eye is always producing aqueous humor.

Behind the anterior chamber is the eye's iris (the colored part of the eye) and the dark hole in the middle called the pupil. Muscles in the iris dilate (widen) or constrict (narrow) the pupil to control the amount of light reaching the back of the eye.

Directly behind the pupil sits the lens. The lens focuses light toward the back of the eye. The lens changes shape to help the eye focus on objects up close. The lens is surrounded by the lens capsule, which is left in place when the lens is removed during cataract surgery. A replacement intraocular lens goes inside the capsule, where the natural lens was.

The vitreous cavity lies between the lens and the back of the eye. A jellylike substance called vitreous humor fills the cavity, nourishing the inside of the eye and helping the eye hold its shape.

Light that is focused into the eye by the cornea and lens passes through the vitreous onto the retina — the light-sensitive tissue lining the back of the eye.

A tiny but very specialized area of the retina called the macula is responsible for giving us our detailed, central vision. The other part of the retina, the peripheral retina, provides us with our peripheral (side) vision.

The retina has special cells called photoreceptors. These cells change light into energy that is transmitted to the brain. There are two types of photoreceptors: rods and cones. Rods perceive black and white, and enable night vision. Cones perceive color, and provide central (detail) vision.

The retina sends light as electrical impulses through the optic nerve to the brain. The optic nerve is made up of millions of nerve fibers that transmit these impulses to the visual cortex — the part of the brain responsible for our sight.

Refraction in the Eye

The vision process relies heavily on the ability of the eye to refract light. The main parts of the optical system of the eye includes the cornea and the lens of the eye.

Cornea

The process of vision first starts with the light passing through the cornea. Since the cornea has a spherical surface it acts like a converging lens.

Pupil and Iris

Once the light passes through the cornea it goes through the pupil which is essentially a hole that regulates light intensity by changing its diameter. So when its dark, the pupils dilate, up to about 8mm, so that more light can enter the eye. And when it is bright the pupil shrinks, to an average of 3mm, to restrict the amount of light. The pupil's size is controlled by the iris. Muscles in the the iris cause the pupil to shrink or dilate.

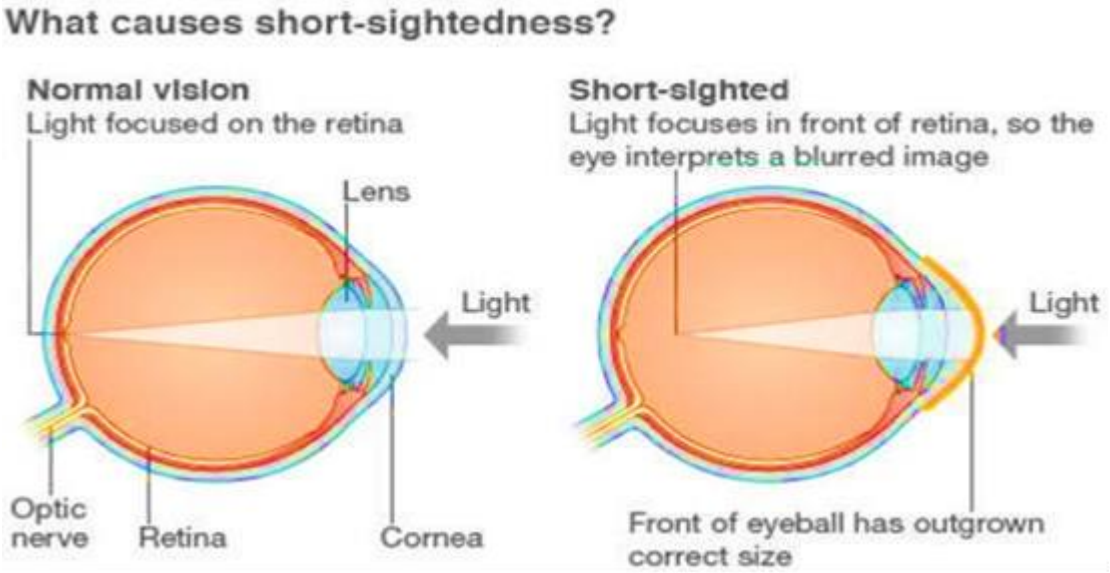
The Lens and Accommodation

After light rays travel through the pupil they hit the lens where refraction also takes place. The eye focuses an image through the process of accommodation, where the ciliary muscles can change the curvature of the lens. When the eye is looking at a distance little accommodation is needed, so the ciliary muscles are relaxed, and the lens has the longest focal length. To see a nearer object, the focal length of the lens needs to decrease to produce the image on the retina, to do this the ciliary muscles contract.

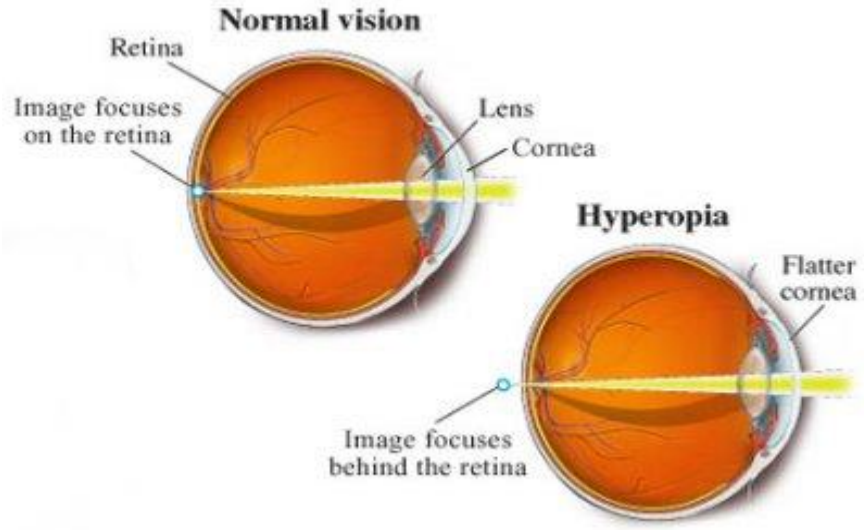
*Refractive Errors*

*Emmetropia is* the term used to describe an eye without any refractive errors.

*Nearsightedness (myopia, shortsightedness*) is a condition in which an image of a distant object becomes focused in front of the retina, making distant objects appear out of focus. The condition is usually caused by an elongation of the eyeball that occurs over time.

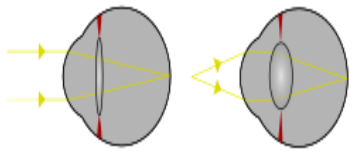


*Farsightedness (hyperopia)* is a condition in which an image of a distant object becomes focused behind the retina making objects up close appear out of focus. It is opposite of myopia, and is usually caused by shortening of the eyeball.




*Astigmatism i*s a condition in which an abnormal curvature of the cornea can cause two focal points to fall in two different locations, making objects up close and at a distance appear blurry. This problem may occur along with either myopia or hyperopia. These frequent conditions are termed "refractive errors."

Presbyopia is a condition associated with the aging of the eye that results in progressively worsening ability to focus clearly on close objects. Presbyopia is a natural part of the aging process.



*Diagnosis*

The visual acuity test is used to determine the smallest letters you can read on a standardized chart (Snellen chart) or a card held 20 feet (6 meters) away. Special charts are used when testing at distances shorter than 20 feet (6 meters). Some Snellen charts are actually video monitors showing letters or images.

Ophthalmologists also diagnose a decline in vision using refraction and retinoscopy and, when necessary, automated computerized devices.

Treatment

Optometrists and ophthalmologists prescribe eyeglasses and contact lenses to compensate for most refractive errors. In addition, newer techniques actually change the curved shape of the cornea, causing it to focus light directly onto the retina, thus producing a clear image.

*Types of Lenses for Vision Correction*

A corrective lens is a lens worn on (contact lens) or before the eye (eyeglass lenses). They are used to treat short-sightedness, long-sightedness, presbyopia, and astigmatism. Biconcave or diverging lenses are required for near-sightedness and biconvex or converging lenses are required for far-sightedness.

Optometrist usually prescribes corrective lenses. The prescription will involve the necessary corrections for refraction errors in each eye, individually for distance vision and near vision, for a total of four possible correction specifications.

Eye-glasses Prescription Abbreviations

The first step to understanding an eyeglass prescription is knowing what "OD" and “OS" mean. They are abbreviations for oculus Dexter and oculus sinister, which are Latin terms for "right eye" and "left eye."

Your eyeglass prescription also may have a column labeled "OU." This is the abbreviation for the Latin term oculus uterque, which means "both eyes."

Though use of these abbreviated Latin terms is common on prescriptions for glasses, contact lenses and eye medicines, some doctors and clinics have opted to modernize their eyeglass prescriptions and use RE (right eye) and LE (left eye) instead of OD and OS.

On your eyeglasses prescription, the information for your right eye (OD) comes before the information for your left eye (OS).

The eyeglass prescription contains other terms and abbreviations as well. These include:

- Sphere (SPH). This indicates the amount of lens power, measured in diopters D), prescribed to correct nearsightedness or farsightedness. If the number appearing under this heading has a minus sign (–), you are nearsighted; if it has a plus sign (+), you are farsighted.
- The term "sphere" means that the correction for nearsightedness or farsightedness is "spherical," or equal in all meridians of the eye.
- Cylinder (CYL). This indicates the amount of lens power for astigmatism. If nothing appears in this column, you have little or no astigmatism that requires correction. The number in the cylinder column may be preceded with a minus sign (for correction of nearsighted astigmatism) or a plus sign (for farsighted astigmatism). Cylinder power always follows the sphere power in an eyeglass prescription.
- Axis. This describes the lens meridian that contains no cylinder power to correct astigmatism. The axis is defined with a number from 1 to 180. The number 90 corresponds

to the vertical meridian of the eye, and the number 180 corresponds to the horizontal meridian.

If an eyeglass prescription includes cylinder power, it also must include an axis value, which follows the cyl power and is preceded by an "x" when written freehand.

- PD (Pupillary Distance). It's a measurement in millimeters between your eyes from the center of one pupil to the center of the other. Typically, adult's PD falls in a range between 54 and 74 mm, and kids' is somewhere between 43 and 54 mm. In Ukraine, PD is an obligatory part of the eyeglasses prescription. In some countries PD is not actually a part of your prescription. The optometrist or ophthalmologist rarely determines physical measurements, because that is the job of the optician.
- Add. This is the added magnifying power applied to the bottom part of multifocal lenses to correct presbyopia. The number appearing in this section of the prescription is always a "plus" power, even if it is not preceded by a plus sign
- Prism. This is the amount of prismatic power, measured in prism diopters ("p.d.")), prescribed to compensate for eye alignment problems. Only a small percentage of eyeglass prescriptions include prism.

When present, the amount of prism is indicated in either metric or fractional English units (0.5 or ½, for example). Four abbreviations are used for prism direction: BU = base up; BD = base down; BI = base in (toward the wearer's nose); BO = base out (toward the wearer's ear).

Sphere power, cylinder power and add power always appear in diopters. They are in decimal form and generally are written in quarter-diopter (0.25 D) increments.

Axis values are whole numbers from 1 to 180 and signify only a meridional location, not a power. When prism diopters are indicated in decimal form (e.g., 0.5).

Additional Information. Your eye doctor also might write specific lens recommendations on your eyeglass prescription — such as anti-reflective coating, photochromic lenses and/or progressive lenses — to give you the most comfortable vision correction possible.

*An example of an eyeglass prescription*

OD -2.00 SPH +2.00 add 0.5 p.d. BD

OS -1.00 -0.50 x 180 +2.00 add 0.5 p.d. BU

In this case, the eye doctor has prescribed -2.00 D sphere for the correction of myopia in the right eye (OD). There is no astigmatism correction for this eye, so no cylinder power or axis is noted. This doctor has elected to add "SPH," to confirm the right eye is being prescribed only spherical power. (Some doctors will add "DS" for "diopters sphere;" others will leave this area blank.)

The left eye (OS) is being prescribed -1.00 D sphere for myopia and -0.50 D cylinder for the correction of astigmatism. The cyl power has its axis at the 180 meridian, meaning the horizontal (180-degree) meridian of the eye has no added power for astigmatism and the vertical (90-degree) meridian gets the added -0.50 D.

Both eyes are being prescribed an "add power" of +2.00 D for the correction of presbyopia.

This eyeglass prescription also includes prismatic correction of 0.5 prism diopter in each eye. In the right eye, the prism is base down (BD); in the left eye, it's base up (BU).

## Eyeglasses for Vision Correction

Wearing eyeglasses is an easy way to correct refractive errors. There are two different types of eyeglass lens designs: single vision, an all-purpose lens designed to correct distance vision

multifocal, designed to correct both distance vision and near vision (the upper portion is focused for distance vision, while the bottom portion is used for up close activities such as reading).

Multifocal lenses are eyeglasses used to correct presbyopia, the eye's natural diminished ability to focus on near objects that comes with age.

Bifocals have a correction for reading on the bottom half of the lens and another for seeing at a distance on the top.

Trifocals are lenses with three different lens corrections — distance vision, intermediate vision, and near vision — in one set of eyeglasses.

Progressive lenses function generally the same way as bifocals or trifocals; however, they have a smooth transition between distance and near focal areas instead visible dividing lines.

Prism correction is used in eyeglasses for some people who have diplopia, or double vision and strabismus (cross-vision).

