

C.U.SHAH UNIVERSITY

Wadhwan City

Summer Examination-2014

Date: 23/06/2014

Subject Code :5PS02DR11

Subject Name: Drug Regulatory Aspects & IPR

Branch/Semester:- M.Pharm/II

Time:02:00 To 5:00

Examination: Regular

Instructions:-

- (1) Attempt all Questions of both sections in same answer book / Supplementary
- (2) Use of Programmable calculator & any other electronic instrument is prohibited.
- (3) Instructions written on main answer Book are strictly to be obeyed.
- (4) Draw neat diagrams & figures (If necessary) at right places
- (5) Assume suitable & Perfect data if needed

SECTION - I**Q-1 Define the term :**

(7)

- i) EMEA ii) Holder iii) TRIPS iv) Copyright v) Green book
vi) CDER vii) Appellate Board

Q-2

- a) Write a note on Drug Master File(DMF) . (5)
- b) Define CTD & eCTD. Explain modules of CTD. (5)
- c) What is TGA ? Discuss TGA's risk management approach. (4)

OR**Q-2**

- a) Describe the patent rule 2003. (5)
- b) Mention the goals of NDA. Discuss the general requirements for filing NDA. (5)
- c) Which medicines are not accepted as generic by ANVISA. (4)

Q-3

- a) Give an overview of websites that provide free information on patent. (7)
- b) Write a note on Paris convention. (7)

OR

- a) Write a note on Uruguay TRIPS (7)
- b) Discuss in detail guideline for Japan (7)

SECTION - II**Q-4 Define the term :**

(7)

- i) PCT ii) Agent iii) WTO iv) Trademark v) Blue book
vi) WIPO vii) ANVISA

Q-5

- a) Discuss the phases of investigation in context to IND. (5)
- b) Write a note on Hatchwaxman amendments. (5)
- c) Discuss the benefits of IPR. (4)

OR**Q-5**

- a) Explain centralized and decentralized procedure for registration at EMEA with merits and demerits. (5)
- b) Write a short note on CDER. (5)
- c) Write a short note on ARTG. (4)

Q-6

- a) Define the term invention. Write Explanatory note on non-patentable invention. (7)
- b) Discuss in detail Orange Book? (7)

OR**Q-6**

- a) Write a note on CDSCO and DTAB. (7)
- b) Discuss roles of CBER in USFDA. (7)

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