EDUCATIONAL INSTITUTION

**VITEBSK STATE ORDER OF PEOPLES ' FRIENDSHIP MEDICAL UNIVERSITY**

Chair of Pharmaceutical Technologies with the course of FCE and SR

Questions for the differentiated credit on industrial and technological practice and for passing the practical skill of the state exam on industrial technology of medicines, 5th year full-time higher education

2023-2024 academic year

1. Structure and organization of work at a pharmaceutical enterprise.
2. Safety practices at the pharmaceutical enterprise.
3. Delivery of pharmaceutical substances, excipients and packaging materials to the warehouse and their control (in accordance with the specifics of the enterprise).
4. Air preparation system at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
5. Water preparation system at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
6. Characteristics of documentation at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
7. Conducting self-inspection, training of personnel, and organizing work with complaints (in accordance with the specifics of the enterprise).
8. Organization of work with suppliers of pharmaceutical substances, excipients, packaging materials at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
9. Formation of the assortment portfolio of a pharmaceutical company (in accordance with the specifics of the enterprise).
10. Functioning of the sales system, promotion of manufactured products to the pharmaceutical market (in accordance with the specifics of the enterprise).
11. A system for ensuring the quality of finished products at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
12. Procedure for admission to the market of finished products, their storage at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
13. Requirements of good manufacturing practice for the organization of production of finished medicines at a pharmaceutical enterprise.
14. Requirements for occupational health and safety at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
15. Regulatory legal acts on the organization of production and quality assessment of sterile products.
16. Regulatory legal acts on the organization of production and quality assessment of non-sterile products.
17. Conditions of receipt and storage of pharmaceutical substances and excipients at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
18. Conditions of receipt and storage of packaging material at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
19. Storage conditions for finished medicinal products at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
20. Process validation, evaluation and rational selection of appropriate processes and devices at the pharmaceutical enterprise (in accordance with the specifics of the enterprise).
21. Batch dossier and quality assessment of manufactured products at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
22. Preparation of working prescriptions at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
23. Calculation of product yield, technological expenditure, and consumption rates at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
24. Quality assurance system and control and measuring devices at a pharmaceutical enterprise (in accordance with the specifics of the enterprise).
25. Technological and hardware schemes for the production of finished medicines in the conditions of pharmaceutical production (in accordance with the specifics of the enterprise).

Head of the Chair,

Doctor of pharmaceutical sciences, professor O. M. Khishova