DEPARTMENT OF PHARMACUETICAL SCIENCES
MAHARSHI DAYANAND UNIVERSITY, ROHTAK.
SCHEME OF EXAMINATIONS FOR THE PROPOSED SEMESTER SCHEME IN MASTER OF PHARMACY – PHARMACEUTICS
(DRUG REGULATORY AFFAIRS)

M. Pharm.- Pharmaceutics (Drug Regulatory Affairs) Ist Semester

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

Total = 34 hrs / week in M. Pharm. Pharmaceutics (Drug Regulatory Affairs) Ist Semester

M. Pharm.- Pharmaceutics (Drug Regulatory Affairs) Ist Semester

S. No.	Name of the subject	Theory (Teaching hr/w)	Practicals (Teaching hr / w
MPH-01	Modern Analytical Techniques – I	50	50
MPHDRA-02	Drug Regulatory Affairs – I	50	50
MPHDRA-03	Drug Regulatory Affairs – II	50	
MPHDRA-04	Drug Regulatory Affairs – III	50	
	Total =	200	100

Total = 300 marks / M. Pharm. Pharmaceutics (Drug Regulatory Affairs) Ist Semester

M. Pharm.- Pharmaceutics (Drug Regulatory Affairs) IInd Semester

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

Total = 34 hrs / week in M. Pharm. Pharmaceutics (Drug Regulatory Affairs) IInd Semester

M. Pharm.- Pharmaceutics (Drug Regulatory Affairs) Ist Semester

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

Total = 300 marks / M. Pharm. Pharmaceutics (Drug Regulatory Affairs) IInd Semester

M. Pharm. – Pharmaceutics (Drug Regulatory Affairs) III rd Semester

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

M. Pharm. – Pharmaceutics (Drug Regulatory Affairs) 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. Pharmaceutics (Drug Regulatory Affairs) = 1200

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M. PHARMACY PHARMACEUTICS
(Drug Regulatory Affairs)

IST SEMESTER

MPHDRA – 02: Drug Regulatory Affairs - I
THEORY Lectures: 2 hrs / week

Unit I

A detailed study of the following laws, including latest amendments in India :

a. The Drugs and Cosmetics Act, 1940 and Rules thereunder.
b. The Drugs (Prices Controls) Order, 1955.

Unit II

a. The Indian Patents and Designs, Act 1970, including recent amendments.
b. Introduction to the Indian laws on Trade Marks and Copy Rights.

Practicals: (6 hrs / week)

Number of Practicals / assignments based on aforementioned theory.

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IST SEMESTER

MPHDRA – 03: Drug Regulatory Affairs - II
THEORY Lectures: 2 hrs / week

DRUG REGULATORY AFFAIRS – II

Unit I

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on:

a. History of drug regulation in USA.
b. Organization and functions of FDA, including historical developments.
c. General definitions.
d. Adulterated & misbranded drugs/cosmetics/biotechnological products.
e. OTC drugs, Orphan drugs, Orange Book and Fast Track Products.
f. General penalties as applicable to drugs, cosmetics and biotechnological products.

Unit II

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on:

a. General drug approval process.
b. Investigational New Drug application.
c. New Drug Application and BLA.
d. ANDA.
e. SNDA, SUPAC and BACPAC.
f. Post marketing surveillance.

Practicals: (6 hrs / week)

Number of Practicals / assignments based on aforementioned theory.

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M. PHARMACY PHARMACEUTICS
(Drug Regulatory Affairs)

IST SEMESTER

MPHDRA – 04: Drug Regulatory Affairs - III
THEORY Lectures: 2 hrs / week

Unit I

a. Drug regulatory authorities in European Union (EU) -- Introduction, Organization and General Guidelines.
b. Regulatory consideration for pre-clinical testing and clinical testing in EU.

Unit II

a. Registration application for marketing approval (IND, NDA, ANDA) in EU.
b. Drug Master Files in EU.

Practicals: (6 hrs / week)

Number of Practicals / assignments based on aforementioned theory.

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M. PHARMACY PHARMACEUTICS
(Drug Regulatory Affairs)

IIND SEMESTER

MPHDRA – 05: Drug Regulatory Affairs - IV
THEORY Lectures: 2 hrs / week

Unit I

An introductory study of following laws of that affect drug product design, manufacture and distribution in India (with latest amendments) :

a. The Environmental Protection Act
b. Consumer Protection Act
c. Law of Torts

Unit II

I. An introductory study of following laws of that affect drug product design, manufacture and distribution in India (with latest amendments) :
   a. Law of Contracts
   b. Monopolistic & Restrictive Trade Practices Act
II. Auditing of manufacturing facilities by International regulatory agencies. The ISO 9000 series of quality systems standards.

Practicals: (06 hrs / week)

Number of Practicals / assignments based on aforementioned theory.

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M. PHARMACY PHARMACEUTICS
(Drug Regulatory Affairs)

IIND SEMESTER

MPHDRA – 06: Drug Regulatory Affairs - V

THEORY Lectures: 2 hrs / week

Unit I

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on :

a. Labelling and advertising requirements for drugs, cosmetics and biotechnological products.
b. Introduction to environmental protection laws, as applicable to drugs, cosmetics and biotechnological products, including EPA and OSHA.
c. Common Technical Document and Drug Master Files.
d. Factory Inspection.

Unit II

Harmonization of regulatory requirements – The ICH process, guidelines issued by ICH for data collection to establish quality safety of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards.

Practicals: (6 hrs / week)

Number of Practicals / assignments based on aforementioned theory.

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IIND SEMESTER

MPHDRA – 07: Drug Regulatory Affairs - VI
THEORY Lectures: 2 hrs / week

Unit I

Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU.

Unit II

a. The WHO Guidelines – The WHO Guidelines and their relevance in international registration. The WHO certification scheme on the quality of pharmaceutical products moving in international commerce.
b. Introduction to Pharmacovigilance.

Practicals: (6 hrs / week)

Number of Practicals / assignments based on aforementioned theory.