

Roll No. \_\_\_\_\_

Enrollment No. \_\_\_\_\_

**PARUL UNIVERSITY**

**PARUL INSTITUTE OF PHARMACY**

**M.PHARM FIRST SEMESTER · FIRST INTERNAL EXAMINATION: 2018-19**

**Subject Name: Regulatory Affairs**

**Subject Code: MPH104T**

**Time: 10:00 am to 11:30 am**

**Date: 20/09/2018**

**Total Marks: 30**

**Instructions:**

1. Figures to the right indicate full marks.
2. Make suitable assumptions wherever necessary.

**Q.1 Long Answers: (Any One)**

- (1) What is DMF? Give the important facts regarding DMF. **10**
- (2) Explain the following (Any five): **10**
  - (a) CFR
  - (b) MFR
  - (c) BMR
  - (d) 505(b)(2) application
  - (e) 180 days exclusivity
  - (f) Patent certifications under Hatch-Waxman Act
  - (g) Past marketing surveillance

**Q.2 Short Answers: (Any Four)**

- (1) What is Regulatory Affairs? What are the goals & roles of Regulatory affairs professionals? **05**
- (2) Give the importance of Documentation in Pharmaceutical industry. **05**
- (3) Write a note on Significance of Hatch-Waxman Act. **05**
- (4) What do you mean by IND, NDA and ANDA. **05**
- (5) Describe the NDA approval process in USA. **05**

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