### *Types of Eyeglass Lens Materials*

Eyeglass lenses used to be made only of glass, but today most lenses are plastic. Plastic lenses are lighter, more flexible, and safer because they are less likely to shatter. They also have inherent UV light-blocking ability.

For people who wear eyeglasses during sports or other activities that can result in eye injuries, eye doctors often recommend polycarbonate lenses, a safety lens material that is highly resistant.

Another type of lens is a thin, light, plastic lens called a "high index" lens. These are recommended for people who need high visual correction.

## Prescription Glasses - Optical Coatings

The most common types of coatings include anti-reflective coatings which reduce the reflections of the white of the eye as well as bright objects behind the spectacles wearer; UV coatings which reduce the light transmission in the UV or ultraviolet spectrum and; scratch resistant coatings which increase the abrasive properties of plastic lens.

Another option for vision correction with UV protection is prescription sunglasses. Also, for people who prefer one set of eyeglasses for both inside and outdoors, photochromatic lenses are a good

option. Photochromatic lenses have a tint that varies based on their light exposure, with a darker tint in sunlight and lighter indoors.

*Types of Contact Lenses*

There are two general categories of contact lenses – soft and rigid gas permeable (RGP). All contact lenses require a valid prescription.

*Soft Contact Lenses*

Soft contact lenses are made of soft, flexible plastics that allow oxygen to pass through to the cornea. Soft contact lenses may be easier to adjust to and are more comfortable than rigid gas permeable lenses. Newer soft lens materials include silicone-hydrogels to provide more oxygen to your eye while you wear your lenses.

*Rigid Gas Permeable (RGP) Contact Lenses*

Rigid gas permeable contact lenses (RGPs) are more durable and resistant to deposit buildup, and generally give a clearer vision. They are less expensive over the life of the lens since they last longer than soft contact lenses. They are easier to handle and less likely to tear.

*Extended Wear Contact Lenses*

Extended wear contact lenses are available for overnight or continuous wear ranging from one to six nights or up to 30 days. Extended wear contact lenses are usually soft contact lenses. They are made of flexible plastics that allow oxygen to pass through to the cornea.

*Disposable (Replacement Schedule) Contact Lenses*

The majority of soft contact lens wearers are prescribed some type of frequent replacement schedule. "Disposable" means used once and discarded, i.e., a new pair of lenses is used each day.

*Specialized Uses of Contact lenses*

Conventional contact lenses correct vision in the same way that glasses do, only they are in contact with the eye. Two types of lenses that serve a different purpose are orthokeratology lenses and decorative (plano) lenses.

*Orthokeratology (Ortho-K)*

Orthokeratology, or Ortho-K, is a procedure that uses specially designed rigid gas permeable (RGP) contact lenses to change the curvature of the cornea to temporarily improve vision. This procedure is primarily used for the correction of myopia (nearsightedness).

Overnight Ortho-K lenses are the most common type of Ortho-K. There are some Ortho-K lenses that are prescribed only for daytime wear. Overnight Ortho-K lenses are commonly prescribed to be worn while sleeping for at least eight hours each night. The vision correction effect is temporary. If Ortho-

K is discontinued, the corneas will return to their original curvature and the eye to its original amount of nearsightedness.

The Contact Lens Prescription

| Contact lens Parameters | Unit of measurement | Abbreviation | More information |
|---|---|---|---|
| Dioptres | dioptre | PWR, D, SPH, dpt | from −30.00 to +30.00 |
| Curvature | millimeter | BC | from 8.00 to10.00 |
| Average | millimeter | DIA | from 13.00 to 15.00 |
| Cylinder | dioptre | CYL, ZYL | from −0.25 to −10.00, toric contact lenses |
| Cylinder axis | degree | A, AX, AXIS | from 0 to 180, toric contact lenses |
| Addition | dioptre | ADD | from 1.00 to 3.00, multifocal lenses |

Curvature (BC). The base curve of a contact lens describes the curvature of the lens in millimeters, to provide the highest comfort while wearing lenses, i.e. how well the lens attaches to the eye. Normally these parameters are between 8–10 mm.

Diopters / Sphere (D/dpt./S/SPH/PWR)

Sphere is the power of the contact lens. The unit of measure for sphere power is a diopter, or D. In general, the spherical power of a lens is indicated with a plus sign (+) for hyperopia and a minus sign (-) for myopia.

Average (DIA)

This value is the diameter (or size) of the lens. Soft contact lenses have a larger diameter from 13.00 to 15.00 mm than hard contact lenses from 9 to 10 mm.

Cylinder (CYL)

The cylinder value is needed for the manufacture of contact lenses for astigmatism. It is a negative value, which makes any correction for the curvature of the cornea.

Axis (A/ACH/AXIS/AX)

The axis is required for astigmatism as a supplement to the contact lens with cylinder. It describes the exact position of the curvature on the cornea and is given in a range of 0° – 180°. Note that a degree

of zero is also written as 180. The number 90 means the vertical position of the eye, and the number 180 corresponds to the horizontal meridian.

Addition (ADD)

ADD is the difference between the dioptric value of the far vision and the dioptric value of the near vision. Values up to 1.25 are regarded as low, up to 2.00 as average and up to 3.00 as high

The difference between contact lens and eyeglasses prescription

They are completely different because eyeglass lenses are placed roughly 12 millimeters from your eyes, whereas contact lenses are applied directly to the eyes' surface. However, it is necessary to determine both values so that a perfect view is possible.

Furthermore, the measurement method between glasses and contact lenses is slightly different, as eyeglasses prescription needs to measure the distance between the eyes.

Additional information on a contact lens package

The oxygen permeability is given with the value “Dk/t”. The longer the lenses remain on the eyes, the more oxygen permeable they should be. If the value is too low, redness, or itching and burning may occur in sensitive eyes.

Contact Lens Care Systems & Solutions

Lens care systems and solutions are products you use to clean, disinfect, and store contact lenses.

Multipurpose solution is an all-in-one care system used to clean, rinse, disinfect, and store soft contact lenses. This solution is the most commonly used care system among soft contact lens wearers.

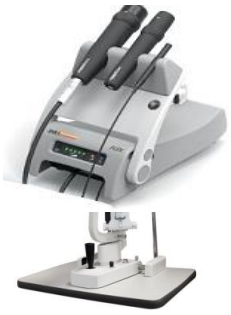
Saline solution does not disinfect contact lenses. Only use saline for rinsing contact lenses after cleaning and disinfecting with another care system.

Daily cleaner is intended for cleaning—not disinfecting—contact lenses. The cleaner loosens and removes deposits and debris from the contact lens. You must use additional products, such as multipurpose solution, for rinsing the daily cleaner off, disinfecting, and storing the contact lenses.

*Ophthalmic Diagnostic Instruments and Devices*

To establish the diagnosis ophthalmologists, use the range of instruments and devices.

**Tonometer’s** are used to measure the Intraocular Pressure, or IOP, of the eye. IOP is often measured in millimeters of Mercury (mmHg).



**A-scan Ultrasound biometry** utilizes an ultrasound device. This device can determine the length of the eye and can be useful in diagnosing common sight disorders. A-scans are also extremely beneficial in cataract surgeries.

**An automatic objective refractor** is used to determine a patient's refractive error. Some refractors on the market today also provide visual acuity capabilities

A visual field test checks the extent and intensity of what you are able to see including your entire peripheral (side) vision. By measuring the extent and the intensity of one's visual field, many visual and general health conditions can be detected.

The Slit Camera The slit lamp gives us a magnified, three-dimensional view of your eye. We can use the slit lamp to look at the front parts of the eye (cornea and sclera), the lens, the colored part (iris), and the front section of the gel-like fluid that fills the large space in the middle of the eye.

## THEME № 6. COMMODITY ANALYSIS OF RELATED PRODUCTS PHARMACY ASSORTMENT PRODUCTS

Mineral water is water from a mineral spring that contains various minerals, such as salts and sulfur compounds. Mineral water may be classified as "still"(without gases) or" sparkling" (carbonated) according to the presence or absence of added gases.

In the European Union, bottled water may be called mineral water when it is bottled at the source and has undergone no or minimal treatment.

Not all waters are created equal – they differ significantly in taste, smell, purity and nutritional value. Here are the main classifications of water according to German (and US) law:

*Natural mineral water*

Natural mineral water comes from underground, is protected from contamination and bottled directly at the source. It contains vital minerals and trace elements and makes a healthy contribution to the

daily diet. The water's composition of minerals and trace elements may differ significantly from source to source.

*Medicinal water*

Medicinal waters are special types of mineral waters: they are characterized by a particularly high content of minerals and have a healing and preventative health effect. Healing waters are subject to the German Federal Pharmaceutical Act and must be approved by the Federal Ministry of Health.

Spring water

Like mineral water, spring water is naturally pure, comes from underground reservoirs and is bottled at source. However, it contains less mineral content and trace elements than mineral water and has limited nutritional value. A bottle labeled "spring water" may contain water from different sources, and bottlers may remove iron and add or remove carbon dioxide.

*Table water*

Table water is not a natural but a manufactured product. Regular tap water, mineral water or spring water may be mixed with ocean water or enriched with minerals or carbon dioxide. Bottled water can be produced and bottled anywhere.

According to the European Legislation (2009/54/EC Directive), physical and chemical characterization is used to make a classification of the different mineral waters, basing on the analysis of main parameters. First of all, natural mineral waters are classified by the fixed residue at 180°, that is the amount of residual mineral salts (in mg) after the evaporation of 1 L of water at 180°C.

Classification of natural mineral waters based on fixed residue at 180°C (14).

| Fixed residue at 180°C | Definition |
|---|---|
| **< 50 mg/L** | Very low mineral content water (or light mineral water) |
| **50–500 mg/L** | Low mineral content water |
| **500–1500 mg/L** | Medium mineral content water |
| **> 1500 mg/L** | Rich mineral content water |

Mineral waters are also classified by other physical parameters, like pH, temperature and hardness. With regard to pH, mineral waters are classified as acid water (pH<7) or alkaline water (pH>7). By

temperature, mineral waters may be cold (< 20°Cat source), hypotermal (20–30°Cat source), mesothermal waters (30–40°Cat source) and hyperthermal waters (> 40°Cat source). Hardness indicates the presence of alkaline earth metals and mineral waters may be very soft (0–100 mg/L of $CaCO_3$), soft (100–200 mg/L of $CaCO_3$), hard (200–300 mg/L of $CaCO_3$) or very hard (> 300 mg/L of $CaCO_3$ )

On the basis of minerals content, waters have been classified in several ways: Marotta and Sica classification (1933) represents in Italy the first reference and it takes into consideration temperature, fixed residue and chemical composition, according to a scheme that includes classes and subclasses. They gave a name to each mineral water considering, firstly, the prevalent anion and secondly, the cation; they classified waters as salt waters, salty-sulfate waters, bicarbonate-sulfate waters, salt-bromine-iodine waters, etc. Although in Europe and in United States there are many categorizations of mineral waters, nowadays the 2009/54/EC Directive is the European reference to classify them. As reported in the EC Directive, mineral waters can be:

- "Water with bicarbonate", if bicarbonate content is >600 mg/L
- "Water with sulfate", if sulfate content is >200 mg/L
- "Water with chloride", if chloride content is >200 mg/L
- "Water with calcium", if calcium content is >150 mg/L
- "Water with magnesium", if magnesium content is >50 mg/L
- "Water with fluoride", if fluoride content is >1 mg/L (More than 1,5 mg/L of fluoride is unsuitable for children below the age of 7)
- "Acid water", if the $CO_2$ content is >250 mg/L
- "Water with sodium", if sodium content is >200 mg/L. The lettering "indicate for low sodium diet" can be added to labels if sodium content is <20 mg/L.

*Baby food. Milk formula*

Infant formulas are foods designed to feed babies and infants less than 12 months of age. These are normally prepared for bottle-feeding and are in a powdered form that is mixed with water or another liquid and is usually considered a substitute for breast milk. Commonly available infant formulas contain purified whey and casein from cow's milk as a protein source, a blend of vegetable oils as a source of fat, lactose as a source of carbohydrates, a mixture of vitamins and minerals, and other materials depending upon the manufacturer. The manufacturers of infant formulas claim that the composition of these formulas is almost same as that of the mother's milk. Although the best food for young ones is breast milk and it is not favorable to replace it with any infant formula. Breastfeeding gives all children the healthiest start in life. Breastmilk stimulates brain development and acts as a baby's first vaccine. Breastfeeding lowers health-care costs, creating healthier families and a smarter workforce. It also protects mothers' health. When mothers breastfeed, everyone

benefits. Still, worldwide, only 43 percent of children younger than six months are exclusively fed breastmilk. By age two, only4 6 per cent receive any breastmilk at all. UNICEF and the World Health Organization (WHO) are leading a global Breastfeeding Advocacy Initiative to increase the political commitment for breastfeeding, which is one of the smartest investments a country can make.

"Breastmilk substitutes (BMS) include all milk products—such as infant formula, follow-up formula, and growing up milks—marketed for use by infants and children up to 36-months old." (WHO)

According to the document REGULATION (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet, definition:

- Infants' means children under the age of 12 months;
- 'Young children' means children aged between one and three years;
- 'Follow-on formulae' means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;
- Infant formulae mean food stuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding;
- Formula milk, also known as baby formula or infant formula, is usually made from cows' milk that has been treated to make it more suitable for babies. There's a wide range of brands and types of formula available in pharmacies and shops. Always check labels carefully to make sure you're buying a suitable milk for your baby.

