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M.Pharm
MPA201T

2nd Semester Regular / Back Examination: 2021-22
ADVANCED INSTRUMENTAL ANALYSIS
BRANCH(S): ANALYSIS & QUALITY ASSURANCE,
PHARMACEUTICAL ANALYSIS

Time : 3 Hour

Max Marks : 75

Q.Code : J405

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions : (2 × 10)

- Write the pharmaceutical application of HPLC.
- Write the name of columns used in GC.
- Write the importance of HPLC in Chiral analysis of pharmaceuticals.
- What is the principles of CE.
- Write the principle of HPTLC.
- What is ¹³CNMR.
- Differentiate parent peak and base peak.
- Define LC-MS hyphenation.
- Define normal and reversed phase of HPLC.
- Write various Mass analysers.

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven) (5 × 7)

- Elaborate new developments in HPLC - Role and principles of ultra, nano liquid chromatography in pharmaceutical analysis.
- Give a overview on CE in pharmaceutical analysis.
- Write a short note on MALD & FAB.
- Briefly outline the principles of FT- NMR with reference to ¹³CNMR.
- Elaborate spin-spin and spin lattice relaxation phenomenon.
- Explain DART. MS Analysis.
- Write the principle, instrumentation and application of ion pair chromatography
- Write short note on gas chromatography
- Write the principle, instrumentation and application of HPTLC

Part-III

Long Answer Type Questions (Answer Any Two)

- Q3 Write the principles, instrumentation and application of LC-MS. (10)
- Q4 Write the principles, instrumentation and application of NMR. (10)
- Q5 Briefly explain the principles, method development and application of CE. (10)
- Q6 Write the principles, instrumentation and application of mass spectroscopy. (10)

Registration No:

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Total Number of Pages : 02

M.Pharm
MPA202T

2nd Semester Regular / Back Examination: 2021-22
MODERN BIO-ANALYTICAL TECHNIQUES
BRANCH(S): ANALYSIS & QUALITY ASSURANCE,
PHARMACEUTICAL ANALYSIS

Time : 3 Hour

Max Marks : 75

Q. Code : J481

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions :

(2 × 10)

- a) What are the challenges in the extraction drugs from biological matrices?
- b) What is cryopreservation?
- c) Mention plasma drug concentration –time profile curve
- d) What do you mean by Cytochrome P450-based drug interactions?
- e) Mention the importance and composition of cell culture media.
- f) What do you mean by pharmaceutical alternatives?
- g) Explain pharmaceutical equivalents with suitable examples.
- h) Differentiate Toxicokinetic and Pharmacokinetics
- i) What do you mean by drug clearance?
- j) What is the role of human liver microsomes in metabolite identification?

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven)

(5 × 7)

- a) What is drug interaction? Explain the pharmacokinetic and pharmacodynamic drug interactions with illustrative examples.
- b) Write a note on bio-analytical method validation according to USFDA guideline.
- c) Discuss biopharmaceutical factors affecting drug bioavailability.
- d) Give details of in-vitro, in-situ and in-vivo methods for drug permeability
- e) Discuss the basic equipments used in the cell culture lab
- f) Mention Principles and applications of flow cytometry.
- g) Describe Biopharmaceutical Classification System of drugs
- h) Explain Microsomal assay
- i) Explain role of LC-MS in bioactivity screening and proteomics

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Enlist various methods for extraction of drugs from biological samples. Explain novel sample preparation approach.

(10)

Q4 Briefly describe Principles and applications of MTT assays

(10)

102	Q5	102	Describe in-vitro assay of drug metabolites and drug metabolizing enzymes.	102	(10)	102
	Q6		a) Define Bioavailability and Bioequivalence. Discuss purpose for BA-BE studies		(5)	
			b) Write methods for assessing bioavailability and bioequivalence studies.		(5)	

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M.Pharm
MPA203T

2nd Semester Regular Examination : 2021-22
QUALITY CONTROL AND QUALITY ASSURANCE
BRANCH(S): ANALYSIS & QUALITY ASSURANCE,
PHARMACEUTICAL ANALYSIS

Time : 3 Hour

Max Marks : 75

Q.Code : J557

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1

Answer the following questions :

(2 × 10)

- a) Define quality control as per ISO 9000 and highlight its goals.
- b) Differentiate between the responsibilities of QA and QC.
- c) Differentiate between Bracketing and matrixing designs process of stability testing of new drug substances.
- d) What are the main objectives of good warehousing practice?
- e) Draw a flow chart representation for maintenance of sterile area in a pharmaceutical industry.
- f) Write the steps to prevent mix-ups and cross contamination.
- g) Signify the importance of maintaining the BMR and its role in assuring production of quality finished product.
- h) Highlight the conditions under which process deviation is permissible and areas when these are not permissible
- i) What is quality audit plan? How does it influence the quality of final product.
- j) What do you mean by purchase specification? Justify its need in raw material procurement.

