

PROPOSED SYLLABUS FORM. Pharm. Course in specialization (Industrial Pharmacy)

M. Pharm. First year 1st semester

PG/PHAR/T/111 D Industrial Pharmacy-I

Theory 4 hrs/week

Basic techniques used in Pharmaceutical industries:

1. Unit operations:

1.(a)Size reduction (theory, apparatus, application, related problems) of solid particles; Separation of solids and liquids(screening, filtration, centrifugation -theory, apparatus, application, related problems); powder technology(theory of flow through hopper, design), blending of solid powder materials and semisolids/ointments(blenders, mixing index),rheological study of semisolid;mixing/agitation of liquid in a vessel (power requirement, vessel design, flow of liquid, related problems) .

1(b).Purification of active pharmaceutical ingredients by crystallization, distillation(theory, apparatus, application, related problems);

1(c) Granulationmethods for tablets; drying (apparatus, theory and problems); application of psychometric chart to drying(humidity, humidifier).

2.Sterilizationfor‘production media’, apparatus, pharmaceutical products, space and air:relatedkinetics,F, D, Z values, del factor , time- temperature regime, calculation, plot,sterilization methods (batch, continuous, dry heat, moist heat) and apparatus/equipments, application of different sterilization methods in pharmaceutical industry such as sterility testing, control tests, sterility testing of pharmaceutical products :ophthalmic preparations, surgical products; parenterals; vaccinebottles, syringes and needles etc.

M. Pharm. First year 2nd semester

PG/PHAR/T/128D (Industrial Pharmacy-II)

Theory 4 hrs/week

1. Instrumentation in pharmaceutical industry: Measuring devices for temperature, pressure, density, humidity, viscosity, flow rate, transducers and pollution control. Instrumentation in processing units (tablets, capsules).

2. Instrumental methods of analysis:

(a) UV-VIS spectrophotometry, theory and application; Chromatography-principle, technique and application; basic studies of X-Ray diffraction, Differential Scanning Calorimetry and Fourier Transmission Infrared, its application.

(b) Stability testing: Introduction, rate equations, physicochemical and biological factors affecting stability of drugs, degradation pathways, objectives and design of stability testing, accelerated stability studies, real-time stability studies, photostability testing, stability testing of dosage forms, prediction of shelf life, overages, ICH guidelines.

3. Preformulation studies: Introduction, purity, particle size, shape and crystallinity, solubility, pH solubility profile, dissolution & intrinsic dissolution rate, partition coefficient, melting point, polymorphism, hygroscopicity, volatility, flow properties, stability, drug excipient compatibility, significance of preformulation studies.

4. Optimization techniques in pharmaceutical formulation and processing: Concept of optimization, optimization parameters, classical optimization, statistical design, models and optimization methods.

5. Compaction and compression: Compaction of powders with particular reference to size distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; effect of particle size, moisture content, lubrication etc. on strength of tablets, various problems of manufacturing.

6. Effect of design of agitator system (shape factors) on the manufacturing of liquid products (solutions, emulsions, suspensions and microspheres).

7. Bio process: Fermentation Technology, Process variables, state variables; batch, continuous, fed batch processes of fermentation, material balance, oxygen uptake rate, volumetric oxygen transfer coefficient, downstream processing (product recovery), equipment (fermenter), flow sheet of microbial product, vitamin and antibiotic.

M. Pharm. First year 2nd semester

PG/PHAR/T/129D (Industrial Pharmacy-III)

Theory 4 hrs/week

1. Materials of construction and prevention of corrosion : Metals and alloys for fabrication. Materials other than metals and alloys; Selection of lining materials; metallic and organic surface coatings, corrosion problems and solutions.

2. Production planning & control: Production scheduling, forecasting, vendor development, capacity assessment (plant, machines, human resources), production management, production organization, objectives and policies. Productivity, management and cost controls.

3. Pilot plant and scale up techniques: similarity concept, regime concept, concept of model, pilot plant, scale equations and problems.

4. Selection and evaluation of packaging materials for Solid /semisolid and liquid products, containers and closures, special problems of container product interactions. Pharmacopoeial specifications, tests and standards for packaging materials, marking and labeling, handling and storage. Conveying and transportation of solid, liquid products/ pharmaceutical raw materials.

5. Finished product release, Quality review, Quality audits – Batch release – Distribution and Distribution records – Complaints and recalls, evaluation of complaints, handling of returned goods. Recovered materials and reprocessing.

6. Ware housing – Design, Construction, maintenance and sanitation for materials and products – good warehousing practices.

7. Industrial hazards, safety, pollution control and effluent treatment: Introduction, factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, electrical hazards, chemicals hazards and management of over exposure to chemicals, gas hazards and handling of gases, dust explosion and its control, fire prevention and control of pollution of waste water from pharmaceutical industries.

8. Term paper leading to thesis- assignment submission

M. Pharm. 2nd year 1st and 2nd semester: M. Pharm thesis work and dissertation submission