Formula comes in 2 different forms: a dry powder you make up with water, or a ready-to-feed liquid formula. While ready-to-feed liquid formula can be convenient, it tends to be more expensive and, once opened, needs to be used more quickly.

*First infant formula (first milk). Suitable from birth*

First infant formula (first milk) should always be the first formula you give to your baby.

The cows' milk in formula contains 2 types of proteins – whey and casein. First infant formula is based on whey protein which is thought to be easier to digest than other types of formula. First infant formula is the only formula your baby needs. Your baby can stay on it when you start to introduce solid foods at around 6 months and drink it throughout their 1st year.

When your baby is 1-year-old, they can start to drink whole cows' milk or sheep's or goats' milk (as long as it's pasteurised).

*Goats' milk formula. Suitable from birth*

They are produced to the same nutritional standards as cow's milk-based formula.

Goats' milk formula is not less likely to cause allergies in babies than cows' milk formula.

Goats' milk formulas are not suitable for infants with cows' milk allergy (also known as cows' milk protein allergy), as the proteins they contain are very similar.

*Hungrier baby formula (hungry milk) Suitable from birth*

This type of formula contains more casein than whey, and casein is harder for babies to digest.

Although it's often described as suitable for "hungrier babies", there's no evidence that babies settle better or sleep longer when fed this type of formula.

*Anti-reflux (stay down) formula. Suitable from birth (but only under medical supervision).*

This type of formula is thickened with the aim of preventing reflux in babies (when babies bring up milk during or after a feed).

*Comfort formula Suitable from birth (but only under medical supervision).*

This type of formula contains cows' milk proteins that have already been partly broken down (partially hydrolyzed). This is supposed to make it easier to digest and help prevent digestive problems such as colic and constipation. Partially hydrolyzed formulas are not suitable for babies who have cows' milk allergy.

*Lactose-free formula. Suitable from birth (but only under medical supervision).*

This formula is suitable for babies who are lactose intolerant. This means they cannot absorb lactose, which is a sugar that's naturally in milk and dairy products. Lactose intolerance is rare in babies. Symptoms include diarrhoea, abdominal pain, wind and bloating.

*Hypoallergenic formula. Suitable from birth (but only under medical supervision).*

If your baby is diagnosed as being allergic to cows' milk, a GP will prescribe an appropriate infant formula with fully hydrolyzed (broken down) proteins. It's not suitable for babies with cows' milk allergy.

*Follow-on formula Suitable from 6 months (but ask a health visitor for advice first).*

Follow-on formula should never be fed to babies under 6 months old. The labels on follow-on formula can look very similar to those on first infant formula. Read the label carefully to avoid making a mistake.

*Good night milk Suitable from 6 months (but ask a health visitor for advice first).*

Some follow-on formula has cereal added to it and is sold as a special formula for babies to have at bedtime. This type of formula is not needed, and there's no evidence that babies settle better or sleep longer after having it. Good night formula should never be given to babies under 6 months old.

Soya formula. Suitable from 6 months (but only under medical supervision).

Soya formula is made from soya beans, not cows' milk. It's occasionally used as an alternative to cows' milk formula for babies who have cows' milk allergy. There are some concerns about the fact

that soya contains phytoestrogens. These are found naturally in some plants. The chemical structure of phytoestrogens is similar to the female hormone oestrogen. Because of this, there are concerns that they could affect a baby's reproductive development, especially in babies who drink only soya-based infant formula. Also, because soya formula contains glucose, so it is more likely to harm a baby's teeth. Only use soya formula if it has been recommended or prescribed by a health visitor or GP.

Growing-up milk (toddler milk) Suitable from 1 year (but ask a health visitor for advice first).

Growing-up and toddler milks are marketed as an alternative to whole cows' milk for toddlers and children over 1-year-old. There's no evidence to suggest that these products provide extra nutritional benefits for young children. Whole cows' milk is a suitable choice as a main drink for your child from age 1. Semi-skimmed cows' milk is a suitable main drink for children over 2 who are eating a balanced diet.

Formula for Preterm Infants

Formulas specifically made for premature babies, made from cow’s milk ingredients. Formula for Infants with Low Birth Weight. Formulas specifically made for babies with low birth weight (less than 2.5 kg)

Types of milk to avoid

Not all milk is suitable for feeding babies. You should never give the following types of milk to a baby under 1 year: condensed milk, evaporated milk, dried milk, goats' or sheep's milk (but it's fine to use them when cooking for your baby, as long as they are pasteurized)

other types of drinks known as "milks", such as soya, rice, oat or almond drinks

STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72-1981 Formerly CAC/RS 72-1972. Adopted as a worldwide Standard in 1981. Amendment: 1983, 1985, 1987, 2011, 2015 and 2016. Revision: 2007. (WHO)

Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.

Infant formula is a product based on milk of cows or other animals or a mixture thereof and / or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.

PACKAGING

The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen andcarbon dioxide may be used as packing media.The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses.

## LABELLING

The requirements of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to infant formula and formula for special medical purposes for infants. Labeling should contain the following information:

1. Food Name

1.1 The text of the label and all other information accompanying the product must be written in relevant language (s).

1.2 The name of the product should be either “Baby formula” or any appropriate designation indicating the true nature of the product, in accordance with national use.

1.3 The sources of protein in the product must be clearly indicated on the label.

1.4 If cows’ milk is the only source of protein, the product may be labelled "Infant Formula Based on Cows ‘milk".

1.5 A product that does not contain any milk or any milk derivatives shall be labeled “does not contain milk or milk” products "or equivalent phrase.

2. List of ingredients

2.1 A complete list of ingredients shall be indicated on the label in decreasing order of proportion, except that if vitamins and minerals are added, these ingredients can be divided into separate groups for vitamins and minerals. Within these groups, vitamins and minerals should not be listed in in decreasing order of proportion.

2.2. For animal or vegetable ingredients and food additives, a specific name must be indicated. IN In addition, appropriate class names for these ingredients and additives may be included on the label.

3. Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, mineral, cholin, etc.

4. Date Marking and Storage Instructions

In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking.

5. Information for Use

5.1 Products in liquid form may be used either directly or in the case of concentrated liquid products Products in powder form should be reconstituted with water that is safeor has been rendered safe by previous boiling for preparation.

5.2 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

5.3 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.

6. Additional Labelling Requirements

6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.

6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

6.3 The terms "humanized", "materialized" or other similar terms shall not be used.

6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs

**Insect Repellents (IR)**

Most emerging infectious diseases today are arthropod-borne and cannot be prevented by vaccinations. Insect repellents offer important topical barriers of personal protection from arthropod-borne infectious diseases. An insect repellant is defined as a chemical or organic agent that makes the atmosphere within 4 centimeters of human skin so noxious to insects as to discourage contact and

biting. On the other hand, an insecticide is a chemical or organic agent, often plant-derived, that kills insects, typically with a neurotoxin. Why Use Insect Repellents?

The 3 major reasons to use insect repellents are: 1) new threats to human health posed by emerging and imported arthropod-borne infectious diseases; 2) the dominance of new, competent insect vectors of infectious diseases; and 3) the inability to primarily prevent the transmission of most arthropod-borne infection diseases by vaccinations with the exceptions of yellow fever vaccine in South America and Africa, Japanese encephalitis vaccine in Southeast Asia, and several regional tick-borne virus vaccines in Eastern Europe.

Properties of Ideal Insect Repellents

Insect repellants must be effective, safe, and pleasant to apply in children and adults and during pregnancy without damaging skin or clothing.

Properties of an ideal insect repellent

1. Effective against broad range or arthropods including fleas, flies, mosquitoes, biting midges ("no-see-ums"), ticks
2. Can be applied to skin without adverse effects
3. No damage to clothing (ie, staining, bleaching, thinning)
4. Can be applied with sunscreen
5. No odor or has pleasing odor
6. No oily residues are left on skin
7. Difficult to remove by washing, wiping, or sweating
8. No effect on plastics (ie, glasses, watches, upholstery)
9. Chemically stable
10. Reasonably priced for broad range of people
11. Nontoxic
12. Duration efficacy is adequate

Insect repellants may be divided into 2 basic chemical classes:

1) the synthetic chemicals, such as DEET, picaridin, and IR3535 (Skin So Soft; Avon Products, Inc., New York, NY);

2) the plant-derived oils and synthetics, such as oil of lemon eucalyptus, oil of citronella, and permethrin.

*The chemical insect repellents*

The first chemical insect repellents included the dialkyl phthalates (dibutyl and dimethyl phthalate), discovered in 1929; By 1946, N, N-diethyl-3-methylbenzamide (or DEET, previously N, N-diethylm-toluamide) was in use by U.S. Armed Forces and later marketed to the public in 1956. DEET is available worldwide today in a variety of formulations including aerosols, creams, lotions, sprays, gels, sticks, and wipes (towelettes) at concentrations ranging from 5% to 100%. Most products contain concentrations of 30% to 40% DEET or less, and human studies have now confirmed a plateau insect repellent effect as the concentration of DEET applied topically exceeds 50%. DEET concentrations in the range of 10% to 35% will provide adequate insect bite protection, with concentrations below 30% recommended for children 2 years of age and older. Some experts also recommend against applying chemicals such as DEET and sunscreen simultaneously since that would increase DEET penetration.

The newest insect repellent, picaridin, or icaridin in Europe, was developed in Europe in the 1990s, released in the United States about 10 years ago, and offered several immediate advantages over DEET including the lack of a chemical odor, a nonsticky or greasy feel, and lack of any damage to clothing or plastics. Like DEET, the exact mechanism of action of picaridin is unknown, but its vapor barrier is so noxious to insects' taste and olfactory senses that it discourages insect contact and biting. Picaridin is effective against mosquitoes, flies, chiggers (larval Trombiculid mites), and ticks and is available as lotions, sprays, and wipes in strengths of 7% to 20%. US Environmental Protection Agency (EPA) registration data indicate that picaridin at a concentration of 20% is effective against mosquitoes and ticks for 8-14 hours. The 10% concentration is effective for 3.5-8 hours. Picaridin is not recommended for use in children under 2 years of age.

IR3535 (ethyl butylacetylaminopropionate) was first marketed in the US as a skin moisturizer but, when noted to be as effective as DEET against biting midges or "no-see-ums", it was adopted for use as an IR.

IR3535 20% offers protection against Aedes and Culex mosquitoes for 7-10 hours but only 3.8 hours of protection against Anopheles in some studies

*The plant-derived insect repellents*

The first effective insect repellents included smoke from burning tar and cooking fires, and a variety of plants and flowers hung in homes or on porches or rubbed on the skin, including chrysanthemum, geranium, and lantana. Many plant oils, such as citronella, clove, geranium, mint, nutmeg, pennyroyal, and soybean would also repel insects for short periods, but their high volatility limited their duration of effectiveness when burned in candles or applied topically.

Oil of lemon eucalyptus or p-menthane-3, 8-diol (PMD) is an extract of the leaves of lemon eucalyptus, Corymbia citriodora, or a synthetic version of its major repellent component, PMD. Commonly available products have a concentration of 30% OLE and 20% PMD. Some studies have suggested that concentrations of 20-26% PMD may be as effective as 15-20% DEET against both mosquitoes and ticks. It is available in pump sprays in concentrations of 10% to 40%. PMD has a mosquito repellant efficacy and duration equal to that of DEET, and, like picaridin, may offer better protection against ticks than DEET. The FDA has recommended that PMD not be used in children under 3 years of age.

Citronella (3, 7-dimethyloct-6-en-1-al) is a natural plant oil obtained from several species of Cymbopogon lemongrasses. Citronella is available as a lotion, oil, or solid wax impregnated into candles and flame pots in strengths ranging from 0.5% to 20%. Because of its high volatility, citronella has a short duration of action but can deter nuisance biting by mosquitoes for up to 2 hours. It is ineffective against flies, fleas, biting midges, and ticks.

Note: Oil of lemon eucalyptus and lemon eucalyptus oil are not the same product. Natural lemon eucalyptus oil has not been tested or approved as an effective repellent.

Most "natural" insect repellents such as citronella, neem oil, and herbal extracts are no longer permitted for sale as insect repellents in the EU due to their lack of effectiveness;

Permethrin, first marketed in 1973, is a laboratory-manufactured pyrethroid insect repellant and contact insecticide that is derived from the crushed dried flowers of Chrysanthemum cinerarifolium. Permethrin is not absorbed topically and requires direct insect contact to be effective. Its mechanism of action is via initial excitation of the insect's nervous system by sodium channel blockade followed by acetylcholinesterase inhibition and fatal paralysis. When applied to clothing, bed nets, tents, and sleeping bags, permethrin and other synthetic pyrethroids (allethrin, alpha-cypermethrin, cyfluthrin, deltamethrin, etofenprox, lambda-cyhalothrin, and metofluthrin) all provide very high-level protection against mosquitoes, flies, biting midges, chiggers, fleas, sandflies, and ticks, especially when combined with topically applied insect repellents. Long-duration, pyrethroid-treated mosquito bed nets are now available that maintain effective insecticide levels for 3 years. Permethrin can kill ticks on contact and provides better tick protection than DEET and picaridin

*Insect repellent use in children*

The FDA has recommended that DEET should not be used in children under 2 years of age, and the American Academy of Pediatrics has recommended a maximum DEET formulation strength of 33% for all children. The FDA has recommended that PMD not be used in children under 3 years of age.

