STATE EXAM PROGRAM

Pharmaceutical Technology and Biopharmaceutics

Powders. Basic technological procedures for preparation of powders. Methods and apparatus.

Physico-mechanical properties of powders. Properties related to individual particles and bulk powder volume.

Granules. Characteristics. Reasons for granulation. Composition of granules. Binders

Granules. Mechanism of granule formation. Methods and apparatus for granulation. Control.

Tablets. Classification. Basic characteristics of tablets. Technological and biopharmaceutical control tests.

Methods for tablet preparation - technological schemes and stages.

Groups of excipients in tablet preparation - fillers, binders and glidants.

Groups of excipients in tablet preparation - disintegrants, lubricants. Mechanism of disintegration. Technological and biopharmaceutical problems associated with lubricants.

Sugar coated tablets – reasons for sugar coating, characteristics, excipients and technological procedure. Apparatus for sugar coating.

Film coated tablets – reasons for film coting, characteristics and excipients. Types of polymers based on their functionality. Mechanism of film formation.

Capsules - hard gelatin capsules - preparation and characteristics of empty capsules. Types and composition of capsule filling materials. Capsule filling apparatus. Control tests.

Soft gelatin capsules - characteristics. Types and composition of capsule filling materials in soft gelatin capsules. Preparation and control.

Phytopreparations - classification and characteristics. Herbal drug standardization. Methods for extraction.

Tinctures and extracts – characteristics, preparation and control tests.

Liquid dosage forms – classification and characteristics. Factors affecting the rate of solubility. Molecular solutions – vehicles, excipients, preparation and control.

Methods for increasing the solubility of slightly soluble active pharmaceutical ingredients.

Emulsions – classification, characteristics. Emulsifiers – types and mechanism of action. Methods for preparation of emulsions. Control parameters.

Suspensions – classification, characteristics. Suspending agents – types and mechanism. Methods for preparation of suspensions. Control parameters.

Biopharmaceutical aspects of oral route of administration. Oral absorption – physiological and pharmaceutical factors.

Parenteral dosage forms – general characteristics, classification. Methods for sterilization. Sterile room – organization of work process.

Injection dosage forms – vehicles, excipients, technological requirements and methods for their achievement. Preparation and control of injections.

Infusion solutions – classification, technological requirements and methods for their achievement. Preparation and control of infusions.

Eye dosage forms – classification, characteristics, and excipients. Technological requirements and methods for their achievement. Preparation of eye solutions and control.

Semisolid dosage forms – classification and characteristics. Percutaneous absorption - physiological and pharmaceutical factors.

Semisolid dosage forms - ointments, creams, gels and pastes. Characteristics, excipients, preparation and control.

Rectal dosage forms – classification and characteristics. Biopharmaceutical aspects of rectal route of administration.

Suppositories – characteristics and suppository bases. Preparation and control.

Vaginal dosage forms – characteristics and classification. Pessaries - preparation and control. Biopharmaceutical aspects of vaginal route of administration.

Modified-release dosage forms – classification, characteristics, advantages and disadvantages. Therapeutic and biopharmaceutical requirements for preparation of modified-release dosage forms. Technological approaches for achievement of sustained release.

Reservoir physical systems – characteristics, excipients, preparation and factors affecting drug release.

Monolithic physical systems – classification, characteristics, excipients, preparation and factors affecting drug release.

Biodegradable and hydrogel systems – characteristics, vehicles, preparation and factors affecting the dissolution process.

Microparticles – characteristics, types, vehicles and technological methods for preparation.

Targeted systems - liposomes and nanoparticles. Characteristics, types and preparation methods. Methods for drug targeting.

Aerosols - administration, components of aerosol products. Preparation and control.

Aerosols – types of aerosol systems and mechanism of action.

Stability of drugs and drug products – types of stability and methods for stabilization. Methods for stability testing.

Biopharmacy. Factors affecting pharmaceutical availability. Pharmaceutical similarity.

Pharmacopoeial methods (tests) for in vitro control of drug dissolution – characteristics and specific conditions. Biopharmaceutical classification system.

Head of department:
(Prof. K. Yoncheva, PhD, DSc)