made this product to be sold in United State but due to increase in demand in India, company wants to sale the same product in India also. Company has designed this according to United States procedure for authorizing medical product. Company has appointed you as a management consultant to prepare a project report to launch this drug molecule both in United State and India.

(1) How will you help Reliance Pharma in this situation ? 7

(2) What procedure will be followed to authorized the new drug in US and India simultaneously. 7

Third Semester M. B. A. Examination

PHARMACEUTICAL REGULATORY ENVIRONMENT

Paper – MBA/3506/PH

P. Pages : 4

Time : Three Hours] [Max. Marks : 70

Note : (1) Attempt all questions.
(2) Figures to the right indicate marks.

SECTION A

1. (a) State and explain the rules of import under the Drug and Cosmetic Rule, 1945? 14

OR

(b) State and explain the provisions related to packaging commodity Act. 14

SECTION B

2. (a) State and explain role and functions of DCI and FDA in regulating the pharmaceutical industry. 7

(b) Elaborate the provisions made under the drug and magic remedies Act, 1954 relating of prohibition of advertisement of certain drugs for treatment of certain diseases and disorders. 7

OR

(c) Explain provisions relating to psychotropic and Narcotic substance Act, 1985. 7

(d) Explain the role of government in manufacturing and distribution of control substances in the Narcotic drugs and psychotropic substances Act, 1985. 7

3. (a) Explain the role of WHO for pharmaceutical industry in India. 7

(b) Explain the procedure to register a newly developed molecule of a pharmaceutical company. 7

OR

(c) Explain the role of the medicines and healthcare agencies with suitable example. 7

(d) If a pharmaceutical company wants to register its product in foreign country. What documents are required ? Explain in detail. 7

4. (a) Explain harmonization of guidelines under ICH process. 7

(b) Pharmaceutical company wants to approved its new drug. Explain key stages in drug approval process. 7

OR

(c) Explain in brief the following :-

(i) Trade related intellectual property right. $3\frac{1}{2}$

(ii) USFDA $3\frac{1}{2}$

(d) Elaborate with suitable example. How an European Union and Untied States have different procedures for authorizial medicinal products. 7

SECTION C

5. Reliance Pharma has developed new drug molecule for Dengue. The company has specially