

**DEPARTMENT OF PHARMACUETICAL SCIENCES
MAHARSHI DAYANAND UNIVERSITY, ROHTAK.**

**SCHEME OF EXAMINATIONS FOR THE PROPOSED SEMESTER SCHEME IN
MASTER OF PHARMACY – INDUSTRIAL PHARMACY**

M. Pharm.- Industrial Pharmacy Ist Semester

S. No.	Name of the subject	Theory (Teaching hr /w)	Practicals (Teaching hs/w)
MPH-01	Modern Analytical Techniques – I	04	06
MPHIP-02	Industrial Pharmacy – I	02	06
MPHIP-03	Industrial Pharmacy – II	02	06
MPHIP-04	Industrial Pharmacy – III	02	06
Total =		10	24

Total = 34 hrs / week in M. Pharm. Industrial Pharmacy Ist Semester

M. Pharm.- Industrial Pharmacy Ist Semester

S. No.	Name of the subject	Theory (Total Marks)	Practicals (Total Marks)
MPH-01	Modern Analytical Techniques – I	50	50
MPHIP-02	Industrial Pharmacy – I	50	50
MPHIP-03	Industrial Pharmacy – II	50	
MPHIP-04	Industrial Pharmacy – III	50	
Total =		200	100

Total = 300 marks / M. Pharm. Industrial Pharmacy Ist Semester

M. Pharm.- Industrial Pharmacy IInd Semester

S. No.	Name of the subject	Theory (Teaching hr /w)	Practicals (Teaching hs/w)
MPH-02	Modern Analytical Techniques – II	04	06
MPHIP-05	Industrial Pharmacy – IV	02	06
MPHIP-06	Industrial Pharmacy – V	02	06
MPHIP-07	Industrial Pharmacy – VI	02	06
Total =		10	24

Total = 34 hrs / week in M. Pharm. Industrial Pharmacy IInd Semester

M. Pharm.- Industrial Pharmacy Ist Semester

S. No.	Name of the subject	Theory (Total Marks)	Practicals (Total Marks)
MPH-02	Modern Analytical Techniques – II	50	50
MPHIP-05	Industrial Pharmacy – IV	50	50
MPHIP-06	Industrial Pharmacy – V	50	
MPHIP-07	Industrial Pharmacy – VI	50	
Total =		200	100

Total = 300 marks / M. Pharm. Industrial Pharmacy IInd Semester

M. Pharm. – Industrial Pharmacy III rd Semester

Research Work	35 hrs / week
Research Work Synopsis	50 marks
Presentation	150 marks
Total =	200 marks

M. Pharm. – Industrial Pharmacy IV th Semester

Research Work	35 hrs / week
Evaluation of thesis	200 marks
Viva voce	200 marks
Total =	400 marks

Total Marks in M. Pharm. Industrial Pharmacy = 1200

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M. PHARMACY INDUSTRIAL PHARMACY

IST SEMESTER

MPHIP – 02: Industrial Pharmacy - I

THEORY Lectures: 2 hrs / week

Unit I

1. Preformulation: General considerations and recent developments.
2. Capsules: Advantages and applications, recent advances in capsule technology, formulation and large scale production of hard and soft gelatin capsules, Quality control of capsules, In-process quality control of capsules.
3. Microencapsulation Technology: General considerations, recent advances, various processes employed for microencapsulation, release kinetics of drugs from microcapsules.

Unit II

Tablets:

Type of tablets, formulation of tablets, granulation techniques, recent advances in granulation technology, equipments and processes involved in granulation, tableting machinery employed for production of single-layer, multi layer, compression coated, inlay tablets and lozenges and tablet tooling.

Physics of tablet making: Strain gauze, measurement of applied and transmitted pressure, distribution of forces during compression, effect of applied pressure on relative volume and forces affecting strength of tablets, Coating of tablet: Coating processes, advances in coating technology and evaluation of coatings
Quality control of tablets, In-process quality control of tablets.

Practicals: (6 hrs / week)

Number of Practical / assignments based on aforementioned theory.

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M. PHARMACY INDUSTRIAL PHARMACY

IST SEMESTER

MPHIP – 03: Industrial Pharmacy - II

THEORY Lectures: 2 hrs / week

Unit I

1. Good Manufacturing Practices: GMP in Manufacturing, processing and quality control of drug, control of facility, personnel, production and process control packaging and labeling controls, documentation. OSHA
2. Pilot Plant, Scale up Techniques and Technology Transfer involved in different dosage forms.

Unit II

1. Pharmaceutical Process Validation, equipment validation and sterile products validation.
2. Optimization in pharmaceutical process and formulation , scope of experimental design in pharmaceutical formulations with special emphasis on factorial designs and central composite design, with suitable examples.

Practicals: (6 hrs / week)

Number of Practical / assignments based on aforementioned theory.

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M. PHARMACY INDUSTRIAL PHARMACY
IST SEMESTER

MPHIP – 04: Industrial Pharmacy - III
THEORY Lectures: 2 hrs / week

Unit I

1. **Introduction:** Purpose of packaging, prerequisites of an ideal package, various types of inner and outer packages used for different pharmaceutical dosage forms, selection of a suitable package, hazards encountered by the package during storage and distribution.
2. **Packaging materials:** Detailed study of various packaging materials in regard to composition, packaging characteristics, advantages, economics and limitations of various packaging materials like paper, board, glass, plastics, laminates, metals and rubber. Evaluation of packaging materials.
3. **Containers and closures :** Various types of containers and closures used in pharmaceutical packaging. Basic steps in container design and development, general and special design considerations with special emphasis on cushioning design. Methods of evaluation of containers and closures.
4. **Environmental considerations** of packaging and recycling of packaging materials along with national and international regulations.

