No. of Printed Pages : 2

MVE-004

00535

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

Term-End Examination

June, 2011

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Answer **any five** questions. All questions **carry equal** marks.*

1. (a) Describe the role of pharmacy council India in pharmacy education. 5
   (b) Write a short note on Indian Pharmaceutical Industry. 5

2. (a) What are different types of toxicity studies and describe any one type of study in details ? 6
   (b) State the limitation of toxicity studies. 4

3. (a) What are different phases of clinical trial and their importance ? 6
   (b) What is safety criteria for large scale experiments and manufacturing adopted by Genetic engineering approval committee ? 4

4. (a) Outline the procedure for pricing of formulation by NPPA ? 6

(b) What are the functions of Reviews Committee on Genetic Manipulation (RCGM) ? 4

5. (a) Give an outline of clinical studies in paediatric special population with reference to clinical trials. 6

(b) Give the full form of the following (**any four**): 4

(i)	BRCPC	(ii)	ICMR
(iii)	NDA	(iv)	RCGM
(v)	IND	(vi)	CDSCO
(vii)	IDMA		

6. Discuss **any two** : 5x2=10

(a) The Drugs and Magic Remedies act

(b) Drug Consultative Committee

(c) Spurious drugs

7. Write short notes on (**any two**) : 5x2=10

(a) Drugs Technical Advisory Board

(b) Expiry date of Drugs

(c) Single and double blind studies

(d) New Drugs

8. (a) Outline the requirement of labelling of Medicine. 6

(b) Describe different types of Investigational new drugs. 4

No. of Printed Pages : 2

MVE-004

00543

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

Term-End Examination

December, 2011

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*
*(ii) All **carry equal (10** each) marks.*

1. What is pre-clinical evaluation of drugs ? Describe the steps involved. **10**

2. List the two main functions of National Pharmaceutical Pricing Authority (NPPA) and describe the methodology of price fixation of bulk drugs by NPPA. **10**

3. (a) Give the full forms of any five. **5x2=10**

(i) DPCO
(ii) GATT
(iii) AIDS
(iv) CDSCO
(v) GEAC
(vi) DBT
(vii) GCP

(b) Discuss the role of ICMR in biomedical research.

4. Discuss on following in brief *(any two)* : 5x2=10
   (a) Phase II of clinical trial
   (b) Post marketing survellience
   (c) Ethics committee

5. Explain *any four* in brief : 2.5x4=10
   (a) Over the Counter Medicine
   (b) Drugs Technical Advisory Board
   (c) Investigational New Drugs
   (d) New Drug Application
   (e) Special Products

6. Discuss in detail the various techniques adopted for storage of drugs. 10

7. Write short notes on *any two* : 5x2=10
   (a) Poison Act
   (b) Generic drugs
   (c) Informed Consent

8. Write short notes on *any two* : 5x2=10
   (a) Drug consultative committee
   (b) MTP (Medical Termination of Pregnancy)
   (c) Drug price control order

No. of Printed Pages : 2

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT PGDPSM

00995

Term-End Examination

June, 2012

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*
*(ii) All carry **equal (10 each)** marks.*

---

1. (a) List any five conditions of Adulterated drugs as per the Drugs and Cosmetics Act. **5x2=10**

(b) What are the details that should appear on the label of container of drugs ?

2. What are the different phases of clinical trials ? Discuss any one in detail. **10**

3. Write short notes on ***any two*** **5x2=10**

(a) The Drugs and Magic Remedis Act

(b) Narcotic Drugs and Psychotropic Substances Act

(c) Drugs Price Control Order (DPCO)

4. (a) What is the process of approval of vaccines and other biologicals ? **5x2=10**

(b) What are the safety criterias to be complied for large scale experiments and manufacture ?

5. Discuss the functioning of CDSCO and its zonal offices in India. **10**

6. Write short notes on ***any two*** : **5x2=10**
   (a) Animal toxicity studies
   (b) Aims of Pharmacy Act 1948
   (c) Drugs Enquiry Committee.

7. Discuss the role of following government organization in clinical research **10**
   (a) ICMR
   (b) DBT
   (c) DST.

8. Write short notes on ***any four*** : **2.5x4=10**
   (a) New Drug Approval (NDA)
   (b) Spurious Drugs
   (c) Informed Consent
   (d) Investigational New Drug (IND)
   (e) Drug Technical Advisory Board (DTAB).