*Area and barrier chemical insect repellents*

In addition to topically applied insect repellents and pyrethroid-impregnated clothing, a number of area and barrier methods are used to repel insects, including permethrin-impregnated curtains, screens, and bed nets; insecticide vaporizers; mosquito coils; knockdown insecticide aerosol sprays; and a variety of plant-oil burning candles. Some of these measures are effective; others are not.

Electric insecticide vaporizers can be set to release pyrethroid insecticides and will inhibit nuisance biting by mosquitoes, but there is no evidence that they will prevent the transmission of arthropod-borne infectious diseases.

Knockdown insecticide aerosol sprays are designed to kill flying insects indoors. Mosquito coils are made from compacted pastes or powders containing pyrethroids and other volatile chemicals, including formaldehyde. When lit, the coils will smolder and smoke for hours, discouraging nuisance biting by mosquitoes but contaminating the atmosphere with particulates and volatile chemicals. Burning a variety of plant oil–based candles may reduce nuisance biting by mosquitoes and flies for a couple of hours.

*Safe Application of Repellents*

DO

Use aerosol or pump sprays for treating skin and clothing, except around the mouth or face. Sprays provide a more even application.

Use liquids, creams, lotions or sticks to more precisely apply the product to exposed skin.

Wash repellents off skin with soap and water when you return indoors.

Keep insect repellents out of the reach of children at all times.

Chemical and Plant-Based Insect Repellents: Efficacy, Safety, and Toxicity

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The graphic will identify the type of pest the product is expected to repel and the amount of time the repellent will be effective. The repellency awareness graphic will be available only for skin-applied insect repellent products.

## THEME №8. ACCEPTANCE OF GOODS AT THE PHARMACY WAREHOUSE.

*Pharmaceutical Warehousing*

Pharmaceuticals are stringently regulated by the authorized bodies such as The European Medicines Agency (EMA) or the Food and Drug Administration (FDA) in the USA. EMA coordinates inspections to verify compliance with current Good Manufacturing Practice (GMP) standards and plays a key role in harmonising GMP activities at European Union (EU) level. FDA's regulatory standards for the industry are referred to GMP standards. These standards apply to warehouses, processes, and to the drugs themselves.

Warehouse - A facility where company stocks are stored. In Pharma business, typically store raw material, packaging material, semi-finished and finished goods..

GMP standards related to warehousing include:

Drugs must be stored to prevent contamination, and be positioned to allow for inspection and cleaning of the area.

Each lot of drug products must be identified with a distinctive (and traceable) code, and the lot's status must be identified (approved, quarantined, rejected).

Written procedures must describe the distribution process for each drug. This includes procedures for recalls. Written procedures must describe the appropriate storage conditions for each drug.

Distribution - The process in which the finished drug product is moved from the initial warehouse to

the final consumer. This process may involve several steps from beginning to end depending on the complexity of any manufacturing /marketing agreements

Good distribution practice (GDP). That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products (by WHO).

Good distribution practice describes the minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain.

Compliance with GDP ensures that:

medicines in the supply chain are authorized in accordance with European Union (EU) legislation;

medicines are stored in the right conditions at all times, including during transportation;

contamination by or of other products is avoided;

an adequate turnover of stored medicines takes place;

the right products reach the right addressee within a satisfactory time period.

The distributor should also put in place a tracing system to enable finding faulty products and an effective recall procedure.

GDP also applies to the sourcing, storage and transportation of active pharmaceutical ingredients and other ingredients used in the production of the medicines.

Good Storage Practice (GSP). That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof (by WHO).

Good Storage Practice requires all pharmaceutical products to be stored in the most adequate ways and in the most proper conditions in order to ensure that their quality will not be compromised and no unanticipated consequences will occur after these products reach consumption. Storage plays an integral role in the total drug control system.

Shelf life is the recommended maximum time for which products produce can be stored, during which the defined quality of a specified proportion of the goods remains acceptable under expected (or specified) conditions of distribution, storage and display (by WHO)

Shelf life is the period of time, from the date of manufacture, that a product is expected to remain within its approved product specification while handled and stored under defined conditions

Expiry date (or expiration date)

The date placed on the container or labels of an API designating the time during which the API (Active Pharmaceutical Ingredients) is expected to remain within established shelf-life specifications if stored under defined conditions and after which it should not be used (by WHO)

The expiration date of pharmaceuticals specifies the date the manufacturer guarantees the full potency and safety of a drug.

Remaining shelf life defined as the period remaining, from the date upon delivery, to the expiry date.

*Premises, warehousing and storage*

Good storage practices (GSP) are applicable in all circumstances where pharmaceutical products are stored and throughout the distribution process. For additional guidance relating to the general principles of storage of pharmaceutical products, refer to the WHO guide to good storage practices for pharmaceuticals.

*Storage areas*

Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the company policies to maintain a safe, secure and efficient working environment.

Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of pharmaceutical products, namely commercial and non-commercial products, products in quarantine, and released, rejected, returned or recalled products as well as those suspected to be counterfeits.

Storage areas should be designed or adapted to ensure appropriate and good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.

Storage areas should be clean and free from accumulated waste and vermin. Organizations in charge of distribution must ensure that premises and storage areas are cleaned regularly. There should also be a written programme for pest control. The pest control agents used should be safe and there should be no risk of contamination of pharmaceutical products. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures should be in place for the sampling areas. Receiving and dispatch bays should protect pharmaceutical products from the weather. Receiving areas should be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.

Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel. Any system replacing physical quarantine should provide equivalent security. For example, computerized systems can be used, provided that they are validated to demonstrate security of access.

Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled or returned products and suspected counterfeits. The products and the areas concerned should be appropriately identified.

Unless there is an appropriate alternative system to prevent the unintentional or unauthorized use of quarantined, rejected, returned, recalled or suspected counterfeit pharmaceutical products, separate storage areas should be assigned for their temporary storage until a decision as to their future has been made.

Radioactive materials, narcotics and other hazardous, sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fi re or explosion (e.g. combustible or flammable liquids and solids and pressurized gases) should be stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.

Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

A system should be in place to ensure that the pharmaceutical products due to expire first are sold and/or distributed first (first expiry/first out (FEFO)). Exceptions may be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

Broken or damaged items should be withdrawn from usable stock and stored separately.

Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.

## Premises

Premises should be of suitable size and construction to facilitate cleaning, maintenance and orderly, segregated storage.

Storage areas must be designed to provide adequate:

- lightening,
- ventilation,
- temperature,
- sanitation,
- humidity,
- space,
- equipment,
- security conditions

Medicinal products should be stored separate from other goods to avoid the risk of cross contamination. Incoming goods should be physically or electronically separated from goods awaiting distribution until approved by the responsible person

segregated area must be provided for the holding and storage of returned and rejected goods prior to a decision on further action secure, segregated area must be provided for the storage of controlled drugs separate, designed area should be provided for the assembly of customer orders

Security

Storage areas should be provided with security to prevent theft or unauthorised entry

Maintain a control of who may enter the facilities Establish system for controlling access to the facility (including all entrances and exits)

Temperature and Humidity Control

All drug products must be stored at appropriate conditions as stated on the label of the product

The temperature of all storage areas should be regularly monitored. Controlled temperature storage areas should be equipped with recorders and devices which indicate when the specific temperature range has not been maintained.

A written procedure must specify the action to be taken when this occurs Control should be adequate to ensure that all parts of the storage area are kept within the specified temperature range

Should always be a backup system in case main system fails

The humidity of all storage areas should be regularly monitored using recorders and devices which document the humidity measures

If the product spec requires a specific humidity, a written procedure must specify the action to be taken when the specified humidity range has not been maintained. Establish a normal operating baseline of humidity if no specific value is required . Records of temperature and humidity in all storage areas should be reviewed and retained by a designated responsible person

Equipments

There should be a planned preventative maintenance programme in place,recording and control equipment should be calibrated and checked at defined intervals by appropriate methods. Alarm set-points should be checked on periodic intervals

A computerised system used for stock control/distribution should be validated

Person

- The organization chart should be in place
- There should be a sufficient number of staff
- There should be clearly defined job description
- Personnel should be trained in relation to good storage and distribution practice and to

- the duties assigned to them
- The current records of training should be in place
- The trainers should have established and approved qualification
- Sanitation
- A written sanitation program should be in place indicating the frequency and method of cleaning the facility
- Storage areas should be cleaned and accumulated waste removed at regular intervals
- A pest control program should be in place
- Smoking, eating and drinking should be permitted only in segregated areas, and not in those areas used for the storage and handling of final drug product
- Spills involving drug products must be promptly cleaned-up and rendered safe in accordance with the relevant health and safety requirements for the product
- Adequate toilet and changing facilities should be provided, and they should be segregated from the main storage and order assembly areas

Receipt of incoming goods

It should be carried out according to approved adequate SOP:

visually examine for identity against the relevant supplier's documentation

visually examine for damage

sub-divide according to batch numbers if more than one batch

reject product if damage or otherwise unfit for use

handle high security materials (control drug, high value items, products requiring a specific storage temperature)

confirm with signature that receiving goods are as specified by supplier or if not provide adequate comments

Assembling orders and issuing goods

It should be carried out according to approved adequate SOP:

Pick up goods according to formal despatch documents

Assemble complete order

>Visually examine for identity and completeness

Visually examine for damage

Confirm with signature properly assembled order

Prepare adequate shipping package to protect any damage of goods, seal pack and provide relevant identification

The heat sensitive drugs if not transported by appropriate specialised means should be provided isolated packing

## Packing for transportation

Products should be packed in such a way that:

the identification of the product is not lost,

the product does not contaminate and is not contaminated by other products or materials

adequate precautions are taken against spillage and breakage

products requiring controlled temperature storage should be provided with insulated packs

there should be in place documented evidence that the insulated packs ensured adequate transport conditions with regards to:

product quantity

ambient temperature

maximum delivery time.

## Transport

Products should be transported in such a way that:

The safety, identity, strength, quality and purity of the product is not lost.The product is not contaminated by other products or materials.Adequate precautions are taken against spillage or breakage. The product and its package are not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influences nor to attack by micro-organisms or pests

Drug products requiring controlled temperature storage by appropriate specialised means or should be packed with adequate insulation

Documents should be provided to cover all shipments. These document should include as minimum: name of the product quantity of the product special storage and handling instructions

*Records*

Following records should be in place:

- receiving goods
- issuing goods
- training
- monitoring temperature and humidity
- cleaning operation
- pest control
- calibration
- preventative maintenance
- recall
- complaints
- inventory
- log of signature

Warehouse - A facility where company stocks are stored. In Pharma business, typically store raw material, packaging material, semi-finished and finished goods.

Distribution - The process in which the finished drug product is moved from the initial warehouse to the final consumer. This process may involve several steps from beginning to end depending on the complexity of any manufacturing /marketing agreements.

## PHARMACEUTICAL WAREHOUSE REQUIREMENTS

The layout of a warehouse is key to its efficient operation. In developing warehouse or distribution center layouts, pharmaceutical corporations face unique challenges due to the nature of their products. Pharmaceuticals are sensitive not only to external contamination from bacteria or chemicals but also to temperature changes. In some cases, even lighting can damage pharmaceuticals. Pharmaceuticals must also be stored in a way that makes it easy to use a first-in, first-out system and that keeps these critical and expensive products safe from theft and deliberate contamination. These unique requirements mean that many factors need to be considered when setting up a warehouse for pharmaceutical storage.

Broadly speaking, there are two types of warehouse workflow patterns. A “through” pattern directs incoming pharmaceutical inventories into one side of the warehouse and out the opposite side, while a circular or “U-shape” warehouse pattern is set up to allow traffic to flow around the storage areas in the center, with input and output through the same entrance/exit. In both patterns, high-demand items are stored closest to the loading dock, while lower demand items are placed farther away from the loading docks. In a “through” warehouse, high-demand items are placed along the shortest path between the entrance and exit, and lower demand items are placed close to exterior walls. In a “U-pattern” warehouse, high-demand items are placed close to the loading bays, with items placed farther away from the doors as the frequency of their demand decreases. Lowest-demand items are placed against the back wall. Each of these layouts has its own advantages and disadvantages:

| | |
|---|---|
| Through Warehouse Advantages:<br>Linear Design: Since products only travel in a single direction, it’s easier to ensure a first-in/first-out shipping schedule is adhered to.<br>Multiple Channels: Warehouse throughput can be easily divided into multiple channels which all flow one way, creating less potential for picking the wrong item. | Circular Warehouse Advantages:<br>Combined Trips: A forklift can be dispatched to put away a load and retrieve inventory in a single trip since it will be returning to the same location.<br>Cross-Docking: Products that arrive on the loading dock can be instantly shipped out without being put away in the case of a rush order. |

| | |
|---|---|
| Discrete Temperature Areas: Different lines of throughput can be designated as temperature-controlled areas or cold storage areas without overlapping with each other. | Enhanced Space Control: Since there is only a single entrance and exit to the warehouse, security over the product can be more easily maintained, as can the internal temperature and atmosphere. |

Of the two warehouse layouts, a through warehouse is likely to be the most efficient choice for a warehouse dealing with pharmaceuticals. The requirement for first-in/first-out shipping is built into the design, and linear product flow makes organization and accurate picking easy. However, through-type warehouses are not a common design. They require access roads at both the input and output ends of the warehouse, while the majority of warehouses are built with a single entry point. However, certain storage and retrieval practices can bring linear throughput inside the warehouse regardless of the external form.