Unit II

5. **Labeling:** Objectives and contents of a pharmaceutical label. Types of label (including Bilingual label, Bar code label, Radiofrequency (RF) label, Structured Program Label, In - mould label and decorative labels), Legal requirements of labeling, packaging inserts and outserts. Adhesives and machinery employed for labeling. Concept of paperless labeling and new developments in labeling technologies.
6. **Liquid Formulation Packaging:** Various containers / closures employed for liquid formulations. Machinery employed for liquid filling – constant level, volumetric, gravimetric etc. Evaluation of liquid formulation packages.
7. **Child Resistant Packaging and Tamper Evident Packaging.**

Practicals: (6 hrs / week)

Number of Practical / assignments based on aforementioned theory.

Books Recommended

1. AI Brody & K S Marsh, “*The Wiley Encyclopedia of Packaging Technology*”, John Wiley & Sons, New York
2. Leon Lachman, H A Liberman and J L Kanig, “*The Theory and Practice of Industrial Pharmacy*”, Lea & Febiger, Philadelphia
3. Deans .
4. Sanju Nanda, Rakesh Pahwa and Arun Nanda. “*Pharmaceutical Packaging Technology*”, New Age Publications, New Delhi.
5. T C KacChesney, “*Packaging of Cosmetics and Toiletries*”, Newness-Butterworth, London
6. “*Remington’ Pharmaceutical Sciences*”, Mack Publishing Co., P.A

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M. PHARMACY INDUSTRIAL PHARMACY
IIND SEMESTER

MPHIP – 05: Industrial Pharmacy - IV
THEORY Lectures: 2 hrs / week

Unit I

1. Disperse systems: General consideration and recent advances in disperse system technology with main emphasis on pharmaceutical suspensions and emulsions, formulation, stabilization and large scale production of pharmaceutical suspensions and emulsions. Quality control of disperse systems.
2. Aerosols: General considerations, recent developments, study of various components of aerosol system, formulation, aerosol filling processes and machinery, evaluation of aerosol. Quality control of aerosols.

Unit II

1. Semisolid dosage forms: General considerations, recent developments, formulation and large scale production of various types of semi solid dosage forms, factors affecting release of drugs from semisolid dosage forms. Quality control of semisolid dosage forms.
2. Parenterals: General considerations, recent developments, formulation, stabilization and manufacturing of small and large volume parenterals, production of injectable grade water, environmental controls and design consideration for parenteral production facility, freeze drying. Quality control of parenterals. In house quality control.

Practicals: (6 hrs / week)

Number of Practical / assignments based on aforementioned theory.

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M. PHARMACY INDUSTRIAL PHARMACY

IIND SEMESTER

MPHIP – 06: Industrial Pharmacy – V

THEORY Lectures: 2 hrs / week

Unit I

Novel Drug delivery Systems: General considerations, fundamentals and applications of controlled drug delivery, with special emphasis on following categories:

- Oral CDDS
- Parental CDDS
- Transdermal CDDS
- Ophthalmic CDDS.

Unit II

Fundamentals, general considerations and applications of

- Liposomes, microspheres and nanoparticles
- Targeted drug delivery systems.
- Implants, Nasal and Transmucosal CDDS.

Practicals: (6 hrs / week)

Number of Practical / assignments based on aforementioned theory.

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IIND SEMESTER

MPHIP – 07: Industrial Pharmacy - VI

THEORY Lectures: 2 hrs / week

Unit I

- Films for Flexible Packages:** Types of films, materials used for film production, production and evaluation of *Oriented* and *Non-oriented*, and *Stretchable* films and *Laminates*.

- Strip Packaging:** Significance of Strip Packing, advantages, economics and limitation of Strip Packing, Strip Packing machinery, films employed in Strip Packing (including composites and laminates) and evaluation of films and strips packs.
 - Blister Packaging:** Blister packing materials, significance of Blister packing, advantages, economics and limitation of blister packing, blister packing machinery, various types of blister packages, evaluation of blister package.
 - Pouch packaging:** Materials used, advantages, economics and limitation of pouch packing, pouch packing machinery, spectrum of applications, and evaluation of pouch packing.
- Unit II**
- Semi-Solid Packaging:** Various types of containers/packages used for semi-solid products, filling and sealing machinery (including collapsible tube filling and sealing machine) merits and limitations of various packages, evaluation of semi-solid product package.
 - Sterile Product Packaging:** General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages

Practicals: (6 hrs / week)

Number of Practical / assignments based on aforementioned theory.

Books Recommended

- AI Brody & K S Marsh, “*The Wiley Encyclopedia of Packaging Technology*”, John Wiley & Sons, New York
- Leon Lachman, H A Liberman and J L Kanig, “*The Theory and Practice of Industrial Pharmacy*”, Lea & Febiger, Philadelphia
- Deans and Evans, *Pharmaceutical packaging*
- Sanju Nanda, Rakesh Pahwa and Arun Nanda. “*Pharmaceutical Packaging Technology*”, New Age Publications, New Delhi.
- T C KacChesney, “*Packaging of Cosmetics and Toiletries*”, Newness-Butterworth, London
- “*Remington’ Pharmaceutical Sciences*”, Mack Publishing Co., P.A