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UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

FOURTH B.PHARM PART I EXAMINATION – DECEMBER 2015

PH 4134: PHARMACEUTICAL TECHNOLOGY (SEQ)

TIME: THREE HOURS

INSTRUCTIONS

- Answer all questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

1.

1.1. What is validation? ***(10 marks)***

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1.2 Why validation is important in Pharmaceutical industry? ***(20 marks)***

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1.3 What are the types of sterilization methods use in a Pharmaceutical manufacturing? ***(15 marks)***

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1.4 What are the factors to be considered in sterilization using gases? *(20*

1.5 What are the main forms of parenteral preparations? ***(10 mark***

1.6 Describe briefly each of above preparation mentioned in 1.5. ***(25 marks)***

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2.

2.1 What is GMP? ***(10 marks)***

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2.2. Why GMP is important in Pharmaceutical manufacturing process? ***(10 marks)***

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2.3 What is clean room in pharmaceutical manufacturing process? ***(10 marks)***

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2.4 Why clean rooms are important in parenteral product manufacturing? ***(10 marks)***

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2.5 List the typical rooms you intend to find in a sterile product manufacturing plant? ***(10 marks)***

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2.6 Describe briefly their purposes and air classifications as per WHO recommendations. (use the table given to explain the Air classification by filling the blank spaces) ***(25 mark***

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Grade/Class	At Rest		In operation	
	Maximum permitted number of particles/m^3			
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.....	3500	0	3500	0
.....	3500	0	350000	2000
.....	350 000	2000	3500000	20000
.....	3500000	20000	-	-

2.7 What are Cosmetics? ***(10 marks)***

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2.8 What are the three main classification systems used for categorization of different types of cosmetic preparations? ***(15 marks)***

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3. During manufacturing of solid oral dosage forms like tablets and capsules it is very important to mix the contents homogeneously to achieve uniform content in each unit dosage form. In order to validate your mixing process you have taken samples from different points of the powder bed and analysed the amount of active ingredient present.

3.1 Distinguish between perfect mixing and random mixing for a pharmaceutical product.

(10 marks)

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3.2 If the active ingredient in your formulation comprised of 0.5 of the whole tablet weight, and number of particles are 48,000 what is the standard deviation of the active ingredient calculated?

(10 marks)

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3.3 If you increase the amount of active ingredient by 0.25 how would it affect the standard deviation and percent coefficient of variations in both situations? (show calculations).

(20 marks)

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3.4 At 99.7% confidence interval the maximum deviation that you can allow for this particul active ingredient is ±5%. Calculate and show the number of particles that should be ideally present in the blend to achieve the random mixing of the API. P=0.5.

(20 mark

3.5 If degree of mixing is given by $M = S_R / S_{ACT}$, what advantages can you gain by calculating this degree of mixing. ***(10 marks)***

3.6. State three main mechanisms of size reduction and briefly describe them. ***(30 marks)***

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4. A study has been carried out to evaluate the suitability of a new excipient as a disintegrant to be used with an immediate release formulation. F01-F03 : new disintegrating agent, F04-F06: Sodium Starch Glycolate, F07-F09: Carmellose sodium. The finding are given in the table bellow.

FORMULATION	wt VARIATION %	HARDNESS	FRIBAILITY	DRUG CONTENT	DT (SECONDS)	INVITRO DISSOLUTIO
F01	2.42	5.8	0.61	99.48	34	82.20
F02	2.93	5.6	0.66	99.46	33	88.80
F03	3.44	6.4	0.61	99.78	21	93.74
F04	2.55	6.3	0.7	99.74	25	90.20
F05	3.23	5.7	0.61	99.53	25	91.50
F06	3.16	5.8	0.63	99.82	20	96.70
F07	2.47	5.7	0.68	99.89	49	79.53
F08	2.47	5.8	0.59	99.71	37	85.89
F09	2.62	5.9	0.63	99.28	30	88.75

4.1 What is the function of a disintegrant? ***(10 marks)***

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4.2 Interpret the results of disintegrating time (DT) and *in-vitro* dissolution of the drug from the dosage form? Is this relationship always predictable? Explain your answer. ***(30 marks)***

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4.3 How would tablet hardness and friability affect tablet properties? ***(10 marks)***

4.4 Compression and consolidation are the two main phases in tablet compression. What are the deformations that can be taken place during compression and briefly explain them?

(30 marks)

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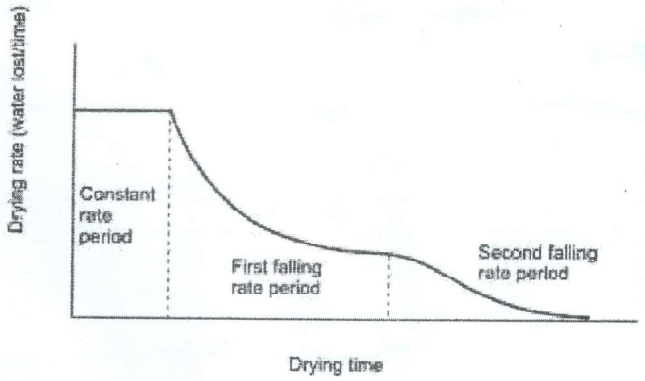
4.5 Drying is a compulsory step in wet granulation. A typical drying curve is given below.



4.5.1 Explain what happens during each phase of the drying curve. ***(20 marks)***

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5.1 Write a small account on reasons for granulation. ***(20 marks)***

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5.2 Describe the mechanisms of granule formation. *(30 marks)*

5.3 Briefly describe following terms in relation to rheology. *(20 marks)*

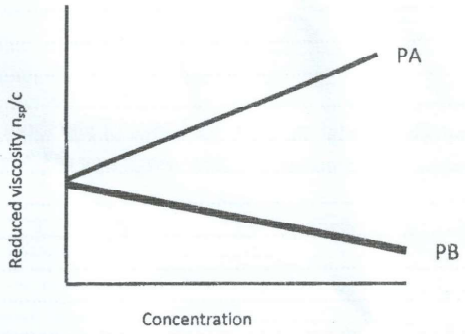
5.3.1 Pseudoplastic material

5.3.2 Dilatant material

5.4 For a colloidal solution with moderate concentrations, following relationship can be obtained. Prove this relationship with specific viscosities and relative viscosities. ***(20 marks)***

$$\frac{\eta_{sp}}{c} = k_1 + k_2 C + k_3 C^2$$

5.5 According to the following graph what can you say about the polymer-solvent interactions of PA and PB polymers. ***(10 marks)***



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6.1 How would you select a suitable location for a pharmaceutical industry? *(20 m*

6.2 Discuss the aims of manufacturing facility design? ***(30 marks)***

6.3 As a formulator you are requested to formulate an immediate release tablet dosage from a potent drug. "x". Drug X is crystalline drug with moderate water solubility. The recommended dose for an adult is 2 mg two times a day. The drug itself has poor compressibility properties and thermos and moisture sensitive. What is the suitable compression method should be used for this drug? Justify your answer ***(15 marks)***

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6.4 Average weight of drug "Y" tablet is equal to 120 mg. When doing uniformity of weight test according BP, Three tablets were found with 109 mg, 131 mg and 108 mg weights.

6.4.1 What can you say about these weights considering the uniformity of weight standards given in the BP? Use calculations if necessary. ***(10 marks)***

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6.4.2 Are these tablets complying with the uniformity of weight test as per the BP. Give reasons for your conclusion? ***(15 marks)***

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6.4.3 "For a moderate to low-dose drugs weight variation test is a suitable method to assure uniform potency. " Do you agree with this statement? Explain your answer? ***(10 marks)***

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