

Code: 17S11104

M.Pharm I Semester Regular Examinations February 2018

**REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES,  
BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND  
INTELLECTUAL PROPERTY RIGHTS**

(Pharmaceutical Regulatory Affairs)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

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- 1 Write in detail about drug and cosmetics act 1940.  
**OR**
- 2 Explain in detail pharmacy act 1948.
- 3 Explain the guidelines and standards for regulatory filing of drugs and cosmetics.  
**OR**
- 4 Write a detailed note on organization and responsibilities of state licensing authority.
- 5 Explain BIS standards for medical devices.  
**OR**
- 6 Explain Indian pharmacopoeia standard for drugs.
- 7 Write a detailed note on regulatory requirements for stability study.  
**OR**
- 8 Explain the following:  
(a) Ethical guidelines for human participants.  
(b) ICMR-DBT guidelines for stem cell research.
- 9 Explain the time line in patent filing in India.  
**OR**
- 10 What is intellectual property? Explain industrial designs and trademarks with examples.

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