

**P.G. Diploma in Pharmaceutical Regulatory Affairs**  
**Annual Examinations – 2006**  
**Paper PGPRAD – 203**  
**International Licensing**

Time allowed: Three hours

Maximum Marks: 100

**SECTION – I**

Marks

Q1. Attempt all the objective type questions given below

1X20=20

a) Fill in the blanks

- i) ANDA include all the information on Chemistry and manufacturing controls found in a new drug application but does not have to include data from studies in \_\_\_\_\_ and \_\_\_\_\_ studies.
- ii) The guidelines for registration of pharmaceutical product in Ethiopia are made available by \_\_\_\_\_.
- iii) The \_\_\_\_\_ has laid down guidelines regarding registration of drugs and medicines in Nigeria.
- iv) Unless the FDA specifically objects the IND, there is a provision of automatic approval after \_\_\_\_\_ days and clinical trials can be initiated.
- v) The two agencies that assess medicines in New Zealand are \_\_\_\_\_ and \_\_\_\_\_.

b) Multiple choice questions

- i) Module 5 under CTD format deals with
  - a) Physicochemical study report
  - b) Analytical report
  - c) Clinical Study report
  - d) Stability Study report
- ii) In the year 1951 the following came into existence under US Drug law
  - a) Food and drugs Act
  - b) Federal Food, Drug and Cosmetic Act
  - c) Dusham – Humphrey Amendment
  - d) Orphan drug Act
- iii) EMR is
  - a) Exempted marketing rights
  - b) Exclusive marketing rights
  - c) Excellent marketing rights
  - d) Exclusive medicinal rights

- iv) EMEA is
  - a) European marketing evaluation agency
  - b) European medicines environment agency
  - c) European medicinal efficacy agency
  - d) European medicines evaluation agency
  
- v) CPMP is
  - a) Committee for Proprietary Medicinal Products
  - b) Committee for Proprietary Medicinal Plants
  - c) Committee for products of medicinal plants
  - d) Committee for patent medicinal products
  
- e) Name the statutory body that was established in terms of the medicines and related substances control Act, 101 of 1965 to oversee the regulation of medicines in South Africa
- d) Define orphan drugs.
- e) What option the applicants for marketing authorization have while submitting the paper CTD to EMEA.
- f) For what type of drug substances a IND is filed in the US.
- g) The module 3 of CTD format deals with pharmaceutical part. (Answer whether the statement is true or false)
- h) CBER is the agency of EMEA ( Answer whether the statement is true or false)
- i) Name the two countries which have been used as benchmark for prevalence criterion for rare diseases under the European regulation for orphan drugs.
- j) Name the form no. which is used as the first document in module I of CTD format.
- k) What is 'Pre-submission Guidance' under dossier submission to the EMEA?
- l) Name the report which is made available by EMEA as assessment report of the medicinal product by the committee and the reasons for its opinion in favour of granting authorization, after deletion of any information of a commercially confidential nature.

## SECTION – II

Q2. Attempt any six questions in about 150 words

5X6=30

- a) What are the various non-clinical pharmacological and toxicological studies carried out for NDA filing?
- b) Briefly give various categories of drug registration applications in China.
- c) What is Kefauver-Harris Drug Amendments?
- d) What are centralized procedures under EMEA for drug marketing authorization application?
- e) What are the various types of INDs?
- f) What is Para IV filing? Give an account on scientific advice of regulatory bodies?
- g) What is Trans Tasman Therapeutic products Agency?

h) Briefly explain Health Policy and Insurance System of USA.

### SECTION – III

Q3. Attempt any four questions in 500 words each

12.5X4=50

- i) Discuss CTD format for filing drug marketing applications in European Union.
- ii) Discuss the procedure for obtaining drug marketing authorization in Indonesia.
- iii) Discuss the objectives and composition of US FDA.
- iv) Explain drug regulatory affairs system in Australia.
- v) Discuss NDA filing process in U.S. FDA
- vi) Describe the procedure for filing Investigational new drug applications.
- vii) Discuss drug licensing procedures in Nigeria.