Exam Seat No:_____ **Enrollment No:**_____

C.U.SHAH UNIVERSITY

Wadhwan City

Subject Code :5PS02DRI1 **Summer Examination-2014** **Date: 23/06/2014**

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 Explainatory 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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