

Bachelor of Pharmacy Final Examination, 2022

(4<sup>th</sup> Year-2<sup>nd</sup> Semester)

**Pharmaceutics - VIII**

Time: Four hours

Full Marks: 70

Answer any five questions taking at least two from each group.

**Group A**

1. What is patent? What are the advantages of patenting? Mention different types of inventions which are not patentable.

2+4+8 =14

2. What are the criteria adopted for grant of a patent? What are the documents to be submitted along with patent application? Describe the term "complete specification".

4+4+6=14

3. Write down short note on the following

3.5x4=14

- a) Industrial design and Trade secret
- b) Right of patentee
- d) Steps involved in filing a patent.
- e) Revocation of patent

**Group B**

4. What are the various studies conducted during preclinical development of a new drug candidate? What do you mean by clinical hold?

10+4=14

5. Who can be the sponsor of an IND application? What do you mean by clinical protocol? What are the contents of the clinical protocol? What is IRB?

2+2+6+4=14

6. Write short notes on any 2 of the following:

7x2=14

- a) Clinical study controls and designs
- b) Dose determination studies during clinical trials
- c) Treatment IND and Abbreviated NDA.