

C.U.SHAH UNIVERSITY

Winter Examination-2018

Subject Name: Regulatory Affairs

Subject Code: MPH104T

Semester: 1

Date: 03/12/2018

Branch: M.Pharm (Pharmaceutics)

Time: 02:30 To 05:30

Marks: 75

Instructions:

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
- (2) Instructions written on main answer book are strictly to be obeyed.
- (3) Draw neat diagrams and figures (if necessary) at right places.
- (4) Assume suitable data if needed.

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- Q-1** **Briefly explain the terms:** **(20)**
- a) Orange Book
 - b) e-CTD
 - c) ANDA
 - d) Blue Book
 - e) MHRA
 - f) DMF
 - g) HIPAA
 - h) Components of FDA
 - i) Activity regulated by CDER
 - j) Investigation of medicinal products dossier
- Q-2** **Attempt any two of following :** **(20)**
- A** Explain the scope of TGA regulations. Discuss the TGA guidelines for OTC product. **10**
 - B** Give the concept of ANDA & prepare flow chart showing ANDA review process. **10**
 - C** Discuss Drug Price Competition and Patent restoration act of 1984 and WAXMAN-HATCH ACT are the same and its economics on the society is important. **10**
- Q-3** **Attempt any Seven of following :** **(35)**
- A** Explain Regulatory requirements of EU **5**
 - B** Explain Guidelines of ICH-M. **5**
 - C** Explain export registration of pharmaceuticals in rest of world countries. **5**
 - D** Explain CFR 21(code of federal regulation). **5**
 - E** Write note on ANVISA. **5**
 - F** Write a note on Post Marketing Surveillance **5**
 - G** Explain regulation for medical devices **5**
 - H** Write a note on NDA. **5**
 - I** Explain pharmacovigilance safety monitoring in clinical trials. **5**