Receipt of incoming materials and pharmaceutical products

On receipt, each incoming delivery is required to be checked against the relevant purchase order and each container should be physically verified, e.g. by the label description, batch number, type of material or pharmaceutical product and quantity.

Furthermore, it is important that the consignment is inspected for consistency of the containers and, if necessary, it should be subdivided in accordance with the supplier's batch number in case the delivery has more than one batch.

Each container should be carefully examined for possible contamination, tampering and damage. Any suspect containers or the whole delivery, if necessary, should be quarantined for additional examination. On required, samples can be taken only by well-trained and experienced personnel. The procedure should be done in thorough accordance with written sampling instructions. Containers from which samples have been taken should be labelled properly and accordingly.

After sampling, the goods should be subject to quarantine. Batch segregation is supposed to be upheld during quarantine and all subsequent storage. All materials and pharmaceutical products should remain in quarantine until an authorized release or rejection is obtained.

The appointed professionals should take adequate measures in order to guarantee that rejected materials and pharmaceutical products cannot be used. Such products should be stored separately from other materials and pharmaceuticals while awaiting destruction or return to the supplier.

Distribution and storage is a very important activity in the supply chain management of the manufacturing of pharmaceutical products. The objective of the GSDP guidelines is to ensure the quality of pharma products during the whole distribution process. Furthermore, it sets out appropriate

steps to assist in fulfilling the responsibilities and to avoid the introduction of counterfeit products into the market.

## THEME №9. PREVENTION OF CIRCULATION OF FALSIFIED MEDICINAL PRODUCTS IN UKRAINE.


The global problem of drug counterfeiting

Medicines of questionable quality are medicines that are stored, transported and sold in violation of the current rules and regulations, have lost their presentation, do not meet the requirements of the AED / MCH for visual indicators, for which there is information about non-compliance with the requirements of the legislation of other series of this drug and the establishment of the fact bans on the territory of other countries, medicinal products that are not accompanied by quality certificates of a series of medicinal products, in which discrepancies in the accompanying documents and a violation of the established conditions for the manufacture of medicinal products in a pharmacy on a prescription, etc. Substandard medicinal products - medicinal products whose quality does not meet the requirements of regulatory documents, medicinal products that have undergone mechanical, chemical, physical, biological or other effects, which makes their further use impossible, as well as medicinal products with a shelf life

The Law of Ukraine "On Medicines" dated 04.04.1996 (as amended) determines that: A falsified medicinal product is a medicinal product that is deliberately marked identical (not by) information (one or more of them) about a medicinal product with the appropriate name entered in the State Register of Medicines of Ukraine, as well as a medicinal product deliberately counterfeit in another way does not respond information (one or more of them), including the composition, about the medicinal product with the appropriate name entered in the State Register of Medicines of Ukraine.

Usually, widely used drugs are subject to falsification, inexpensive in cost, in demand, and over the past five years there have been cases of falsification of vital and especially expensive drugs (anti-HIV / AIDS drugs, cancer drugs, antibiotics, etc.), lifestyle drugs (Viagra, steroid hormones for increasing muscle volume, psychotropic drugs that improve mood and general well-being, etc.). This type of counterfeit product is distributed both by illegal distribution channels (for example, smuggling) and by legal means (sold through networks of pharmacies, pharmacies, hospitals, and other places where medical products are sold).

Each year, forgeries take about 200 thousand lives. On this falsifier earn about 50 billion dollars. The profitability of production and sale of 1 kg of pharmaceutical counterfeits can reach almost 2000%.

In addition, according to a WHO study, India is the world leader in the production of counterfeit drugs (35%), followed by Nigeria (23.1%) and Pakistan (13.3%). Other Asian countries account for another 14.6% of counterfeit medicines. Recently, China has become one of the largest suppliers of counterfeit pharmaceutical products

And yet in developing countries, the problem is more acute due to the weakness of the regulatory system in the field of drug circulation. The level of counterfeits can reach up to 30%, and in some countries (Nigeria) - up to 50%.

Sources of receipt of counterfeit drugs on the pharmaceutical market are: contraband supplies by manufacturers, sale of drugs under the guise of other goods; repackaging of expired medicines for further sale; release at unidentified enterprises of FLS using high-tech equipment with the involvement of qualified specialists.

The most frequently counterfeited drugs are expensive drugs that bring high profits even with a small sales volume, and drugs that are widely used and profit from high sales volumes. Also, antimicrobial drugs (28% of the total number of counterfeit products), hormonal drugs (22%), antihistamines (17%), vasodilating drugs (7%), drugs used for sexual disorders (5%) 25. Examples of counterfeits include commonly used drugs such as atorvastatin or paracetamol; drugs with limited use, such as growth hormone, paclitaxel, and filgrastim; other types of medicines, such as sildenafil and tadalafil. The study found that prescription drugs were more often counterfeited (60%) than over-the-counter drugs. According to the release forms, tablet preparations, medicines for external use and injections were forged.

Healthcare products include contact lenses, condoms and test strips used by people with diabetes to control blood sugar levels. Both expensive and cheap products, both branded and generic, are subject to counterfeiting.

Quality assurance of medicines is a general concept in the pharmaceutical sector, the main elements of which are quality assurance of medicines at all stages of the "life" cycle: from development to medical use. The problem of the quality of medicines becomes especially important at the stage of their implementation.

2. Analysis of the causes of falsification of drugs

The International Pharmaceutical Association (FIP) and the International Federation of Drug Manufacturers Associations (EFRIA) treat drug falsification as a deliberate and deceptive inconsistency of labeling with respect to the composition and / or manufacturer of the final medicinal product or ingredients prior to its manufacture.

The WHO provides the following definition of counterfeit pharmaceutical products: "A counterfeit (counterfeit) medicinal product (CMP) is a product that is intentionally and unlawfully provided with a label that correctly indicates the authenticity of a drug or manufacturer. Both original and reproduced medicinal products may be falsified; The fact that the first of them are produced by a legal manufacturer may not be safe, as the production of such goods is illegal, they do not pass quality control, and, accordingly, the technology of their manufacture and the content of raw materials may not correspond. norms.

The concept of "counterfeiting" includes both counterfeits and drugs imported illegally (smuggling). It is important to understand that even if the drug is purchased in another country and it is genuine, there is no guarantee of quality, compliance with the rules of transportation and storage. As a result, the therapeutic effect may be reduced or absent.


According to the WHO, inappropriate and counterfeit medicines increase resistance to antimicrobials and drug-resistant infections.

Counterfeits include pseudo-drugs and products that are considered by fraudsters to have a therapeutic or prophylactic effect.

Distinctive features for such products are:

- difference in state registration (certification, conformity assessment);
- lack of product in the pharmacy network, sale only through websites or MLM (multi-level marketing, ie from hand to hand);
- uniqueness of technology, composition;
- guaranteed effect or very high efficiency;
- no side effects;
- limited offer, promotional price.

In July 2019, the Ministry of Health of Ukraine published information that the attackers offer the drug Normalize, which is allegedly recommended by the Ministry of Health of Ukraine for the treatment of hypertension and cardiovascular disease. In fact, this drug has no state registration, ie it is sold illegally. Five websites selling the drug were closed. But in October 2019, new websites appeared, calling to buy the drug, promising a miraculous cure. This example has everything: a unique technology with an unclear composition, and guaranteed relief from the causes and consequences of hypertension, and 100% no side effects, and the remaining 67 packages at a promotional price, and orders only through the site. CMP and medical devices can be sold in pharmacies, through manual sales by doctors, and the largest percentage - through the Internet.

A small amount of counterfeit is sold through the pharmacy network, as pharmacy owners and most staff are well aware of whether the product is official. Exceptions are cases of "breeding" of official series with fakes: packaging design, instructions, batch number are thoroughly copied, counterfeit products go on sale at the same time as the official one.

More than 80% of counterfeits are sold via the Internet, and there are many objective reasons for this: online pharmacies and aggregators often work without a license and other permits: that is, their activities are not controlled, there is no quality control of drugs, there is no control of storage conditions (temperature, contamination, etc.);

online shopping is impersonal: the buyer does not have the opportunity to inspect the packaging, instructions and accompanying documents until he receives the goods on hand, does not see the seller; when buying online, the buyer almost never receives a check, and if he does - the check can also be a fake;

*The main criterion for choosing on the Internet is the cheapest price.*

This is all well known to fraudsters who can put almost any value on counterfeit goods. After all, the cost and costs of marketing are almost absent. According to official information from Interpol, in 2018 11,790,800 packages were seized as a result of operations aimed at combating trade in counterfeit and illicit medicines and medical products. More than 10 million of which were seized in the course of operational measures to combat illegal websites.

With regard to illegally imported goods (so-called "gray imports"), the following options are possible: products are manufactured in compliance with all regulations, and only the law of import was violated; production technology is not observed.

In any case, such goods are just as dangerous as counterfeit and produced by a legal manufacturer during non-working hours.

Medicines in glass bottles are most often falsified (which is also typical for the perfume industry). To combat this phenomenon, the following techniques are now used: labeling with special ink, laser engraving, radio frequency identification (RFID). However, all these technologies have a number of disadvantages. Ink marks are easily erased. Laser engraving causes microcracks on the glass, which increases the risk of violating the integrity of the vials during transportation. The widespread introduction of RFID, which requires the installation of special readers in all pharmacies, proposed by the US Food and Drug Administration as the main measure to combat counterfeiting of medicines, the European expert community called difficult.

3. The main types of falsified medicines and types of falsifications

According to one of the classifications, there are four types of CMP depending on the method of manufacture:

• Illegal copy of the original medicinal product (so-called unaccounted for medicinal products.) Such counterfeits contain the same active substance and in the same quantities as claimed. And in contrast to the previous groups of counterfeit, this has the character of legal production, as it is created at the appropriate enterprises, but the purpose of which is to evade tax payments and (or) legal remuneration of owners of intellectual property rights

• illegal copy of a generic drug with an insufficient amount of active substances - counterfeit drug of a legal manufacturer, which is made with an insufficient amount of active ingredients and does not provide the desired therapeutic effect;

• falsified substitute drug - a substitute for a drug from a legal manufacturer, which contains active ingredients of a different nature of pharmacological action and does not provide the therapeutic effect specified in the instructions for use of this drug. These are drugs-imitators. Most often, the packaging of a cheap drug is replaced by the packaging of an expensive one. For example, a vial with an isotonic sodium chloride solution is labeled with an expensive painkiller or cancer drug. This group of counterfeits is the most dangerous due to a different therapeutic effect than expected;

• placebo drug (fake) - a counterfeit drug from a legal manufacturer that does not contain active ingredients. Instead of the active ingredient, a neutral component is taken - talc, lime, soda, chalk, as well as natural dyes (beets, carrots, etc.). The components are mixed to achieve similarity with the color of the original drug. In this way tablets, and also ointments and gels are forged;

• complete forgery of a medicinal product - intentional and deceptive non-compliance with the labeling, composition, ingredients, their quantity, manufacturer, as well as the packaging of the medicinal product. The first two variants of counterfeits are typical of legal pharmaceutical industries, from small to large. In world practice, according to various estimates, this is done by 6-8% of pharmaceutical companies. And most often so do subsidiaries of well-known companies in a particular region. These are the groups of fakes that are the most difficult to identify. Most often, such a forgery can be distinguished from the original only in a specialized chemical laboratory. According to experts, absolutely all counterfeits are potentially dangerous to health, as they are not subject to the quality control provided for legal products.

Also, during counterfeiting, one or more characteristics of the product are forged, which allows to distinguish several types of counterfeiting on these grounds: assortment, qualitative, quantitative, informational and cost.

Assortment falsification of goods is called counterfeiting, which is carried out by full or partial replacement of goods of one type or the name of another type of product or name while maintaining the similarity of one or more features.

Qualitative falsification is the replacement of a product of a higher level of quality with a product of a lower level.

Cost falsification is a misleading of the consumer by selling low-quality goods at the prices of high-quality or goods of smaller dimensional characteristics at the prices of goods with large dimensional characteristics.

Quantitative falsification is the misleading of the consumer by significant deviations of the parameters of the product (for example, the weight of the tablets, the volume of tincture), exceeding the permissible norms of regulatory documentation. The main ways to reduce the quantity of goods:

- falsified measuring instruments: measures, devices;
- incorrect measurement methods (packing of oils by volume, not by weight);
- falsified measurement results (release of goods by gross weight without taking into account net weight).

Information falsification is the misleading of the consumer by means of inaccurate or distorted information about the product, accompanying documents, consumer labeling, advertising. Most often distorted: product name, barcode, quantity, manufacturer, country of manufacture.

4. Determination of falsified drugs during commodity analysis at incoming control.

Carrying out commodity analysis at the acceptance of the goods is a simple and effective method, which consists of checking the original packaging, appearance and content of the drug in order to withdraw from circulation counterfeit or substandard drugs.

Verification of the sample is carried out using the senses - by the method of organoleptic analysis. It should be noted that organoleptic analysis should be performed very carefully, especially with toxic, potent drugs.

From the beginning, check the appearance and shape of the transport container, and then the secondary and primary packaging, which is in direct contact with the drug. Check whether the packaging is deformed due to falling, inconsistency of storage conditions (temperature, excessive humidity, etc.).

