# Entrance exam program in training of highly qualified personnel (Ph.D. programme) 3.4. "PHARMACEUTICAL SCIENCES"

Entrance exam program for the postgraduate Ph.D. programme in training of highly qualified personnel 3.4. "PHARMACEUTICAL SCIENCES" includes the following sections:

# **Industrial Pharmacy and Technology of Obtaining Drugs**

Current State and Development Prospects of Pharmaceutical Technology. Pharmaceutical Technology as a Science and its Tasks at the Present Stage. State Regulation of Production and Quality Control of Drugs. Legal Basis for the Manufacture of Drugs. International and State (National) Requirements and Standards. Organization of Medicine Preparation in Accordance with Modern GMP Requirements. Main Methodological Approaches to the Creation and Design of Therapeutic Systems (Intraocular, Transdermal, Implantation and Others). Biopharmacy is a modern methodology and the basis for the creation of modern drugs, including those with controlled pharmacokinetics. Concept of Release Mechanisms and Mechanisms of Absorption of Drugs from Different Dosage Forms. Modern Aspects of the Use of Excipients, their Role, Purpose and Requirements. Classification of EXPLOSIVES by Nature, Chemical Structure, Functional Role in the Dosage Form. High Molecular Weight Compounds (HMWC) as Excipients. Formers and Dispersion Media. Water and Other Solvents Used in Pharmaceutical Technology. Pharmacopoeia and Technological Classification of Water. Non-aqueous Solvents and Co-Solvents. Propellants. Solubilizers. pH Regulators, Buffer Systems. HMWC Use. Surfactants for the Stabilization of Microheterogeneous Disperse Systems. Preservatives, Requirements to Them. Speed of Release and Absorption Regulators. Prolongators. Taste, Color and Smell Corrigents. Isotonic Explosives. Technological Processes Underlying Pharmaceutical Technology and their Instrumentation. Modern Aspects of Implementation of the Main Processes and Devices of Pharmaceutical Technology. Dissolution. Filtration. Mass-transfer Processes. Extraction. Stages of the Extraction Process. Isolation and Purification of Biologically-Active Substances. Adsorption and Ion Exchange, Crystallization. Mass-transfer through Semipermeable Membranes. Drying. Quality Control of Raw Materials, Intermediates, Dosage Forms and Preparations, etc. Modern Approaches to the Organization of Technological Process (International and Regional GMP Rules, Industry Standards, etc.). Auxiliary Substances used in the Manufacture of Medicines and Medical and Cosmetic Products. Innovative Drugs. Features of the Production of Pharmaceutical Dosage Forms of Medical Immunobiological Drugs, MIBD (including Ensuring Microbial Purity, Range of Modern Excipients. Sprays and Aerosols. Cell and Enzyme Immobilization.

#### **Recommended literature:**

- 1. Validation of Analytical Procedures for Drug Manufacturers. HPLC, TLC, Titrimetry and GLC. Reference Standard Rationale. System Suitability Tests, Method Transfer, Revalidation. Translated by J. Aladysheva, O. Spitsky. Scientific edition by V. Beregovykh. M., 2012, 132 p.
- 2. Guideline on Good Manufacturing Practices for Human Medicine Production. Methodical Recommendation. S. Maximov, N. Lyapunov, E. Bezuglaya, O. Bykov, V. Dmitriev, I. Kashkin, V. Kosenko, E. Lopatukhin, A. Meshkovsky, O. Mirolyubova, T. Chibilyaev, T. Shmalko. M., 2013, 157 p.
- 3. Beregovykh V., Pyatigorskaya N., Belyaev V., Aladysheva Z., Meshkovsky A. Validation in the Production of Medicines M., 2014., 286 p.

4. Beregovykh V., Sapozhnikova E., Dzhalilov K., Kuzmicheva E. Pyatigorskaya N. Theoretical Foundations of Drug Technology. Textbook, 2015, 244 p.

# Pharmaceutical Chemistry, Pharmacognosy

Pharmaceutical Chemistry. Characteristics of some Therapeutically-Important Drug Groups (as per the Pharmacy Program Specialty). State Standardization System. Current State and Ways of Improving the Standardization of Medicines. Role and Place of Metrology and Standardization in Medicine Quality Control. General Pharmacopoeial Articles on Statistical Processing of the Results of Biological and Chemical Analysis Methods. Step-By-Step Drug Control System in Pharmacies, Ensuring Product Quality, Prospects for Development. Methods of Quantitative Determination of Drugs (Chemical Analysis). Thin-Layer Chromatography. Problem of Falsification of Medicines. Normative Documentation on Drugs. Standardization of Medicines as an Organizational and Technical Basis for Product Quality Management. State Pharmacopoeia, Pharmacopeial Articles (PA) and Pharmacopoeial Articles of Enterprises (PAE). Pharmacognosy as a Science. Basic Terms and Concepts of the Module. Nomenclature of Medicinal Plants and Medicinal Plant Raw Materials. Main Stages of the Use and Study of Medicinal Plants in World Medicine. Basics of the Medicinal Plant Raw Materials. Procurement Process. Chemical Composition of Medicinal Plants and Classification of Medicinal Plant Raw Materials. Standardization of Medicinal Plant Raw Materials. Main Directions of Scientific Research in the Study of Medicinal Plants. Methods of Detection of New Types of Medicinal Plants. Foliage as a Medicinal Plant Raw Materials. Herbs as Medicinal Plant Raw Materials. Roots as Medicinal Plant Raw Materials. Rhizomes as Medicinal Plant Raw Materials. Rhizomes and Roots as Medicinal Plant Raw Materials. Bark as a Medicinal Plant Raw Materials. Flowers as Medicinal Plant Raw Materials. Fruit as a Medicinal Plant Raw Material. Determination of the Purity of Medicinal Plant Raw Materials. Chromatography in the Analysis of Medicinal Plant Raw Materials. Concept of "Essential Oil". Concept of "Polysaccharides". Concept of "Cardiac Glycosides". Concept of "Saponins". Concept of "Flavonoids". Concept of "Tannins". Concept of "Anthracenediones". Concept of "Vitamins". Concept of "Alkaloids". Concept of "Alkaloids".