Part-II

Q2

Focused-Short Answer Type Questions- (Answer Any Seven)

(5 × 7)

- a) Briefly describe the protocol for conduct of nonclinical testing
- b) Write a short note on personnel and their responsibilities in a manufacturing area along with organizational structure
- c) Write down the IPQC followed for packing material selection and use.
- d) What are the QC test carried out for container and closure system based on IP highlight the same with specifications
- e) Explain how retention and retrieval documents are maintained in a pharmaceutical industry?
- f) What do you mean by production record review brief out its significance in risk analysis study?
- g) Briefly explain the quality parameters that are to be met for creams as per BP
- h) Explain in brief about 3 tier documentation with a note on risk management
- i) Write a note on time limitations on production and calculation of yields

Part-III

Long Answer Type Questions (Answer Any Two)

- ~~Q3~~ What are the goals, objectives of CPCSEA. Give a detail note on its guideline for animal base study (10)
- Q4 Give a detail account on expiry date calculation for a pharmaceutical product. (10)
- Q5 Give a detail note on the IPQC followed for sterile and surgical products. (10)
- ~~Q6~~ Highlighting the Overview of ICH Guidelines write a note on Q-series guidelines (10)

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M.Pharm
MPA204T

2nd Semester Regular / Back Examination: 2021-22

Herbal and Cosmetic Analysis

BRANCH(S): ANALYSIS & QUALITY ASSURANCE,
PHARMACEUTICAL ANALYSIS

Time: 3 Hour

Max Marks: 75

Q.Code : J631

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions:

(2 × 10)

- a) What is herbal drug standardization?
- b) Write a short note on DNA finger printing techniques in identification of heavy metals.
- c) Give a short note on international patent law as applicable on herbal drugs.
- d) What is Saponification value?
- e) What do you mean by Bio drug- food interactions?
- f) Give a brief note on evaluation of Viscosity of cosmetic raw materials.
- g) What are herbal remedies?
- h) Elaborate monographs of herbal drugs in Ayurvedic Pharmacopoeia.
- i) What is rancidity?
- j) Write a short note on testing of Dental products.

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven)

(5 × 7)

- a) Give a detail differentiation between herbal and Conventional drugs.
- b) What do you mean by adulteration? Write about types of adulteration of herbal drugs. What are the causes and measures of adulteration?
- c) Describe WHO guidelines and AYUSH guidelines for herbal drug standardization.
- d) What do you mean by spontaneous reporting schemes for bio drug adverse reactions?
- e) Give a comparative study of monographs of herbal drugs in IP and USP.
- f) Write a short note on Adulterant screening using modern analytical Instruments.
- g) What are the WHO guidelines for safety monitoring of natural medicine?
- h) Describe in details about Validation of herbal therapies.
- i) What do you mean by adulteration? Write in brief about different types of adulteration and their causes

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Enumerate Herbs vs Conventional drugs. Discuss the efficacy of herbal medicinal products.

(10)

Q4 Write in brief about Indian and international patent law as applicable to herbal drugs and natural products and describe its protocol.

(10)

- Q5** Discuss the Screening of Adulterant using modern analytical instruments (10)
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- Q6** Describe the different methods for Evaluation of cosmetic products (10)
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M.Pharm
MPC201T

2nd Semester Regular Examination: 2021-22

ADVANCED SPECTRAL ANALYSIS

BRANCH(S): CHEMISTRY

Time : 3 Hour

Max Marks : 75

Q.Code : J408

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions :

(2 × 10)

- a) Write the application of ELISA.
- b) Write the application of DTA.
- c) What is Raman Spectroscopy?
- d) What is flash chromatography?
- e) What is meta stable ion?
- f) Write the importance of LC-NMR.
- g) Write the application of DSC.
- h) Elaborate NOESY.
- i) Define thermal method of analysis and write its application.
- j) What is Mc Lafferty rearrangement?

