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UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

FOURTH BPHARM PART I EXAMINATION – DECEMBER 2016

PH 4134 PHARMACEUTICAL TECNOLOGY (SEQ)

TIME: THREE HOURS

INSTRUCTIONS

- *Answer all questions.*
- *Do not use any correction fluid.*
- *Answer questions in the booklet/s provided.*
- *Marks will be deducted for illegible hand writing.*

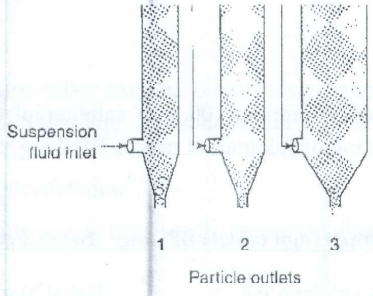
1.

1.1 Explain the reasons for granulation. (***20 marks***)

1.2 Explain the three (**03**) mechanisms of granule formation in wet granulation. (***30 marks***)

1.3 Give a brief account on methods that can be utilized to increase the filtration rate of a fluid. (***15 marks***)

1.4 Following figure show a continuous elutriation process. Describe how this process can efficiently separate particles. (***15 marks***)



1.5 Explain briefly the extrusion and spheronization. (***20 marks***)

2. Write short notes on followings (Sketch the diagrams wherever necessary).

2.1 Shear thinning and shear thickening rheological systems (***25 marks***)

2.2 Negative and positive mixtures (***25 marks***)

2.3 Bed drying and oven drying (***25 marks***)

2.4 Hammer mill (***25 marks***)

3.

3.1 What is meant by scale of scrutiny? (*05 marks*)

3.2 If number of particles are 36000, calculate the standard deviation of active ingredient in the mixture. (*10 marks*)

3.3 Using necessary equations show how changes in active ingredient would affect the variation of the active ingredients. (*15 marks*)

3.4 The relative viscosity (η_r) of a solution is given by the equation given below,

$$\eta_r = \frac{\eta}{\eta_0}$$

Where viscosity of solution (η) and viscosity of the solvent (η_o),

Using relative viscosity and specific viscosity, derive an equation to calculate the viscosity of a colloidal suspension. (*10 marks*)

3.5 Briefly describe why some hydrates show higher solubility where as some show lower solubility characteristics. (*20 marks*)

3.6 "Formulation of drugs using amorphous materials is a prominent solution for poorly soluble drugs". Do you agree with this statement? Justify your answer. (*20 marks*)

3.8 Electricity and steam can be used as heating media. Discuss briefly the pros and cons of both of these media. (*20 marks*)

4. Assume that you are requested to prepare 100 g of salbutamol tablet BP 2 mg batch. The master formula for the production of salbutamol tablets BP 2 mg, 500 g batch is given below.

Formula for salbutamol tablets BP 2mg Batch size 500g

Salbutamol sulphate BP	006.020 g
Lactose BP	334.780 g
Maize starch BP	115.000 g
Maize starch BP	030.000 g
Purified talc BP	025.000 g
Magnesium stearate BP	022.500 g
Purified water 60°C	075.000 mL
Purified water 100°C	130.000 mL

4.1 Calculate the working formula. (*10 marks*)

4.2 State the purpose of using following ingredients in above production. (*15 marks*)

4.2.1 Salbutamol sulphate BP

4.2.2 Lactose BP

4.2.3 Purified talc

4.3 During the production process of salbutamol tablets, maize starch mucilage is prepared by mixing 30 g of maize starch in 75 mL of purified water at 60 °C and then transferring that in to 130 mL of boiling water.

4.3.1 State the purpose of adding maize starch mucilage in this salbutamol tablet production process. (*05 marks*)

4.3.2 Name three (**03**) types of granulators that can be used for above process. (*10 marks*)

4.4 Name steps that used to prepare the powder mixture mentioned in above 4.1 to be compressed. (*20 marks*)

4.5 Explain the "tableting procedure" of above 4.3.2 prepared granules using single punch tablet press. (*40 marks*)

5.

5.1 Briefly describe the rotary die process used to prepare soft gelatin capsules. (*30 marks*)

5.2 State two (**02**) methods to modify the release profile of capsules. (*10 marks*)

5.3 Describe the importance of conducting pilot plant studies. (*20 marks*)

5.4 Briefly describe the use of "stem cell technology" in cosmetology. (*25 marks*)

5.5 In industries, safety devices are used to prevent, reduce or eliminate hazards which cause harmful effects. Sate five (**05**) such devices available in industries. (*15 marks*)

6. Parenteral dosage forms differ from all other dosage forms, because they are injected directly in to the body tissues. Therefore, all products must be sterile.

6.1 Define the term "sterilization". (*05 marks*)

6.2 List five (**05**) requirements for a sterile pharmaceutical product manufacturing plant. (*15 marks*)

6.3 State the reason for adding preservatives to the parenteral products even though those products are sterilized. (*05 marks*)

6.4 Using labeled diagrams, briefly explain the reason for using vertical laminar airflow hoods instead of horizontal airflow hoods in the preparation of chemotherapy drugs. (*20 marks*)

6.5 Briefly describe the "barrier isolator technology" used in parenteral production. (*25 marks*)

6.6 For the production of parenteral products, water for injection (WFI) produced by distillation.

6.6.1 Sketch a cross section of a multiple effect still. (*10 marks*)

6.6.2 Briefly describe the production process of WFI and mark the material flow path on the drawn sketch. (*20 marks*)

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