When checking the integrity of transport containers, mainly pay attention to the top, side surfaces and bottom. Check for changes in color, shape, weakening of the attachment, for damage or renewal of packaging, certificate stamps, tapes, etc. The top, sides and bottom of the sample package shall be inspected for signs of disclosure.

You should also pay attention to the size of the secondary packaging and their compliance with the standard. Then check the packaging materials, shades of its color, the presence of contamination, and so on. At the same time pay attention to the change of color of the package or its contents, damage, impregnation, leakage of content, contamination, sediment, turbidity, reducing the amount of contents.

The labeling check consists of checking for the necessary information, including batch number, registration number, contents and dosage, shelf life and conditions, warnings during use, etc.

Be sure to compare the labeling with the available information. When comparing the batch number and registration number with the information of the Ministry of Health, the State Service of Ukraine for Quality Control, it should be verified whether the production of these drugs or the sale of these batches of drugs has been stopped. Organoleptic tests with the opening of the package are performed after the initial examination of the container. After printing the container, the drug should be inspected for dosage form, color, taste, odor, weight, particle size, diameter, coating, and so on. If the organoleptic analysis reveals a discrepancy of a tested indicator (color, odor, taste, form of packaging, its quality, design, non-compliance or discontinuation of certain registration numbers or batch numbers, etc.) conclude that the drug is counterfeit or not meets the standards. Test results in such cases should be sent to the territorial State Inspectorate for Quality Control of Medicines. In cases where based on the results of only an organoleptic test is difficult to do. Certain conclusions regarding the fact of counterfeiting or loss of compliance with the standard, conduct a more detailed analysis in accordance with the relevant regulatory documentation (QCM) In any case, the identified discrepancies in the indicators of tested drugs immediately notify the State Inspectorate for Quality Control.

5. Methods to prevent the spread of counterfeit medicines.

To prevent falsification of medicinal products, various means of protection of packaging and labels of medicinal products or medical devices are used, namely: design, material for manufacture, paints and methods of labeling.

Various technological processes and printing methods are used for the production of packaging and labels. The most common printing methods are offset (indirect flat printing, in which the ink from the printing plate is transferred to the paper through an intermediate, offset cylinder) and flexographic (letterpress printing using flexible rubber molds and quick-drying liquid paints). The elements that protect the packaging (label) from scanning and increase the complexity of reproduction on traditional printing equipment are micro text and elements with a three-dimensional effect. Micro text is a string of symbols that are perceived by the human eye as a solid line, but are read with magnifying devices.

To obtain relief images use special printing methods - stencil (a method of reproducing text and graphics using a printed form (stencil), through which the ink penetrates the printed material), metallography (a method of gravure printing, when the ink fills the recesses in printed form, transferred to high pressure on paper), as well as blind embossing (method of marking under pressure using heated metal (usually used magnesium, brass, copper and zinc) or polymer cliche).

The use of special materials for the manufacture of packaging (labels) is a very effective way to combat counterfeiting), the use of fibers of different nature (wood, cotton, straw, etc.), structure (uniform distribution inside the sheet) and shape (size), reducing or increasing the opacity of paper, Depending on the need to see with the naked eye, protective elements, such as shiny labels, which are part of the pulp and therefore cannot be reproduced by optical scanning devices, materials with reduced tensile strength.

They are used in the manufacture of packaging (labels) to protect against re-unauthorized use, ie materials that are sensitive to various solvents. When you try to remove the sticker with solvents, stains remain on it.

Also change the properties of paper under the action of chemical agents and dyes-developers. For example, paper (cardboard) may contain a transparent chemical that, if necessary, to establish reliability.

To protect against counterfeiting, as one of the methods used partial or complete staining of the paper in the mass or on the surface. Such paper is characterized by unsatisfactory color fastness to wet processing, so special substances are used to fix the paint, for example, the product of dicyandiamide with formaldehyde. To improve the color fastness during the coloring of the paper in the mass and on the surface, fixatives based on diazo and triazo dyes are used.

As a result of changes in the thickness of the paper, watermarks are formed, which are clearly visible in the lumen, slightly blurred, blurred contours. Watermarks can be light or multicolored, general or local. The general watermark is located on all area of a sheet, local occupies any part of it.

Special inclusions in the composition of the sticker material can be both on its surface and inside, under the surface layers. The most common are the following inclusions:

protective fiber strips. Fibers and strips of different lengths and colors can be visible under normal or special lighting (for example in UV rays). These inclusions are not reproduced by copying equipment;

metallized threads and strips. Threads and strips of various length and color to be visible at usual or special, sometimes on them the image or the text is put;

microparticles - multicolored particles of different sizes may have different properties to appear under certain conditions (for example, when illuminated by an IR laser after special treatment, to form a hidden or visible marking;

radiation particles. Microscopic doses of rare earth elements with weak radiation are introduced into the material - harmless to humans, but very easy to diagnose with special detectors.

In order to increase the protective properties of materials in the manufacturing process can be given special physical or chemical properties. Specific properties are selected based on the purpose of the package (label). Examples include the following common options:

• change of paper properties by introduction of technologies concerning the improved stability of paper (for example, introduction of bases from polyurethane of reliability of packing (labels) enters with the corresponding developer into reaction which is characterized by irreversibility of change of color;

• chemical labels. After application to the material, these marks can be detected by special detectors.

Special stickers or microseals are usually used as protective elements. The main property of such protective elements is their easy destruction when trying to remove. After destruction, the sticker or seal leaves a mark on the protected surface, which indicates the use of packaging. Materials used for the manufacture of stickers are divided into single-layer and multilayer.

Our country has ratified the Convention on Combating Counterfeiting of Medical Products and Similar Crimes (The Medicrime Convention Combating Counterfeiting of Medical Products and Similar Crimes - MEDICRIME Convention). It is an instrument of international cooperation between law enforcement agencies, state control bodies in the field of detection and prevention of counterfeiting in the pharmaceutical markets of Europe.

Effective measures to combat the production and spread of CMP are criminal and administrative investigations to identify sources of production and legalization channels. Law enforcement agencies must respond immediately to all communications from pharmaceutical market participants and ordinary consumers regarding CMP or substandard drugs, as there is an immediate threat to the health and lives of citizens, and their protection and protection is a priority for the state.

## THEME 10. COMMODITY ANALYSISMEDICAL DEVICES FOR DIAGNOSIS AND TREATMENT.

*Medical devices. irrigators.*

*Irrigators* -it is a technical device designed for oral cavity care. It is used to clean the interdental space and the gingival fold. Strong pulsating water pressure massages the gums and the entire oral cavity,

improving blood circulation.

The irrigator is recommended for use in the following cases:

- the need to care for brace systems, dental crowns, prostheses;
- with bleeding gums and the risk of periodontitis;
- for prevention rejection implants and acceleration healing of the gingival surface;
- to eliminate the unpleasant smell caused by the presence of bacteria and microorganisms;
- can be used for continuous care in order to maintain hygiene and prevent caries or periodontal disease.

The irrigator owes its appearance to the American engineer John Mantingla and dentist Gerard Moer from the town of Fort Collins, who conducted experiments with the oral irrigation system. And the result of these experiments in 1958 was the first model of an irrigator - a device that cleaned teeth, interdental spaces and massaged gums under the pressure of a jet of water.

The patent for the invention was received in 1962. At first, the inventors were engaged in the production of the device at home, and the sale carried out only among his patients. This continued until one patient, very satisfied with the use of the irrigator, invested 50,000 dollars in the production of the irrigator, so that the device was brought to the market and became available to everyone. This is how the Waterpik company was founded, which is still a leader in the production of irrigators.

The name of the first device was "Octopus" and it caused a real sensation in the dental industry. Already five years later, irrigators began to be sold in every pharmacy or home appliance store.

Since then, many clinical tests of the irrigator have been conducted, which proved the effectiveness of its use and the fact that this hygiene tool is more effective and safer than dental floss. .

During the research conducted inSouthern Californian university, it was found that a second treatment with pulsating water (at 1200 pulsations per minute) at an average pressure (490 kPa) removes 99.9% of biofilm plaque from the treated areas. Clinical efficacy was shown when using average power parameters and above.

The principle of action is that a stream is fed into the oral cavity under pressure, washing out food residues and pathogenic microorganisms. When the irrigator is turned on, the compressor creates pressure in the container, under its influence, the liquid enters the nozzle.

Cleaning occurs under the action of a pulsating water jet. Water pressure can be adjusted. The adjustable pressure of the jet allows you to thoroughly clean the interdental spaces where the toothbrush is ineffective, and also makes it possible to massage the gums,thereby improving blood supply in them.

All surfaces of the teeth, contact points, gums, and tongue are cleaned. All clinical tests have shown that the pulsation of the jet has the key effect. Short, strong pulses ensure the removal of bacteria from under the gums and between the teeth. Purified water is supplied from the tank (its volume is larger in stationary models). The irrigator device allows you to use other liquids that have a number of effects (antiseptic, refreshing, medicinal, etc.). This is due to the fact that ordinary water does not have a disinfecting effect. It is better to choose a solution based on the existing problems, because different diseases require the use of different drugs.

## *Classification of irrigators*

Irrigators are classified by types of energy sources into: stationary, portable, flowing and mechanical. Stationary irrigators- these are quite large devices that must be constantly in the bathroom. They are powered by an outlet, so they need to provide a suitable place with electricity. Such irrigators are large, with a volume tank, which allows you to use them for the whole family (of course, if there is a sufficient number of individual nozzles).


Fig. 1. The general structure of a stationary irrigator: 1- cover of the water tank with a compartment for storing nozzles; 2 - water tank; 3 - base; 4- on/off button; 5 - pressure regulator; 6 – nozzle; 7- nozzle release button; 8 – handle; 9 – pause button.

### *Main technical characteristics of irrigators*

Technical capabilities of irrigators are the most important characteristics that affect productivity, efficiency and cost.

The power of the water jet. According to this indicator, it is possible to fairly objectively assess the capabilities of the device. As a rule, this indicator is higher in expensive models. Stationary models, as a rule, have more jet power than portable ones. Although there are exceptions - the portable Revyline RL 400 develops a pressure of up to 820 kPa, which is higher than that of many stationary models. The power (pressure) of the irrigator jet is measured in kilopascals (kPa). In the vast majority models are provided with power regulation, which allows you to choose the pressure of the liquid

individually.

*Jet pulsation.* Most modern models of irrigators use a pulsating type of working jet. The optimal frequency that provides effective and comfortable cleaning is 1,200 pulsations per minute. There are models with a higher jet pulsation (1700 and higher).

*Tank volume.* As a rule, one full brushing requires 150-200 ml of water. The volume of the tank, even in portable models, allows such cleaning to be carried out without additional water filling. In stationary models, the tanks are much more capacious (from 0.5 l). This volume is enough for several procedures.

Number of modes. The possibility of changing the operating mode, the pressure level of the liquid flow significantly expands the capabilities of the device, and allows you to choose the necessary ones Portable irrigators- small and battery operated. They can be charged, and then used anywhere - at least in the bathroom, at least on some long trip. Usually, such irrigators are more compact, lighter, and cheaper. They are convenient to take with you, but their power is less, and it is convenient to use it alone, not with the whole family.

*Flow irrigators.* They are installed on a water tap and use the pressure of the water system. No electricity is required for their operation. Liquid pressure is regulated by tap valves.

Mechanical irrigators. These are portable devices in which the pressure necessary for the formation of a jet is achieved due to the mechanical effect on the piston. There is a button or key on the body of the device, which must be pressed with the brush of the hand to create the necessary pressure.

Irrigators are classified by water supply into devices: *with monojet, pulsating jet, pulse feed, microbubble technology.*

Monojet. Such devices form a thin, continuous stream. This technology is considered outdated, because it does not clean the oral cavity effectively enough.

Pulsating jet (turboflow). The stream of water is thin and pulsating. The pulsation is very short, so it is difficult to notice it. Approximately 1200 micropulses occur per minute. Thanks to this feature, micro-hydraulic impacts are created, with the help of which there is a more effective removal of food residues and soft plaque.

Impulse feed. The liquid flows in waves, pulsating. These impulses are minimal and are not felt in a normal environment, but they remove tartar and plaque well.

Microbubble technology. This technology is considered the most advanced. The water flow mixes with air bubbles, thanks to which micro-hydraulic shocks are created. They help to completely remove food residues between the teeth. Moreover, the water is saturated with oxygen, which helps to destroy pathogenic microflora. This is especially important for patients suffering from

periodontitis.

Irrigators can also be classified into: family (stationary) and individual (portable, road, portable).

Types of interchangeable nozzles

For most modern models of irrigators, replaceable nozzles have been developed that c

an be used to solve various hygienic tasks.

- Standard nozzle. They are used for regular cleaning of the oral cavity.
- Periodontal attachment. Intended for cleaning periapical (periodontal) pockets.
- Nozzle for cleaning the tongue. Gets rid of plaque on the tongue, freshens breath.
- Orthodontic nozzle. It is used for the care of braces and other orthodontic structures. Maintains cleanliness of nodes and parts of systems, extends their service life.
- Brush nozzle. Cleans teeth like a classic toothbrush, massages gums.
- Nozzle for whitening teeth. It is used for whitening and polishing enamel.
- Nozzle for washing the nasopharynx. A special nozzle for irrigation and cleaning of the nasal cavity.

