

M. Pharm 1<sup>st</sup> Year 2<sup>nd</sup> Semester Examination 2019

Subject: Pharmaceutical Biotechnology – II

Time : 3 hrs

Full Marks : 100

Answer any five questions taking at least one from each group

Group – A

1. a) Briefly discuss the sterility testing procedure as per IP guidelines.  
b) Write in short about the validation process of membrane filter used in pharma industry.  
15+5=20
2. Define the term intellectual property. How it could be protected ? Write the process of patent filling. What is trade mark ? Define the term royalty.  
4+4+6+4+2=20
3. Write short notes on **any four** of the following  
4×5=20
  - a. Bio-hazards and its control.
  - b. Integrity test of HEPA filter
  - c. Depyrogenation of parenterals
  - d. Xenobiotics in relation to the health hazards
  - e. Organ transplantation covering the ethical issues
  - f. Pharmaceutical importance of 3-methyl indole

**MASTER OF PHARMACY EXAMINATION, 2019**

**1<sup>st</sup> year 2<sup>nd</sup> Semester**

**Pharmaceutical Biotechnology -II**

**Time –Three hours**

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**Answer any five questions taking at least one from each group**

4. Write an account on the PK/PD model of protein pharmacodynamics. 20
5. Write the different ways of modifications of pharmacokinetic profile of protein therapeutics. 20

**Group- B**

1. Write down the design and development protein and peptide drug based on biopharmaceutics and protein engineering. What are the direct and indirect link PK/PD models? What is pegylation. What are the properties of pegylation. 8+5+2+5=20
2. Write details about method of isolation protein. What are steps for purification of protein? 10+10=20
3. What is therapeutic protein? Describe the method protein drug delivery by rDNA technology. Write the dual mechanism of elimination of filgrastim. How to characterization protein and peptide? 2+7+3+8=20