This question paper contains 3 printed pages]

OM—12—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharmacy (First Year) (Second Semester) EXAMINATION

July, 2026

REGULATORY ASPECTS OF DRUGS AND COSMETICS

(Thursday, 2-7-2026) MRA-201T **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Solve the following : 2×10=20

(*a*) What is class 2 drug in Japan ?

(*b*) Write objectives of Active Substance Master File (ASMF).

(*c*) What stands for PANDRH ?

(*d*) Differentiate between IND and CTA.

(*e*) Write purpose of certificate of pharmaceutical product.

(*f*) Enlist the functions of USFDA.

P.T.O.

(*g*) What is the long form of EDQM ? Enlist different activities of EDQM.

(*h*) What is ASMF in Europian union ?

(*i*) What is the use of purple book ?

(*j*) Enlist name of countries involved in regulating ACTD.

2. Solve any *two* of the following : 2×10=20

(*a*) Explain regulatory approval process for IND.

(*b*) Explain contents of investigational new drug.

(*c*) Describe in detail about content and approval process of investigational medicinal product dossiers in European Union.

3. Solve any *seven* of the following : 7×5=35

(*a*) Write a note on NDA.

(*b*) What are regulations for manufacture and sale of cosmetics in USA.

(*c*) Write a note on ASMF.

(*d*) Describe content and exclusion in orange book.

(*e*) Explain electronic active substance master file.

(*f*) Write substantial amendment and format of an IMPD.

(*g*) Write guidelines for labeling of pharmaceuticals in European Union.

(*h*) Discuss marketing process of drugs in common-wealth independent states.

(*i*) Discuss about post marketing surveillance in Japan.

This question paper contains 3 printed pages]

OM—26—2026

FACULTY OF PHARMACEUTICAL SCIENCE

M.Pharm. (First Year) (Second Semester) EXAMINATION

July, 2026

REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS

MRA-202-T

(Saturday, 4-7-2026) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Figures to the right indicate full marks.

1. Solve all the following : 2×10=20

(*a*) What is the meaning of biosimilarity ?

(*b*) Write *two* objectives of pharmacovigilance in biologics.

(*c*) Define GDP and mention its importance.

(*d*) What is the function of FDA in biologics regulation ?

(*e*) State any *two* regulatory pathway for biologics in the USA.

P.T.O.

(*f*) Define plasma master file.

(*g*) What is the purpose of stability testing in biologics ?

(*h*) Mention *two* key parameters assessed during vaccine quality evaluation.

(*i*) What is BLA ?

(*j*) Mention *two* aspects covered under herbal product legislation in USA.

2. Solve any *two* of the following : 2×10=20

(*a*) Explain the approval process for biologics and biosimilars in the European Union, including TSE/BSE evaluation.

(*b*) Describe the regulatory requirement for vaccines in India and USA.

(*c*) Discuss the applicable regulation guidelines and data requirement for preclinical and clinical studies of similar biologics in India.

3. Solve any *seven* of the following : 7×5=35

(*a*) Discuss the role of ISBT and IHN in blood products regulation.

(*b*) Explain the regulator requirement for blood and its components in India.

(*c*) Outline the process of vaccine registration and marketing authorization in EU.

(*d*) Describe the steps involved in IND application in USA.

(*e*) Explain quality, safety and legislation of herbal products in the EU.

(*f*) Describe the advertising, labelling and packaging regulation of biologics in the USA.

(*g*) Write a note on pharmacovigilance requirements for vaccines.

(*h*) Discuss GMP and GDP guidelines for biological products.

(*i*) Write a note on data requirement for market authorization of similar biologics in India.

This question paper contains 3 printed pages]

OM—40—2026

FACULTY OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY

M.Pharmacy (First Year) (Second Semester) EXAMINATION

July, 2026

REGULATORY ASPECTS OF MEDICAL DEVICES

MRA-203T

(Tuesday, 7-7-2026) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Answer the following questions : 10×2=20

(*a*) What is validation and verification of medical device ?

(*b*) What is adverse event reproting of medical device ?

(*c*) What is STED ?

(*d*) What is GMDN ?

(*e*) Classify the medical devices.

P.T.O.

(*f*) What are good clinical practices ?

(*g*) What is pre-market approval of medical devices in US market ?

(*h*) What is investigational device exemption in US market ?

(*i*) What is IMDRF ?

(*j*) What is GHTF ?

2. Solve *two* out of three : 2×10=20

(*a*) Write down the regulatory registration procedures for medical devices in China, Japan and ASEAN countries.

(*b*) Explain the quality system requirements as per 21 CFR part 820 for medical devices.

(*c*) Explain the regulatory approval process for medical devices in US market.

3. Solve *seven* out of nine : 7×5=35

(*a*) Write in brief about classification of medical devices and regulatory approval process in European Union.

(*b*) Write in detail about clinical investigation of medical devices.

(*c*) Explain in detail quality risk management of medical devices ISO 14971.

(*d*) Explain in detial GHTF organisation, structure, purpose, functions and regulatory guidelines.

(*e*) Explain the product life cycle of medical devices.

(*f*) Explain the basics of *In-vitro* diagnostics classification and approval process in US market.

(*g*) Write in detail about regulatory approval process for medical devices for US market.

(*h*) What are the quality system requirements for China and Japan market for medical devices.

(*i*) Explain in detail about good clinical practice for clinical investigation of medical devices ISO 14155 : 2011.