HINDU COLLEGE OF PHARMACY (AUTONOMOUS)
Amaravathi Road – GUNTUR -522002. A.P.

Regd. No: …… **MRA-101T**

Total No. of Questions: 14 **Total No. of Pages:**

I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations
April, 2026 - (Admitted in 2025-2026 Autonomous Batch)
Pharmaceutical Regulatory Affairs Specialization

Subject Code & Name: MRA-101T Good Regulatory Practices.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO 1	Prepare checklists and SOPs for various good regulatory practices.
CO 2	Develop good regulatory practices in the healthcare and related industries
CO 3	Demonstrate a plan for the readiness and conduct of audits and inspections.
CO 4	Categorize the key regulatory and compliance elements with respect to GMP.
CO 5	Categorize the key regulatory and compliance elements with respect to GLP.
CO 6	Categorize the key regulatory and compliance elements with respect to GALP.
CO 7	Categorize the key regulatory and compliance elements with respect to GDP.
CO 8	Describe the quality management system in the Pharmaceutical Industry.

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	Why was GLP created ? Explain the regulations of GLP and its fundamental points ?	10	CO5	L1
2	Elaborate on general principles and legal regulation of distribution of pharmaceutical, products on GDP.	10	CO7	L3
3	Demonstrate the EC principles of GMP Guidelines?	10	CO4	L3
4	Demonstrate the purpose of Quality by Design. Discuss about terminologies of QbD.	10	CO8	L3
5	Write about cGMP on medical devices?	10	CO2	L1
6	What is an audit? What are the different types of Audits and what tools are used in the Auditing process?	10	CO4	L5
7	List out the types of ISO standards and write a note on ISO standards of quality management system	10	CO3	L6

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Outline the general checklist for 21 CFR Part 211 compliance	5	CO4	L2
9	Summarize the GHTF guidance documents	5	CO2	L2
10	Give the importance of validation. Explain in detail about VMP.	5	CO4	L6
11	Write the principles of GALP	5	CO6	L3
12	Write in detail about stability testing principles.	5	CO5	L2
13	Provide an overview of ISO 13485	5	CO3	L5

14	What are the objectives of a laboratory quality audit?	**5**	**CO3**	**L1**

****All the Best ****

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I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations
April, 2026 - (Admitted in 2025-2026 Autonomous Batch)
Pharmaceutical Regulatory Affairs Specialization

Subject Code & Name: MRA-102T Documentation and Regulatory Writing.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO1	Discuss the basic Documentation in pharmaceutical industry
CO2	Discuss on dossier preparation and CTD submission
CO3	Learn about eCTD and technologies available
CO4	Understand the basics of CTD submission in India through Sugam system
CO5	Learn the basics of internal and external audits
CO6	Learn ISO standards and guidelines on audits
CO7	Understand inspection systems in pharmaceutical companies and follow up actions
CO8	Learn the regulatory aspects of product life-cycle management and product recalls

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	Explain the documentation system in the pharmaceutical industry. Discuss Master Formula Record and Batch Manufacturing Record.	10	CO1	BL2
2	Describe the preparation and importance of Product Development Plan (PDP) and Product Development Report (PDR).	10	CO1	BL2
3	Explain the Common Technical Document (CTD) structure and modules used in regulatory dossier submissions.	10	CO2	BL2
4	Discuss the process of electronic dossier submission including eCTD, NeeS, ACTD and submission through the Sugam portal of Central Drugs Standard Control Organisation	10	CO2	BL3
5	Explain different types of audits in pharmaceutical industries and describe the procedure for conducting GMP compliance audits.	10	CO3	BL2
6	Discuss the process of regulatory inspections of pharmaceutical manufacturers and explain CAPA and root cause analysis.	10	CO3	BL3
7	Explain product life cycle management in pharmaceuticals including PAS & SUPAC	10	CO4	BL2

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Write short notes on Drug Master File (DMF) and Site Master File (SMF).	5	CO1	BL1
9	Explain the contents and importance of a Certificate of Analysis (CoA).	5	CO1	BL2
10	List the modules of CTD used in regulatory submissions.	5	CO2	BL1
11	Write short notes on Electronic Submission Gateway (ESG).	5	CO2	BL1
12	Differentiate between internal audit and external audit.	5	CO3	BL2
13	Write short notes on pre-approval inspections of pharmaceutical manufacturing facilities.	5	CO3	BL1
14	Explain recalls and warning letters issued by the U.S. Food and Drug Administration.	5	CO4	BL2

****All the Best ****

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Total No. of Questions: 14 **Total No. of Pages: 01**

I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations
April, 2026 - (Admitted in 2025-2026 Autonomous Batch)
Pharmaceutical Regulatory Affairs Specialization

Subject Code & Name: MRA-103T Clinical Research Regulations.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO1	Understand the History, origin and ethics of clinical and biomedical research and evaluation
CO2	Know Clinical drug, medical device development process, different types and phases of clinical trials
CO3	Know the regulatory requirements and guidance for conduct of clinical trials and research
CO4	Understand the European union guidance for clinical evaluation and safety for medicinal products and medical devices.
CO5	Understand the clinical, ethical principles, informed consent form, process and documentation.
CO6	Know the General biostatic principles applied in clinical research.
CO7	Understand FDA guidance for bioavailability and bioequivalence requirements for Medicinal products
CO8	Understand Indian GCP, CDSCO and ICMR guidelines for biomedical research.