Fig. 2. Types of nozzles for irrigators

*Packaging and labeling of irrigators*

The components of irrigators are stored in plastic bags, covers or bags-covers. The device itself is marked with the name of the manufacturer.

The following data is applied to the secondary packaging (mostly bundles):

- the name of the device is "mouth irrigator";
- conditional designation of the device;
- name of the manufacturer;
- model;
- trademark and address of the manufacturer;

- technical characteristics of the device;
- the number and purpose of nozzles for the device;
- bar code;
- tank volume for stationary and portable models of irrigators.
- service life (3 or 5 years)
- application method;
- informational and operational signs.

*Storage of irrigators*

Store irrigators in rooms with relative humidity up to 80% (without condensation and at a temperature from 10 to 35 °C. It is necessary to regularly clean the device and all things. Before cleaning the device, it is necessary to disconnect the cord from the electrical outlet. Clean the device regularly with a damp cloth. The handle of the irrigator must be wiped with a dry cloth. The container for solutions and nozzles can be washed in a dishwasher. Compartment for nozzle howl has to and him you can wash under running water or in the dishwasher. The space under the compartment must also be periodically cleaned. Do not use rough cloths, brushes or abrasives to clean the device. Cleaning should be done at least once a week. If the device is used by several patients, it is necessary to clean the device between sessions of use by different patients. The device must be protected from direct sunlight and impacts.

Do not store or use the device in the immediate vicinity of heating devices and open flames. Protect from contamination. Avoid contact of the device with aggressive solutions. If necessary, repairs should be carried out only in specialized organizations.

The service life of the irrigator is 3 or 5 years from the moment of its production. The storage period is not limited.

In order for the irrigator for the oral cavity to serve for a long time, it is worth following some recommendations:

- during the first 7 days the stream of water should be weak. Otherwise, the gums of those who are not used to this procedure will begin to bleed (this phenomenon passes after 1-2 weeks);
- care of the irrigator, the temperature of the liquid should be a maximum of 40 °C. The optimal angle of inclination of the head in relation to the mouth is 90;
- if there are any orthodontic structures, then cleaning should take up to 10 minutes a day 1 or 2 times;
- the device cannot be completely immersed in liquid;
- to prevent scale formation, use filtered or distilled water;
- after merging remnants liquid turn on irrigator on 2-3 seconds for

drying;

- Save instrument to next using necessary in dry place

## *Medical devices. nebulizers and inhalers*

Inhalation (from the Latin Inhalo — I inhale) — the way of introducing medicines or biologically active substances into the body with the flow of inhaled air. Such a targeted effect on the respiratory system gives a quick therapeutic effect.

Inhalations can be done in several ways:

1. Steam inhalations. During the procedure, it is necessary to inhale from a special mask or vessel steam of hot water, to which medicinal substances are added

drugs Indications for steam inhalation are diseases such as acute respiratory syndrome, flu, bronchitis, pharyngitis, etc. When performing this procedure, it should be borne in mind that you cannot use very hot steam, as this can cause burns to the respiratory tract.

2. Oil inhalations. They are performed with the help of heated essential oils, which are sprayed on the mucous membranes of the respiratory organs

using an inhaler. They make oil inhalations with acute inflammation of the mucous membranes of the respiratory organs, a feeling of dryness in the larynx and in the mouth, with

preventive purpose.

3. Dry inhalations involve inhalation of powdered drugs that easily dissolve on the surface of the mucous membrane. Antibiotics, anti-allergic and anti-asthma drugs, sulfonamides are used in this way. Indications for dry inhalation are sinusitis, flu, rhinitis, tonsillitis, adenoids, acute laryngitis, bronchial asthma, etc.

4. Aerosol inhalations consist in inhaling a drug sprayed into an aerosol using compressor inhalers (nebulizers).

### CLASSIFICATION OF INHALERS

An inhaler (from the Latin "Inhalo" - to inhale) is a device for administering drugs by inhalation.

Today there is the following classification of inhalers

1. Thermal inhalers

2. Steam inhalers

3. Salt inhalers

4. Individual dosed

5. Powder

6. Compressor inhalers (nebulizers)

*THERMAL MOISTURE INHALER*

Intended for thermal inhalations of steam-heated solutions of liquid medicines, including herbal infusions and decoctions. It is used for the treatment and prevention of diseases of the upper respiratory tract and lungs. Contraindicated in use with active tuberculosis of the lungs, the presence of neoplasms of the upper respiratory tract, bronchi, lungs, severe respiratory or heart failure, etc.

The inhaler kit includes: body, lid, bowl, mask. Features of the use of thermo-moist inhalers Before using the parts of the inhaler, it is necessary to wash them with a 3% solution of baking soda or a washing solution and rinse all parts under running water and dry them, then cool them in the air.

For inhalations with decoctions of medicinal herbs, it is necessary to use decoctions at a temperature of 30 to 45 ºC

To carry out inhalations with tinctures of medicinal herbs, it is necessary to dissolve approximately 20 ml in water (heated from 30 to 45 ºC). Tinctures To carry out inhalations with essential oils, it is necessary to add essential oil recommended by the doctor in the required amount to heated water from 30 to 45 ºC.

It should be remembered that:

 you need to be careful when using the inhaler, yes

as it is filled with hot solution;

 to avoid leakage of liquid, use the inhaler only in a vertical position;

 do not leave children without adult supervision during inhalation with this type of inhaler.

*STEAM INHALER*

The steam inhaler is used for the treatment of acute respiratory diseases, allergies, colds, angina, as well as other diseases of the upper respiratory tract. The device allows you to make inhalations with aqueous solutions of LP, mineral waters, and various decoctions

and infusions of herbs and essential oils and other oily solutions.

*Contraindications to inhalation with a steam inhaler:*

- ✓ allergic reactions to certain plants, substances and oils.
- ✓ body temperature exceeding 37.5 degrees.
- ✓ periodic bleeding from the nose.
- ✓ vascular and heart diseases, such as atherosclerosis of the brain.
- ✓ to people with arterial hypertension, who had symptoms of heart failure, arrhythmia.
- ✓ dangerous diseases of respiratory organs (for example, pulmonary insufficiency of the 3rd degree, emphysema)

The steam inhaler set includes: main body, top cover, measuring cup, mask for inhalation, mask for cleaning and moisturizing the face.

After using the steam inhaler, the following recommendations must be followed:

- Do not open the lid of the heater tank immediately after use, as the lid may be very hot. Wait about 10 minutes and then open

- drain the remaining water from all tanks
- the main parts of the device must be washed with water and wiped
- soft cloth
- disinfection of the main parts of the inhaler (top cover, masks and suction tube) is carried out using disinfectants (for example, ethyl alcohol).

*SALT INHALER*

Salt inhaler - allows you to create a microclimate of cave salt at home for individual use. Natural salt crystals or their composition are located between the ceramic walls of the salt inhaler (NaCl - 98.7%, Ca SO4 - 0.1%, MgCl2 - 0.028%, CaCl2 - 0.13%, Fe2O3 - 0.00056%, and also in a small amount of K, I, Br).

Used for colds, nasal congestion, respiratory allergies, bronchitis, asthma, cough.

Contraindications: individual

The salt inhaler consists of a body, filters, crystals

salt, an air hole and a color indicator (

*Features of using a salt inhaler*

1. The process of inhalation is carried out through the mouth, and exhalation - through the nose.

2. Do not breathe rapidly - breathing should be natural.

3. Avoid exhaling back into the inhaler

4. After carrying out each inhalation procedure, as well as before

with it, it is recommended to wipe the inhaler with a clean damp cloth (do not allow water to get inside!!!!).

5. Store at room temperature, in a dry place.

6. Do not allow dust to settle on the inhaler.

7. Saline inhalers are intended for individual use.

COMPASSOR INHALER (NEBULISER)

Nebulizer* (lat. nebula – fog, cloud) is a medical device designed for inhalation with a number of medicines (in liquid or powder form) by spraying them into microparticles that can penetrate deep into the respiratory tract and detect

therapeutic effect directly at the site of inflammation due to delivery

high doses of drugs.

*Advantages of nebulizer therapy*

1. Simple inhalation technique.

2. Painless administration of medicines

3. Rapid and significant improvement of the condition

4. Creation of high concentrations of the drug directly in the lesion

5. The speed of absorption through the mucous membrane of the respiratory tract

6. Medicinal products enter the small circle of blood circulation, bypassing the liver - in an unchanged form. When choosing a nebulizer, it is important to pay attention to the following technical parameters:

*Respirable fraction (RF)* is the number of particles in an aerosol cloud with a size of less than 5 μm, expressed as a percentage. The higher the respirable fraction, the more medicine will enter the respiratory tract.

The residual volume (RO) of the nebulizer chamber is the amount of the drug that cannot be sprayed, because part of the drug remains on the walls of the nebulizer chamber. This indicator should not exceed 1.0 ml. The smaller the residual volume, the more LP will be converted into an aerosol.

Type of nebulizer chamber. The choice of design allows to increase the penetration of the drug into the respiratory tract, ensuring a natural breathing regime.

Spraying speed (performance). Aerosol output volume per unit of time (ml/min.). Determines the rate of inhalation; affects the patient's adherence to nebulizer therapy.

Also, when working with nebulizers, it is necessary to take into account the following main indicators:

Respirable particles (RF) are particles with an aerodynamic diameter of 0.5-5 μm.

Respirable volume (RO) - the total number of respirable particles.

The filling volume (OH) is the initial amount (dose) of the drug placed in the inhaler.

Respiratory (inhaled or inspired) volume (RO) - the amount of medicine that entered the patient's respiratory tract.

Losses (P) to the environment (wasted volume) - the amount of aerosol wasted, that is, what did not enter the patient's respiratory tract during inhalation.

Nebulizer volume (NO) is the sum of RO + B.

Inhalation time (t or ttot) is the period of time required to spray the medicinal solution placed in the nebulizer.

Inspiratory time (tl) - the time interval during which the atomized medicinal product is directly inhaled.

Inspiratory fraction (IF) - the ratio of inhalation time to the total duration of the respiratory cycle

*Today, there are the following types of nebulizers:*

- *Compression (jet)*
- *Ultrasonic*
- *Membrane or "mesh-nebulizers"*

*COMPRESSOR (JET) nebulizers* are intended for inhalation therapeutic treatment with the possibility of adjusting the size of the aerosol particles. Thanks to the regulation of the particle size of the medicinal aerosol, it enters all parts of the respiratory system (upper, middle, lower). It is successfully used for inhalation therapy for both adult patients and children.

*Advantages:* High spray speed compared to ultrasonic, greater versatility.

*Disadvantages:* Bulkiness and heaviness (from 1.2 to 2 kg), as well as the need to hold the nebulizer chamber in a vertical position, which significantly complicates inhalation in infants and bedridden patients.

*Compressor nebulizers are divided "according to the principle of operation of the nebulizer chamber" into 3 types:*

- Convection - function in a continuous mode, producing an aerosol both during inhalation and exhalation of the patient.
- With manual control - it is possible to regulate the flow of LP. That is, the "inhalation key" that is equipped with improved convection nebulizers helps to regulate the supply of LP.
- Nebulizers that are activated by breathing - during inhalation, an additional flow of air enters the aerosol chamber through a special valve; during exhalation, air does not enter, so there is no aerosol spraying into the environment, as it happens when using a simple convection nebulizer.
- Dosimetric - equipped with air flow sensors that suspend the formation of aerosol during exhalation and activate it during inhalation with the help of special valves.

*ULTRASOUND (US) NEBULISER* used both at home and in medical institutions. All types of standardized medical solutions in liquid form are used for ultrasonic nebulizer therapy.

Standard equipment consists of: nebulizer, inhalation mask for adults, inhalation mask for children, nose nozzle, inhalation mouthpiece, instructions for use and packaging.

*Advantages*: Relative silence, portability, minimal

residual volume of the drug.

*Disadvantages:* It is not possible to use antibiotics and hormone preparations, the molecular structure of which is destroyed by ultrasound

processing


*MEMBRANE NEBULISERS (or "mesh-nebulizers") -*

The new generation of nebulizers has a fundamentally new device of operation

- they use a vibrating membrane or a plate with multiple microscopic holes (sieve), through which the liquid form of the medicinal substance is passed, which leads to the generation of an aerosol.

This type of nebulizers has several names: membrane nebulizers, electronic nebulizers, nebulizers based on vibrating mesh technology (Vibrating MESH Technology - VMT). In these devices, the particles of the primary aerosol correspond to the size of respirable particles (slightly larger than the diameter of the holes), so there is no need to use a damper and long-term recirculation of the primary aerosol. The technology of membrane nebulizers involves the use of small filling volumes and the achievement of higher lung deposition values compared to conventional compressor or ultrasound nebulizers.

*Advantages:*

- ✓ does not destroy high molecular weight LPs
- ✓ works effectively with a small volume of LP (from 0.5 ml).
- ✓ a wide range of LP applications.
- ✓ silent inhalations in the mode of natural breathing under any condition
- ✓ angle of inclination at any age.

*Disadvantages*: High cost, thorough care and cleaning after each inhalation.

