

M.Pharm.
(SEM II) THEORY EXAMINATION 2017-18
BIOLOGICS REGULATIONS

Time: 3 Hours**Total Marks: 70****Note:** Attempt all Sections.**SECTION A****1. Attempt all questions in brief. 2 x 7 = 14**

- a. What are the significances of preclinical studies?
- b. What is clinical trial?
- c. Define the term biosimilars.
- d. Define the term biologics.
- e. What do you mean by plasma master file?
- f. What is marketing authorization?
- g. Explain the term Clinical evaluation.

SECTION B**2. Attempt any three of the following: 7 x 3 = 21**

- a. Give a detail, note on principles for development of similar biologics.
- b. Write a short note on development and approval of biologics and biosimilars.
- c. Discuss advertising, labeling and packing of biologics in the EU.
- d. Write in detail about vaccine regulations in US and European Union.
- e. Give a brief account on regulatory requirements of blood and/or its components including blood products in India.

SECTION C**3. Attempt any one part of the following: 7 x 1 = 7**

- a. Discuss data requirements for clinical trial application.
- b. Write briefly about data requirements for market authorization application

4. Attempt any one part of the following: 7 x 1 = 7

- a. Explain difference between generic drug and biosimilars.
- b. Describe the pre-clinical and clinical development considerations in USA.

5. Attempt any one part of the following: 7 x 1 = 7

- a. Elaborate directives, scientific guidelines and guidance related to biologic in the EU.
- b. Write in detail about development and regulatory approval of biologic in EU.

6. Attempt any one part of the following: 7 x 1 = 7

- a. Discuss briefly about pharmacovigilance.
- b. Disuss the vaccine regulations in India.

7. Attempt any one part of the following: 7 x 1 = 7

- a. Give a brief account on ISBT.
- b. Write a note on International Haemovigilence Network.