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	Give a brief description of different phases of clinical trials	10	CO2	L2
2	Give composition of ethics committee. Outline its role and responsibilities in clinical trials.	10	CO5	L1
3	Write a note on ICH GCP guidelines	10	CO8	L1
4	Give an overview of clinical trail regulations prevailing in India.	10	CO3	L2
5	Explain ICH GCP E6 guidelines	10	CO8	L4
6	When NDA is applied in regulatory authority. Mention the important aspects of NDA.	10	CO5	L3
7	Explain the Bioavailability and Bioequivalence guidelines as per USFDA.	10	CO7	L2

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Write a note phase 0 studies.	5	CO2	
9	Illustrate the declaration of Helsinki.	5	CO2	
10	Give a brief note on biostatic principles applied in clinical research.	5	CO6	
11	Briefly write about the content of PSUR	5	CO3	
12	What are the functions of the Med Watch	5	CO6	
13	Describe ICMR guidelines for biomedical research.	5	CO8	
14	What is schedule 'Y'? Elaborate the significance of schedule Y with respect to clinical research in India.	5	CO6	

****All the Best ****

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Regd. No: …… **MRA-104T**

Total No. of Questions: 14 **Total No. of Pages:02**

I/II M. Pharmacy Regular Degree 1st Semester end Theory Examinations
April, 2026 - (Admitted in 2025-2026 Autonomous Batch)
Pharmaceutical Regulatory Affairs Specialization

Subject Code & Name: MRA-104T Regulations and legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights.

Time Duration: 3.00 Hrs. **Max. Marks: 75 Marks.**

CO 1	Assess the approval process and regulatory requirements for drugs & cosmetics, medical devices, biological & herbals, and food & nutraceuticals
CO 2	Examine the Indian Pharmacopeial and BIS standards
CO 3	Review and validate the guidelines for drug testing in animals
CO 4	Practice the concept of Intellectual Property Rights
CO 5	Describe the different acts and guidelines that regulate drugs & cosmetics, medical devices, biological & herbals, and food & nutraceuticals industry in India
CO 6	Categorize the guidelines for drug testing in animals
CO 7	Assess the regulatory requirements for bioequivalence study
CO 8	Describe the role of IPR in regulatory affairs.

Bloom's Taxonomy Levels-(BL) (L1-Remembering, L2-Understanding, L3–Applying, L4-Analysing, L5–Evaluating, L6-Creating)

SECTION – A

ANSWER ANY FIVE QUESTIONS **(5 X 10M = 50 Marks)**

Q. No.	Questions	Marks	CO	BL
1	What are the objectives of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945? List the provisions for approval of drugs, cosmetics, biologicals, and medical devices in India.	**10**	**1**	**1**
2	Compare the roles and responsibilities of the Central Drugs Standard Control Organization and the State Licensing Authority in drug approval and licensing.	**10**	**1**	**2**
3	Construct a model showing how International Organization for Standardization (ISO) standards can be utilized in pharmaceutical manufacturing and quality control.	**10**	**2**	**3**
4	Examine the Bioavailability and Bioequivalence requirements and classify the regulatory steps involved in BE study approval in India.	**10**	**7**	**4**
5	Distinguish and examine the rationale and regulatory guidelines for animal testing under the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).	**10**	**3**	**4**
6	Evaluate the importance of Patent, Trademark, and Copyright in	**10**	**4**	**5**

	protecting pharmaceutical innovations and justify their role in the Indian patent scenario.			
7	Construct a regulatory plan to control misleading drug advertisements according to the Drugs and Magic Remedies Act, 1954.	**10**	**5**	**6**

SECTION – B

ANSWER ANY FIVE QUESTIONS **(5 X 5M = 25 Marks)**

Q. No.	Questions	Marks	CO	BL
8	Define Drug Price Control Order (DPCO) and name the authority responsible for drug price regulation under the National Pharmaceutical Pricing Authority.	**5**	**5**	**1**
9	Outline the format and contents of a regulatory dossier for drug approval filing in India.	**5**	**1**	**2**
10	Choose appropriate standards from the Indian Pharmacopoeia for testing the purity of pharmaceutical substances. (CO2)	**5**	**2**	**3**
11	Analyze the principles and guidelines for stem cell research issued by the Indian Council of Medical Research and the Department of Biotechnology.	**5**	**5**	**4**
12	Classify drugs based on the Biopharmaceutics Classification System and analyze their impact on bioequivalence studies.	**5**	**7**	**4**
13	Assess the importance of Geographical Indications and Industrial Design in protecting pharmaceutical and herbal products.	**5**	**4**	**5**
14	Recommend suitable Intellectual Property Rights strategies for safeguarding pharmaceutical products in regulatory affairs.	**5**	**8**	**5**

****All the Best ****