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PY 134201

Roll No. of candidate | | | | | | | | | | |

2017

M. Pharm 2nd Semester End-Term Examination

DOSAGE FORM DESIGN AND PRODUCT DEVELOPMENT

Full Marks – 100 Pass Marks – 35 Time – Three hours

The figures in the margin indicate full marks for the questions.

1. Answer the following questions (any *ten*) : 3×10=30

   (i) State and mention existence of pressurized package dosage form. Write the advantages of this system over other dosage form.

   (ii) Write the function of actuators used in aerosol system. Enlist the different types of actuators along with their uses.

   (iii) Mention and discuss different steps of sugar coating.

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(iv) What are the functions of opaquant-extenders in tablet coating ? Give the examples of commonly used opaquants in tablet coating.

(v) How viscosity of oral liquid formulation can be controlled during the manufacturing ? Justify your answer with suitable examples.

(vi) Write the chemical structure and salient features of Aspartame.

(vii) Specify the space requirements for a pilot plant organization.

(viii) Write in details about the checklist of GMP items that should be part of scale-up or process introduction.

(ix) Differentiate Nebulizers with DPIs and MDIs.

(x) Write the stability requirements of DPIs as per International Conference on Harmonization.

(xi) Write the significance of microbial air testing in parenteral dosage form development.

(xii) Discuss co-solvency and solubilization with examples.

2. Answer the following questions (any *eight*) : 5×8=40

(i) Explain the desirable rheological attributes of pharmaceutical suspension and emulsion.

(ii) Discuss in details the preparation of master manufacturing procedures as per pilot plant scale up techniques.

(iii) What are the components of aerosol package? Write notes on manufacture of aerosol containers.

(iv) How will you ensure the proper performance and safety during use and storage of "pressurized package" ? Justify your answer.

(v) What are the challenges in production of DPIs ? Discuss different secondary processing techniques for manufacturing of stable DPIs.

(vi) Discuss the recent advances in formulation and manufacturing aspects of oral liquid formulation.

(vii) What is parenteral admixture and incompatibility ? Write in brief about fluid dynamics of IV control system.

(viii) Discuss in brief about the recent technologies of test masking for bitter pharmaceuticals.

(ix) Give a brief resume about classic optimization and evolutionary operation. What approach is taken in a Canonical type of optimization ?

(x) Give a detail note on dermatological vehicles and terms used to explain rheological behaviour.

3. Answer the following questions (any *three*) : 3×10=30

(i) Describe the essential requirements in a pilot plant scale up unit and various functions of a pilot plant team. 6+4=10

(ii) Discuss in details the large scale manufacturing and optimization process of soft gelatin capsule. 6+4=10

(iii) Discuss different types of packaging system of DPIs. Write about the performance and regulatory requirements for DPIs. 2+4+4=10

(iv) Write notes on any *two* : 5×2=10

(a) Rotary press

(b) Specialized coatings

(c) 3^2 factorial design.