STANDARDIZATION AND CERTIFICATION OF THE PHARMACEUTICAL ACTIVITY. THE DRUG QUALITY ASSURANCE SYSTEM

Theoretical questions

1. Standardization and certification in pharmacy.
2. Certification in the pharmaceutical activity as a guarantee of quality.
3. Legal and regulatory framework of the drug quality assurance system.
4. The state control over drug promotion at the market. Advertising of drugs.

List of recommended literature

1. Pharmaceutical Law and Legislation : the textbook for applicants for higher education / A.A. Kotvitskaya, I.V. Kubarieva, A.V. Volkova, A.V. Cherkashyna, I.V. Zhirova, A.A. Surikov, I.A. Surikova. – Kharkiv : NUPh : Golden Pages, 2019. – 204 p. http://irbis.nuph.edu.ua/full_text/2019/2019_Farm_law_textbook_angl.pdf

Tasks:

It's possible to work in your training manual «Pharmaceutical Law and Legislation

1. Match the terms and definitions given in the table:

Terms	*Definitions*
1. Certification	**A.** set of organizational measures to be taken in order to guarantee compliance with quality drugs their assignment, including ensure that drugs are developed and studied with regard GLP/GMP requirements
2. *Standardization*	**B.** a set of properties that give consumers the ability to meet drugs in accordance with its purpose and correspond to the requirements established by legislation
3. Quality assurance	**C.** procedure whereby an independent third face provides the individual guarantee that the product is in the form of a good or service, process or structure of the organization to meet the requirements
4. The quality certificate manufacturer	**D.** work on establishment rules, regulations and specifications for common and repeated use in the existing or potential problems in order to achieve the optimum degree of order in the sphere of development, production, quality control, registration and sale of drugs
5. Quality of drug	**E.** document issued by the producer about accordance of a series of drugs with the requirements established during its registration
6. Series of drug	**F.** document with information about samples tested drugs with the results of laboratory tests and the conclusion of compliance to acting Ukraine AND issued analyzing laboratory medicine quality subordinate or authorized by state administration of Ukraine on medicinal products

7. Conclusion about the quality	**H.** a certain amount of product discharged from a certain amount of raw materials in a single production cycle or homogenized during the production and preparation process in accordance with normative documentation

ANSWERS

1.	**2.**	**3.**	**4.**	**5.**	**6.**	**7.**

2. Match the basic requirements for drug quality with their characteristics

Terms	*Definitions*
1. Reliability	a) the state of the object in which the risk of harm or loss is limited by the acceptable level
2. Compatibility	b) compliance with the requirements set (usually used in quality standards)
3. Safety	c) unfulfillment to meet the requirements set in terms of one or more quality characteristics, or elements of the quality system, or their deviation from the requirements set
4. Conformity	d) provides a description of the availability of products for use
5. Discrepancy	e) the suitability of jointly used facilities under specific conditions to meet the relevant

ANSWERS

1.	**2.**	**3.**	**4.**	**5.**

3. Give definition "authorized person" and write requirements to authorized person in pharmacy

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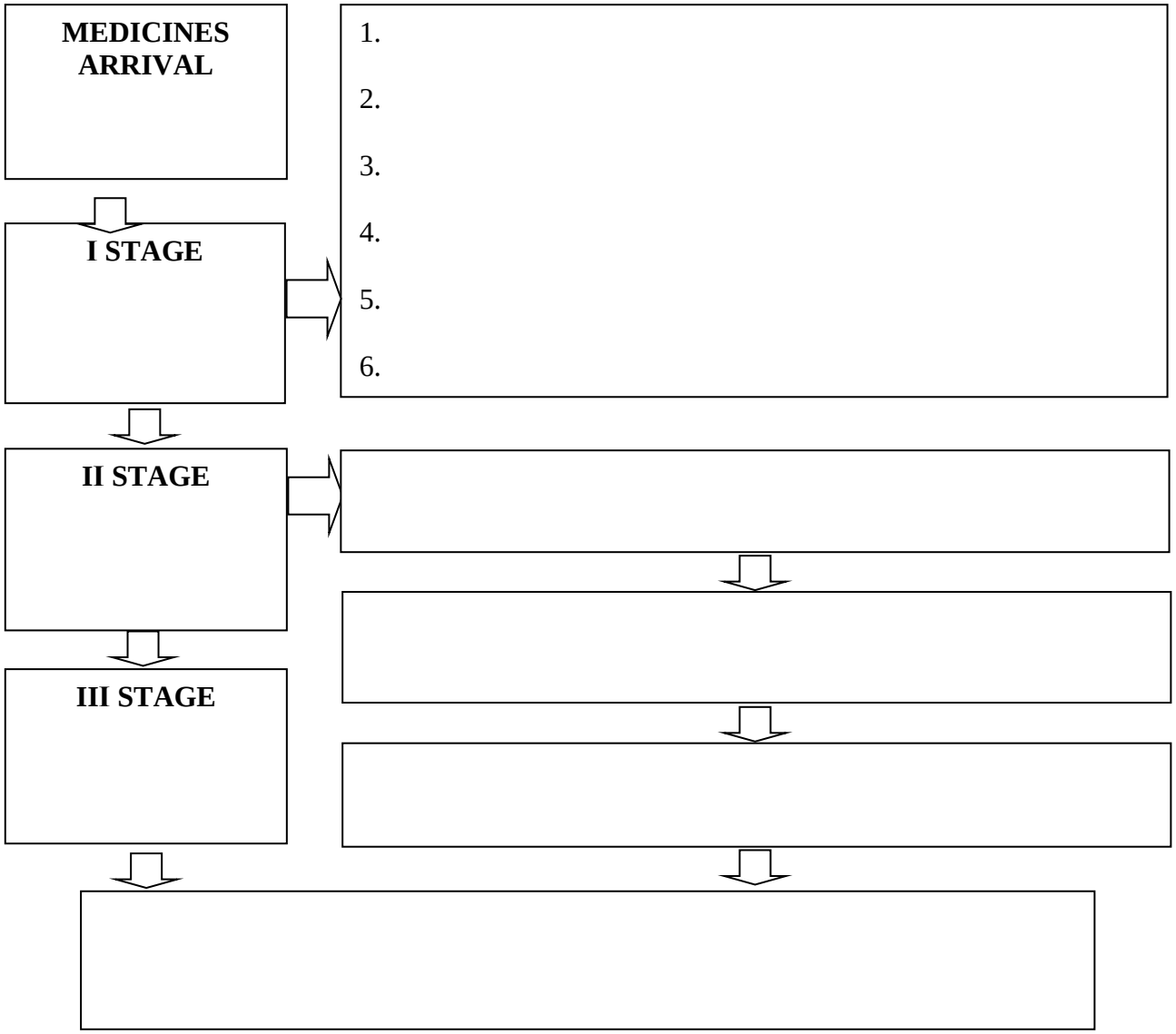
4. Medicines were brought to the pharmacy from a wholesale warehouse. Carry out the entrance quality control of medicines in pharmacy and complete the scheme in accordance with the stages of control.



5. Medicines may be withdrawn from commercial markets because of risks or harms to patients, this will usually have been prompted by unexpected adverse effects that were not detected during clinical trials, but they were only made apparent from postmarketing surveillance data collected from the wider community over period of time. Describe reasons of prohibitions of medicines turnover in the market and complete the table.

Class	*Reasons*	*Events*
I		
II		
III		