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven)

(5 × 7)

- a) Elaborate Woodward Fieser rule for 1,3-butadienes.
- b) Explain IR Interpretation of organic compounds.
- c) Briefly explain NOESY & COSY.
- d) Write the principle, instrumentation and application of mass spectroscopy.
- e) Write a brief note on meta stable ions and ring rule.
- f) Write the principle, instrumentation and application of GC-MS.
- g) Explain RIA.
- h) Explain briefly about Raman Spectroscopy.
- i) Write the principle, instrumentation and application of DSC.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Write the principle, instrumentation and application of LC- FTIR. **(10)**

Q4 Differentiate DTA & TGA. **(10)**

Q5 Write a brief note on Super critical fluid chromatography , Ion Chromatography and I-EC . **(10)**

Q6 Write the principle, instrumentation and application of IR spectroscopy. **(10)**

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M.Pharm
MPC202T

2nd Semester Regular Examination: 2021-22

ADVANCED ORGANIC CHEMISTRY -II

BRANCH(S): Chemistry

Time : 3 Hour

Max Marks : 75

Q.Code : J477

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I
Q1 Answer the following questions : (2 × 10)

- What is Sigmatropic rearrangement reaction?
- What is stereoselective synthesis?
- Write a note on Fischer's D and L notation.
- Write short note on continuous flow reaction.
- Define catalysis, write the types and advantages.
- Define phase transfer catalysis and applications.
- What is optical activity, give example.
- What is cyclo addition reaction.
- Give the importance of use of enzymes in organic synthesis.
- Write examples of homogenous catalysis used in synthesis of drugs.

Part-II
Q2 Focused-Short Answer Type Questions- (Answer Any Seven) (5 × 7)

- Explain coupling reactions in peptide synthesis.
- What is cis-trans isomerism? Explain E-Z nomenclature with suitable examples.
- Explain physical process in photochemical reactions.
- Describe the applications of transition metals in organic synthesis.
- Write short notes on Diastereoisomers and enantiomers.
- Explain super heating effect of microwave.
- Explain electrolytic reactions with example.
- Write a brief note on C-terminal residue analysis.
- Give the types and applications of Sonochemical reactions.

Part-III
Q3 Long Answer Type Questions (Answer Any Two)
What are microwave assisted reactions? Write merits and demerits. Explain mechanism & superheating effects of microwave. (10)

Q4 What are the groups commonly used to protect groups during peptide synthesis, explain with examples. Explain solution phase peptide synthesis. (10)

Q5 Explain the basic principles and applications of green chemistry. (10)

Q6 Give detailed account on Microwave technology in process optimisation and applications. (10)

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M.Pharm
MPC203T

2nd Semester Regular Examination: 2021-22

COMPUTER AIDED DRUG DESIGN

BRANCH(S): CHEMISTRY

Time : 3 Hour

Max Marks : 75

Q.Code : J553

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions :

(2 × 10)

- Define molecular docking.
- What is Verloop Steric Parameter?
- Differentiate between SAR and QSAR.
- What is the purpose of homology modeling?
- How does CoMSIA differ from CoMFA?
- What is rigid docking?
- What is LUDI programme?
- Write the equation for Free Wilson approach.
- State the significance of Monte Carlo method.
- Write the importance of DHFR in design of drugs.

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven)

(5 × 7)

- Write about the role of CADD in drug discovery.
- Write a short note on Hammett substituent constant.
- What are the advantages of contour map analysis?
- Explain the steps involved in 3D QSAR.
- Write about the concept of pharmacophore mapping.
- Give a brief note on the stages of *de novo* drug design.
- Write about the applications of molecular docking.
- Explain in short about pharmacophore modeling.
- Give a brief note on applications of QSAR.

