Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm-Semester-III May-2012 Examination

Subject code: 230002

Subject Name: Pharmaceutical Engineering-II

Time: 2:30pm to 5:30pm **Date: 09-05-2012**

Total Marks: 80

Instructions:

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1 (a) (1)What are the factors influencing flow of powders. **06**
(2)What is content uniformity and state its importance in pharmacy.

(b) (1)What are different types of control charts. **05**
(2)Why is supercritical CO_2 used widely in pharmacy

(c) (1)Microcrystalline cellulose is the golden standard to manufacture spherical pellets because……. **05**
(2) The upper control limit UCL and lower control limit LCL is
(a) 1 (b) 2 (c) 3 standard deviation away from the centre line.
(3)Define super critical point.
(4)Define angle of repose.
(5)SCF has gas like viscosity and liquid like density. (true or false)

Q.2 (a) (1) What are the factors affecting content uniformity. **06**
(2)What is the importance of powder flow in solid dosage form formulations

(b) (1) What is the conventional method of producing micro particles. **05**
(2)What are advantages of pellets over conventional drug delivery systems.

(c) (1)In a control chart if 8 points run on one side of centre line then it indicates **05**

(a)a shift in the process output from changes in equipment methods or materials or a shift in the measurement system.
(b) gradual deterioration or wear in equipment.
(c) temperature or other recurring changes in the environment.

(2) In a batch of 2 lakh tablets of a very potent drug if the acceptance quality level of its assay is kept at 98% to 102% ,the no. of samples to be withdrawn for testing for assay would be
(a) 10 (b) 20 (c) 30.

(3)Define Hausner's ratio.

(4)SCFs acting as solvent means

(a) Drug of interest is soluble in solvent
(b) Drug of interest is soluble in SCF
(c) Drug of interest is insoluble in SCF .

(5)Extrusion mixtures are formulated to produce a cohesive plastic mass.(True or false) .

Q.3 Answer the following

(a) (1)What are the means of achieving content uniformity. **06**
(2)Write indirect methods for powder flow measurement.

(b) (1) Explain in detail analysis of control charts. **05**
(2)What are the process steps involved in extrusion and spheronization.

(c) (1)Define sampling. **05**
(2) In super critical antisolvent technology
(a)solute is miscible with SCF
(b)solute is immiscible in solvent
(c)solvent is miscible in SCF.
(3)Define Carr's compressibility index.
(4)Define pharmaceutical pellets.
(5)Define content uniformity.

Q.4 Answer the following

(a) (1)What are different sampling techniques. **06**

(2)Mention direct methods for powder flow measurement.

(b) (1)What are non pharmaceutical applications of supercritical fluids. **05**
(2)Explain in detail rotary gear extruder.

(c) (1)IP does not recommend content uniformity test for …… **05**
(2)Define angle of repose.
(3)Define cryopelletization.
(4) The temperature and pressure of supercritical carbon dioxide are……
(5) The size of pharmaceutical pellets is 2 to 4 mm. in mean diameter.(true or false)

Q.5 Answer the following

(a) (1)What are different sampling techniques. **06**

(2)How can you improve powder flow.

(b) (1) What are different elements of control charts. **05**

(2)Explain PGSS process. (Particles from gas saturated solution).

(c) (1) Super critical carbon dioxide is a good solvent for **05**
(a)low molecular weight and polar compound
(b)high molecular weight and non polar compound
(c)low molecular weight and non polar compound
(2) Direct measusrement of powder flow uses
(a) kinetic method (b) static method.
(3) Advantages of hot melt extrusion over the traditional processing technique are ……..
(4)Classify the following into variable and attributes;
(a)weight (b) content uniformity
(c)microbial growth (d)particle contamination.
(5) Define control charts.

Q. 6 Answer the following

(a) (1) Explain in detail screw extruder **06**
(2) How will a control chart benefit a pharmaceutical firm.

(b) (1) Explain superiority of SC CO_2 in sterilization over autoclaving. **05**
(2) What are the factors affecting quality of products in Extrusion and spheronization

(c) (1)As you narrow the acceptance quality level (AQL) the number of samples **05**

increases for testing. Explain with graph.

(2) Compare the following particle design technologies:

Characteristics	Spray drying	RESS	PGSS
Nanoparticles Yes/no			
Crystallinity Amorphous/crystalline			
Size distribution Broad/narrow			
Residual solvent Yes/no			
Encapsulation Yes/no			

Q.7 Answer the following

(a) (1) Explain the concentrated powder form process using super critical carbon dioxide. **06**

(2)Give a schematic diagram of supercritical fluid extraction apparatus and explain.

(b) (1) Explain in detail hot melt extrusion. **05**

(2) Explain eudragit 's use in extrusion.

(c) (1) Excellent flow character is shown by **05**

(a) angle of repose 25 to 30 , compressibility index <10, Hausner's ratio 1.0 to1.1

(b)angle of repose 25 to30, compressibility index25 to 30, Hausner's ratio 1.45 to1.6

(c)angle of repose40 to 45, compressibility index <10, Hausner;s ratio 1.1to1.2

(2) The principle of spray congealing method for preparing pellets is …….

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