### **Recommended literature:**

- 1. Pharmaceutical Chemistry. (Textbook for Universities): Aksenov, E., Andrianova O., Arzamastsev A., and others. M.: GEOTAR MED., 2012. 640 p.
- 2. Belikov V. Pharmaceutical Chemistry. M.: MEDpress-inform, 2015.
- 3. Functional Analysis of Organic Medicinal Substances. Slivkin, A., Sadchikova N., Voronezh. VSU, 2014. 426 p.
- 4. Muravyova D., Samylina I., Yakovlev G. Pharmacognosy, M., "Medicine", 2014. 652 p.
- 5. Samylina I., Anosova O., Ermakova V., Bobkova N. Pharmacognosy. Atlas. Volumes 1,2,3 M., GEOTAR, 2007, 188 p., 380 p. 2013, 420 p.
- 6. Samylina I., Sorokina A. Atlas of Medicinal Plants and Raw Materials. M., "Author Academy", 2012, 218 p. Electronic library. Volume 36 Pharmacognosy (Compiled by I. Samilina, A. Sorokina). GOU VPO MMA, M., 2013.

## **Organization of Pharmaceutical Business**

Pharmaceutical Marketing: Organization of Commodity Circulation in the Pharmaceutical Market. Organization of Pharmaceutical Care as a Science. Pharmacy as a Retail Link of the Pharmacy System. Marketing Methods for Determining the Need and Studying the Demand for

Drugs. Organization of Pharmacy Operations on the Reception of Prescriptions and Release of Medicines. Pharmaceutical Prescription Expertise. Peculiar Properties of Drug Manufacture. Rational Organization and Certification of Workplaces. Organization of Intra-Pharmaceutical Quality Control of Drugs. Main Forms of Pharmacological Support of Inpatients. Pharmacoeconomic Analysis. Pharmaceutical Logistics: Sales, Procurement, Storage, Transport. Warehousing Logistics: Pharmaceutical Warehouse. Features of the Basic Economic Laws and Consumer Behavior in the Pharmaceutical Market. Fundamental Drug Pricing Principles. Basic Planning Methods. Economic Performance of a Pharmaceutical Trade Organization. Turnover Planning. Inventory and Commodity Collateral Trade. Cost Planning. Revenue Planning, Net Profit Planning. Accounting Information System. Types of Accounting and Accounting Meters. Legal Framework and International Accounting Standards. Accounting Objects, Subjects and Methods: Documentation, Inventory, Bookkeeping Reporting. Accounting Methods: Balance Sheet and Accounts. Types of Balance Sheet Changes. Accounting of Fixed Assets and Intangible Assets. Accounting of Inventory Exchange. Accounting of Cash and Payments. Accounting of Labor and Wages. Accounting of Income and Expenses, Analysis of Economic and Financial Activities of the Pharmacy Organization. Documentary Sources of Scientific Pharmaceutical Information. Types of ASPI. Marketing Methods for Information Requirement Research. Methodical Approaches to Drug Advertising. Introduction to Pharmaceutical Management: Study Methodology, Methods and Models. Organizational Design in Pharmacy: Types of Organization, Management Structures, Effective Distribution of Powers. Fundamentals of Personnel Management in Pharmacy Organizations. Communications in the Management of Pharmaceutical Organizations. Technology of Development and Implementation of Solutions in Pharmaceutical Practice. Methodology of Management of Social and Psychological Processes in a Pharmacy Team. Fundamentals of Record Keeping in Pharmacy Organizations: Documentation and Workflow Rules. Licensing of Pharmaceutical Activities: Documentary Registration Procedure. Pharmaceutical Business. Concept of Pharmaceutical Marketing.

## **Recommended literature:**

- 1. Pharmacy Management and Economics. Textbook / Edited by V. Bagirova. M.: JSC Medicina, 2012. 720 p.
- 2. Ibragimova G., Sboeva S. Pharmaceutical Bioethics. Textbook. Ufa: Virtual, 2014. 354 p.
- 3. Ryzhkov M., Sboeva S. Logistics Management of Pharmaceutical Organizations. M.: Professional Center, 2013. 218 p.
- 4. Dzhuparova I., Sboeva S., Belova Y. Organizational and Methodological Foundations of Benchmarking in Pharmacy Chain Management. New Pharmacy No. 8, 2013. P. 23-30.
- 5. Glembotskaya G. In Pharmaceutical Management Mazes. M.: Literature, 2015. 256 p. 6. Federal Law of the Russian Federation Concerning the Fundamentals of Public Health Protection in the Russian Federation.