Part-III

Long Answer Type Questions (Answer Any Two)

- Q3 Discuss about the various physicochemical parameters of QSAR. (10)
- Q4 Describe briefly about virtual screening techniques and *in silico* drug design. (10)
- Q5 Illustrate different techniques of molecular docking in detail. (10)
- Q6 Describe briefly about the analysis of ADMET properties of new molecules and its importance in drug design. (10)

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M.Pharm
MPC204T

2nd Semester Regular / Back Examination: 2021-22
PHARMACEUTICAL PROCESS CHEMISTRY
BRANCH(S): CHEMISTRY

Time : 3 Hour

Max Marks : 75

Q.Code : J633

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

- Q1 Answer the following questions :** (2 × 10)
- a) What are the objectives of pharmaceutical process chemistry?
 - b) Define nucleation.
 - c) What is MSDS?
 - d) Define azeotropic distillation.
 - e) What is genotoxic impurity? Give its two examples.
 - f) Explain the term Nitration.
 - g) What are different types of oxidative reactions.
 - h) Write the principle of climbing film evaporator.
 - i) How does fire extinguisher work?
 - j) What is catalytic halogenation?

Part-II

- Q2 Focused-Short Answer Type Questions- (Answer Any Seven)** (5 × 7)
- a) Write about the production of penicillin.
 - b) Write a short note on homogeneous catalyst.
 - c) How are effluents managed?
 - d) Explain different theories of filtration.
 - e) State the principle and applications of steam distillation.
 - f) Give a brief note on catalytic halogenation.
 - g) Write about the ozonolysis.
 - h) Explain counter current extraction.
 - i) Give a brief note on Personal Protection Equipment (PPE).

Part-III

- Long Answer Type Questions (Answer Any Two)**
- Q3** Describe briefly about the in-process control and validation of large-scale process. (10)
- Q4** Illustrate the different types of evaporators and write in details about the factors affecting evaporation. (10)
- Q5** Discuss about the kinetics of halogenation and mention case study on industrial halogenation process. (10)
- Q6** Describe briefly about ISO 14001 environmental management system standard. (10)

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M.Pharm
MPH201T

2nd Semester Regular / Back Examination: 2021- 22
MOLECULAR PHARMACEUTICS (NANO TECH AND TARGETED DDS)
BRANCH(S): PHARMACEUTICAL TECHNOLOGY,
PHARMACEUTICS, PT

Time : 3 Hour

Max Marks : 75

Q.Code : J411

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions :

(2 × 10)

- a) Define active and passive targeting
- b) Define the term aerosol as per IP.
- c) Write any two applications of Monoclonal Antibodies in pharmacy
- d) Define Phytosomes,
- e) Differentiate between niosome and liposome
- f) What is Magnetic microspheres
- g) Define Biodistribution.
- h) How microsphere can be differed from microcapsules.
- i) Mention the uses of Aptamers.
- j) Describe Antisense molecules.

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven)

(5 × 7)

- a) Describe briefly about preparation and application of niosomes
- b) Give the principle of microencapsulation. Explain about Coacervation phase separation technique.
- c) Explain the significance of gene therapy.
- d) Write notes on basic concepts of drug targeting.
- e) Describe in brief about pulmonary drug delivery system.
- f) Write a note on Brain specific delivery.
- g) Write on Gene expression systems in reference to viral gene transfer.
- h) Describe the recent advancement in production of microparticles.
- i) Write brief note on electrosomes.

Part-III

Q3 Long Answer Type Questions (Answer Any Two)

Explain the basic concept of target oriented drug delivery system. Write note on Tumour targeting. **(10)**

Q4 Explain in detail about the types of propellants, preparation and evaluation of aerosols. **(10)**

Q5 Explain in detail about types, preparation and evaluation of Intra Nasal Route Delivery System **(10)**

Q6 Explain the principle and techniques of formulating Nanoparticles. **(10)**

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M.Pharm
MPH202T

2nd Semester Regular / Back Examination: 2021-22
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS

Time : 3 Hour

Max Marks : 75

Q.Code : J476

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions : (2 × 10)

- a) Differentiate between Delayed-release and Extended-release
- b) Define the compartments in two compartment model.
- c) Mention drug formulation factors affecting drug product performance.
- d) What are the different types of vaccines?
- e) What are generic Biologics? Give examples.
- f) Define Noyes-Whitney equation for explaining rate of dissolution.
- g) Write the mechanisms of drug absorption.
- h) What are different types of modified-release drug products?
- i) Define absolute and relative bioavailability
- j) What are the rate limiting steps in drug absorption?