*Factors determining the effectiveness of nebulizer use*

Conditionally, all factors that determine the effectiveness of use

nebulizers, as devices for inhalation, can be divided into three

large groups:

- ✓ factors related to the inhalation device - nebulizer;
- ✓ factors related to the medicinal product
- ✓ factors related to the patient

*The main differences between inhalers and nebulizers*

| *Inhalers* | *Nebulizers* |
|---|---|
| Used for steam inhalations (steam injection) | It is used to transform liquid and/or solid dosage forms into suspended particles (drip administration) |
| LPs are heated to produce steam | LP under the influence of ultrasound, a compressor or a membrane become a fine aerosol |

| | |
|---|---|
| Delivers LP mainly to the upper parts of the respiratory system | Ensures the delivery of drugs to any part of the respiratory system, including the lower respiratory tract |
| Herbal decoctions, homeopathic preparations and essential oils can be used for the procedures | The use of decoctions of herbs and essential oils is prohibited |
| Suitable for the treatment of common colds and SARS with a mild course | It is in demand for the treatment of complex diseases of the respiratory tract, for example, bronchial asthma or acute bronchitis |
| Use in early childhood can be dangerous due to hot steam | Safe to use from birth |
| It is not used for the treatment of drugs of the antibiotic, mucolytic, hormonal group | Delivers drugs from the group of bronchodilators, antibiotics, mucolytics, hormones, etc. in the bronchi and lungs in liquid form |

## PACKAGING

Inhalers and nebulizers are delivered to pharmacies and their structural divisions in factory packaging (cardboard pack). A bag (case) can be used as the primary packaging for nebulizers. All components of inhalers and nebulizers are packed in separate plastic bags.

## MARKING

Marking of inhalers and nebulizers is carried out in accordance with the requirements of GOST 20790-93 "Medicine devices, apparatus and equipment", Article 15 of the Law of Ukraine "On the Protection of Consumer Rights".

The following information is applied to the primary and/or secondary packaging and the device itself:

- name of the product;
- name or designation of the type (type, model) of the product;
- name of the enterprise - manufacturer, address, trademark;
- series;
- party
- production date;
- designation of standards or technical conditions on the product,
- other data depending on product requirements (service symbols, nominal network voltage, power consumption at
- nominal mode of operation, etc.);
- bar code;
- signs of compliance;
- operational information signs;
- information on storage conditions.

Application of operational and informational signs on packaging is carried out in accordance with DSTU EN 980:2007 "Graphic symbols for labeling of medical devices" (EN 980:2003, IDT). Since most inhalers and nebulizers belong to electrical medical devices, they have additional information and operational signs in their composition according to DSTU 3798- 98 "Eclectic medical products. Part 1. General safety requirements".

## STORAGE

All inhalers and nebulizers upon arrival at pharmacies are stored in undamaged factory packaging and must be compliance with the following requirements:

- optimal air humidity – 65%;
- temperature – +5 ºC to +25 ºC
- do not allow high or low temperatures, drafts to affect the compressor unit and other components;
- provide protection from direct sunlight, dust and caustic fumes;
- do not allow tight twisting of tubes;
- do not store on an inclined surface;
- protect against shaking, vibrations, shocks.

*MEDICAL DEVICES. GLUCOMETERS. SPECIES TEST STRIP.*


The topic of diseases of the human body, diabetes the last sometimes becomes one with most spread out and discussed problems modern medicine and pharmacy

Glucometer – it i devices, designed for definition equal sugar (glucose) in of blood He allows conduct regular measurements and on based on received data control changes Glucometers irreplaceable for people who are sick for diabetes.

Systematization of knowledge modern commodity assortment glucometers medical will help specialist to clarify to the consumer all the advantages or disadvantages of this type of product, orient it to choice and purchase data devices

The main thing task technologies measurement equal glucose of blood consists in determining the color or flow of electrons, which is generated when glucose is oxidized to

gluconolactone in the reaction, catalyzed by glucose dehydrogenase. That is, with the help of chemical the reaction that occurs when blood is applied to a chemical enzyme test- stripes, is defined change color or flow electrons, which in in turn, are analyzed and converted into glucose level values by using one of the methods.

Building glucometers

To composition any glucometer include: semi-automatic scarifies - blades for piercing a finger or a lancet; if lancets – pen to them; electronic bloc with liquid crystal display; rechargeable batteries; test - strips (unique for each specific models).

Calibration solutions may also be included in the package, nozzles for fence of blood with alternative places coding strip or encoding port.

Kinds glucometers

Exist sprat ways to determine glycemic index: photochemical, electromechanical, biosensory, spectrometric. going out with this you can highlight such species glucometers:

Invasive:

- Photometric;
- Electrochemical; Non-invasive:
- Ramanovsky (spectrometric);
- Optical.

Photometric glucometers

Glucometers (Fig. 1) given type are recognized change color in test zone, what occurs in as a result of the reaction of sugar with reagents test - tape. It appliances the first generation.

Electrochemical glucometers (Fig. 2) Measured level glycemia in accordance to values current, what appears at reactions sugar of blood with reagents on test - tape Method founded on laws of amperometry.

At electrochemical method are used biosensors – bioelectrochemical converters, which together with portable the analyzer registers the electrical signal produced at reactions between glucose of blood and test strip reagents.

There is also a coulometric measurement method based on measurements general charge electrons These devices carry to second generation

Optical biosensors (Fig. 3) is hypersensitive and they can expect level glycemia measuring number sugar in saliva, urine and then

Works on the basis of surface plasma resonance. Such the device is a sensor chip covered with a microscopic layer gold IN present time instead gold are applied spherical particles that increase sensitivity tenfold and allow determine the concentration of glucose not in the blood, but in other biological ones liquids (drool, urine). Dana technology until is staying on stage development, but very promising.

Raman (spectrometric) (Fig. 4) glucometers measure spectrum scattering skin and determine level glucose by selection of its spectrum from the full spectrum of the skin. This technology is not is used widely and, as biosensory, is staying in stage developments.

Glucometers also are different by volume necessary of blood and method her fence So, example, test strips for glucometers of the first generation required at least 50 μl of blood, and in the newest glucometers, this volume is less than 2 μl. Methods there are two blood draws. The first is when blood drips onto the strip and this volume of blood should control that, who conducts measurement. The second (capillary) - when touching the installed v glucometer test strips drop of blood itself absorbed in the required volume. The first method requires up to 50 μl of blood, and the second - 0.3-3 mcl

general technical characteristics glucometers:

- range measurement should draw up 0-33.3 mmol/l Separate models with an indicator that exceed the upper limit are output to screen inscription "No" - high;
- time measurement I am composing from 5 to 45 seconds;
- memory with date sometimes carrying out analysis and possibility

"signature" result: to breakfast after breakfast and etc.;

- calculation average value equal sugar;
- taking into account the influence of the hematocrit index. Most glucometers have an extended working range at the hematocrit indicator 15-65 % (in norms 37 – 47 %), because samples of blood with tall hematocrit or increased viscosity they can influence on speed or number absorbed plasma, mechanically hinder the diffusion of glucose, which as a result reduces indicators glycemia Accordingly, a sample with a low hematocrit overestimates the level glucose blood;
- calibration device is carried out manufacturer, however users should have information about the calibration of each packaging of test strips or electrodes. The first models of glucometers demanded checks code, specified on containers with test- stripes, with by code specified on displays glucometer, according to with control table, or introduction in program manually changes code with help special buttons on appliances, what was for users, especially inclined age, significant a disadvantage Since calibration significantly affects the results, manufacturers tried to minimize operator errors during manual operation change code

The newest models glucometers equipped additional functions, such as:

- display with logical indicators;
- sound reminder about necessity carrying out analysis;
- automatic inclusion/exclusion;
- protected test strip – at conducting analysis you can to touch to any her sites;
- function "information about insulin";
- possibility application more of blood for 60 seconds;
- automatic removal of the used test strip from device;
- setting a personal threshold warning about hypoglycemia;
- possibility transfers data in personal computer;
- simple coding with help code plates;

They have indefinite guarantee (free replacement device the manufacturer after end

term him using. Term services glucometer makes up ~ 7-10 years (at proper operation).

These medical devices must be registered in the State Register medical techniques and products medical appointment.

Marking, packaging, transportation and storage glucometers is carried out according to DSTU EN 980:2007. Symbols graphic for marking medical products (EN 980: 2003, IDT), DSTU ISO 1771:2006.

*Packaging glucometers*

IN quality consumer primary and secondary containers for glucometers include:

- boxes and packs cardboard;
- packages with paper, polymeric and combined materials;
- pencil cases or cases made of fabric, polymer or combined materials

Modern requirements for containers take into account manufacturing technology, properties product and necessity their sterile storage. She must also meet the climatic conditions of transportation and storage, endure are sufficient mechanical load and be impenetrable for biological influences

The packaging should provide protection against the flow of mechanical and climatic factors under time storage and transportation

Components of products and their accessories must be concluded in nests cases (penalties, etc) or consumer container Consumer container with packed in her products must be protected

control of the first disclosure so that it cannot be disclosed without violation integrity of packaging.

*Marking glucometers*

Every medical product should to be accompanied information, necessary for him safe and correct application with taking into account equal preparation and qualifications consumers and users, and also for identification manufacturer

As far as it may be and expedient information, necessary for safe application medical product, is placed directly on medical produce and/or on packaging each units medical product or in case need - on packaging for sales If individual packaging of each unit is not possible, then this information is placed on a tab attached to one or more medical devices.

If possible, information that should accompany the medical ware, must to indicate in form symbols All of them used symbols and identification colors should answer harmonized standards. IN case absence such standards the symbols and colors used must be described in the documentation, what is supplied together with medical products

Marking of consumer packaging of glucometers must contain such data:

1) name;

2) marking models (such as species article) and (or) implementation medical product, complete set (at necessary);

3) name producing countries (manufacturer);

4) name, trademark (if available), location (legal address) manufacturer (manufacturer), address places production (manufacturing);

5) number and date registration certification on glucometer;

6) the main properties and characteristics of the glucometer, specified in metric system of measures;

7) dashed code (by availability);

8) expiration date of the glucometer (month, year) or service life, installed the manufacturer;

9) date production (production) glucometers;

10) special conditions storage and (or) application (operations);

11) indication of sterility indicating the method of sterilization (for sterile medical products);

12) number series (parties);

13) special instructions manufacturer (manufacturer) (warning and precautionary activities, which necessary perform);

14) sign State register (for means measurement) (If sign State register specified normative documentation, then is allowed by consent from the customer not point him on consumer container).

**List of used literature.**

1. Guide to Federal Pharmacy Law, 9-th Edition 9th Edition by Barry S. Reiss & Gary D. Hall (Author) 2015

2. Pharmaceutical Packaging Technology 1st Edition by D. A. Dean (Editor), E. R. Evans (Editor), I. H. Hall (Editor) 646 p. 2014

3. Packaging of Pharmaceuticals and Healthcare Products / H. Lockhart, F. A. Paine. – London: Blackie academic& Professional - 230 p. 2017.

4. Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements: ISO 15223-1:2012– 23 p.

5. Good pharmacy practice in community and hospital pharmacy settings http://apps.who.int/medicinedocs/documents/s21088en/s21088en.pdf

6. International health systems http://www.pnhp.org/facts/international_health_systems.php?page=all

7. ISO 13485:2003 Medical devices – Quality management systems [Electronic resource]:

8. Requirements for regulatory purposes. – Retrieved from: http://www.iso.org/iso/catalogue_detail?csnumber=36786. (Reference date of 10.12.2017).

9. Standards for quality of pharmacy services http://fip.org/files/fip/Statements/latest/Dossier%20004%20total.PDF

**Information resources:**


1. European Pharmacopoeia. https://www.edqm.eu/en/european-pharmacopoeia-ph-eur-10th-edition
2. U.S. Food and Drug Administration. https://www.fda.gov/
3. World Health Organization (WHO) i https://www.who.int/
4. European Medicines Agency (EMA) https://www.ema.europa.eu/en
5. European Directorate for the Quality of Medicines and HealthCare (EDQM), https://www.edqm.eu/
6. Harmonized System (HS) Codes https://www.trade.gov/harmonized-system-hs-codes
7. https://eltident.com/wp-content/uploads/2016/12/41_suturmanual-5.pdf
8. DSTU ISO 780-2001. Package, image labeling for operating with goods.
9. ISO 37:1994, Rubber; vulcanized or thermoplastic — Determination of tensile stress-strain properties.
10. ISO 188:1982, Rubber; vulcanized — Accelerated ageing or heat-resistance tests.
11. ISO 2859-1:1989, Sampling procedures for inspection by attributes — Part 7: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection. ISO 4648:1991, Rubber, vulcanized or thermoplastic — Determination of dimensions of test pieces and products for test purposes.
12. ISO 7000:1989, Graphical symbols for use on equipment — Index and synopsis.
13. Legislation of Ukraine [Electronic resource]. - Access mode http://zakon.rada.gov.ua/laws
14. Normative-directive documents of the Ministry of Health of Ukraine [Electronic resource]. - Access mode: / http: // mozdocs.kiev.ua
15. State Service of Ukraine for Medicines and Drug Control https://www.dls.gov.ua/
16. Medicines of Ukraine. All about medicines and their qualityhttps: //lick.ukr/
17. Compendium online. [Electronic resource]. - Access mode: https://compendium.com.ua/bad/...
18. Weekly "Pharmacy" [Electronic resource]. - Access mode: https://www.apteka.ua/...
19. Search base for drugs [Electronic resource]. - Access mode: https://tabletki.ua/uk/...
20. Search base for drugs [Electronic resource]. - Access mode: http://likicontrol.com.ua/...