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven) (5 × 7)

- a) Permeability experimental method.
- b) Michaelis-Menten equation
- c) Oligonucleotides
- d) Dissolution profile comparison
- e) Active transport
- f) Drug product stability.
- g) Crossover study designs
- h) Properties of the Gastrointestinal Tract
- i) Monoclonal antibodies

Part-III

Long Answer Type Questions (Answer Any Two)

- Q3** Write about bio-pharmaceutics classification system. How bioavailability can be evaluated by plasma-concentration time study? Write on clinical significance of bio-equivalence studies. **(10)**
- Q4** How targeted drug delivery or, site-specific drug delivery can be classified? Write the passive targeting and active targeting approaches. **(10)**

102 Q5 102 What do you mean by non-linear pharmacokinetics? Write the causes of non-102 linearity. Explain protein-binding interaction. (10) 102

Q6 What are the several one compartment open models depending on rate of input? (10)
Describe one compartment open model after iv infusion. What is steady state condition?

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M.Pharm
MPH203T

2nd Semester Regular / Back Examination: 2021-22
COMPUTER AIDED DRUG DELIVERY SYSTEM
BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS

Time : 3 Hour

Max Marks : 75

Q.Code : J552

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right-hand margin indicate marks.

Part-I

Q1 Answer the following questions: (2 × 10)

- a) What is sensitivity analysis and what are its advantages.
- b) What is clinical data management.
- c) What is population modeling and name the major types of population modeling.
- d) What is robotics?
- e) What is biowaiver consideration?
- f) What is Computational fluid dynamics?
- g) What are advantages of Artificial Intelligence?
- h) Where is P-glycoprotein found and write its role of in pharmacokinetics?
- i) What is computational Modelling of drug disposition? Write its importance.
- j) Write the role of hPepT1 transporter.

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven) (5 × 7)

- a) Discuss the essential elements of quality by design
- b) Give general overview on Artificial Intelligence (AI)
- c) Differentiate descriptive and mechanistics modeling
- d) Discuss the role of nucleoside transporters
- e) Discuss ethics of computing in pharmaceutical research.
- f) Discuss the concept of optimization and its benefits in formulation development
- g) Describe the ethical issues of computing in pharmaceutical Research.
- h) Write a short note on Pharmaceutical automation.
- i) Write a note on Computer simulations of the Proteins and Genes.

Part-III

Long Answer Type Questions (Answer Any Two)

- Q3** Discuss ICH Q8 guideline in details. (10)
- Q4** Discuss the role of computer in Clinical drug development. (10)
- Q5** Write about factorial design and its types in details. (10)
- Q6** Describe a detail note on Gastrointestinal absorption simulation - Gastro Plus ^(TM). (10)

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M.Pharm
MPH204T

2nd Semester Regular / Back Examination: 2021-22

COSMETIC AND COSMECEUTICALS

BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS

Time : 3 Hour

Max Marks : 75

Q.Code : J630

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 Answer the following questions :

(2 × 10)

- a) Define cosmetics as per Indian regulations and European Union
- b) What do you mean by Misbranded and spurious cosmetics
- c) What do you mean by loan license.
- d) What are prickly heat, wrinkles skin problems.
- e) Write the problems associated with preparation of scalp.
- f) What are Soaps and syndetbars
- g) Mention applications of emollients.
- h) What do you mean by herbal cosmetics?
- i) What are fuming agents used for preparation of herbal cosmetics?
- j) What do you mean by bleeding gums?

Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven)

(5 × 7)

- a) Discuss hair growth cycle.
- b) Write notes on Common problems associated with oral cavity.
- c) Briefly describe Cleansing and care needs for face, eye lids
- d) Classify different types Surfactants used in cosmetics formulation.
- e) What are common problems associated with body and under arm.
- f) Write different Factors affecting microbial preservative efficacy
- g) What are different Building blocks for formulation of a moisturizing cream and vanishing cream,
- h) What ingredients used for formulations of shampoo and toothpaste
- i) What are regulatory requirements for manufacturing of cosmetics?

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 What are Regulatory provisions relating to import of cosmetics

(10)

Q4 Discuss the building blocks for different product formulations of cosmetics/cosmeceuticals

(10)

Q5

What are Regulatory aspects of design of cosmetics products? Describe with suitable examples.

(10)

Q6

Classify Perfumes. Describe what Perfume ingredients listed as allergens in EU regulation

(10)