No. of Printed Pages : **2**

MVE-004

00186

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2012

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*
*(ii) All carry **equal** marks (**10** each).*

1. (a) Give the composition and function of Ethics committee. **6**

(b) Discuss the out look of Indian Pharmaceutical Industry. **4**

2. (a) Describe Pre - clinical evaluation of drugs. **6**

(b) Discuss the role of Drugs Consultative Committee (DCC). **4**

3. (a) State the various activities of Dept. of Science & Technology (DST) **6**

(b) Give the organisational set up and functions of Indian Council of Medical Research (ICMR) **4**

4. (a) Discuss the role of Placebo in clinical trial. **6**

(b) Discuss shelf - life of drug **4**

5. (a) Discuss the genesis of Drug Act, 1940 7

(b) Discuss the functions of NPPA. 3

6. (a) Discuss the objectives and function of Review Committee on Genetic Manipulation (RCGM) 5

(b) Discuss Drug & Magic Remedies Act. 5

7. Write a short notes on *(any Four)* **2.5x4=10**

(a) Poison Act

(b) MTP Act

(c) DPCO

(d) Toilet Preparations

(e) Post Marketing Surveillance (PMS)

(f) Placebo

8. Discuss in detail current status of Pharmaceutical Industry in India. **10**

No. of Printed Pages : 2

MVE-004

00486

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2013

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*
*(ii) All questions carry **equal** marks (**10** each).*

1. (a) Discuss the constitution and function of Drug Technical Advisory Board (DTAB). 6
   (b) Discuss phase - one of clinical - trial. 4

2. (a) Describe the role and responsibilities of Indian Council of Medical Research. 6
   (b) Briefly describe Drug Price Control Order (DPCO) 1995. 4

3. (a) State the objective and function of Central Drugs Standard Control Organisation. 6
   (b) Discuss the importance of Informed consent in clinical trial. 4

4. (a) Discuss the approval procedure of Investigational New Drugs (IND). 7
   (b) Describe shelf life of drugs. 3

5. Discuss the responsibilities of sponsor, regulator, investigator and ethics committee before initiation of clinical trials. 10

6. (a) Briefly state the Medical Termination of Pregnancy (MTP) Act 1971. 5

   (b) Discuss the role of Genetic Engineering Approval Committee (GEAC). 5

7. Write short notes on (*any four*) : 2.5x4=10

   (a) Placebo
   (b) Blindness
   (c) Pharmacy Council of India
   (d) Informed consent
   (e) OTC drugs
   (f) Post Marketing Surveillance (PMS)

8. Discuss in detail, the procedure for pricing of drugs. 10

No. of Printed Pages : **2**

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

00811

Term-End Examination

December, 2013

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*

*(ii) All questions carry **equal** marks (**10** each).*

1. (a) What is the full form of ***any five*** of the following ? **5**

(i) CRAMS

(ii) UNICEF

(iii) DPCO

(iv) NDP

(v) IPA

(vi) IPI

(vii) WHO

(viii) GATT

(b) What are Over the Counter Medicine ? **5**

2. (a) How the retail prices of formulations are calculated ? **5**

(b) List the task performed by Central Drug Standard Control Organization. **5**

3. (a) What are the Phase III Clinical trial ? 5

(b) What is Placebo ? 5

4. Discuss *any two* in brief : 5x2=10

(a) Preclinical evaluation of Drugs.

(b) Informed consent.

(c) Post Marketing Surveilence Study.

5. (a) What are special products ? 5

(b) What is the process of approval of Vaccines and biologicals ? 5

6. Explain *any two* in brief : 5x2=10

(a) Investigational New Drugs.

(b) New Drug Approval Process.

(c) Rules of Drugs & Cosmetics Act.

(d) Bulk Drug.

7. Write short notes on *any two :* 5x2=10

(a) Pharmacy Act 1948.

(b) Spurious drugs.

(c) Drug Consultative Committee (DCC).

8. (a) Discuss the requirement of Labelling and Packaging of Medicines in Drugs and Cosmetics Act. 5

(b) What is 'Narcotic Drugs and Psychotropic Substances' Act (NDPS) ? 5

No. of Printed Pages : 2

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

00314

Term-End Examination

June, 2014

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Answer any* ***five*** *questions. All questions carry equal marks.*

1. (a) Discuss in detail the various techniques adopted for storage of drugs. 5

(b) What do you understand by Regulatory Authority ? 5

2. (a) Give full forms of any ***five*** : 5

(i) OTC

(ii) TRIPS

(iii) GATT

(iv) DGTD

(v) DPCO

(vi) CRAMS

(vii) IPA

(b) Tabulate the various phases of evolution of Indian Pharma Industry. 5

3. Describe the procedure for pricing of formulations. Give the functions of National Pharmaceutical Pricing Authority. *10*

4. (a) Discuss the different types of Toxicity Studies. *5*

   (b) What are the requirements and guidelines on clinical trials for import and manufacture of a new drug ? *5*

5. Discuss any ***two*** in brief : *5×2=10*

   (a) Approval process for Vaccines and Biologicals

   (b) Studies in Special Populations

   (c) Preclinical evaluation of Drugs

6. Define "Drug" and explain adulterated, misbranded and spurious drugs. *10*

7. Explain any ***two*** in brief : *5×2=10*

   (a) New Drugs

   (b) Formulations

   (c) Drug Approval Process

   (d) Rules of Drugs and Cosmetics Act

8. Write short notes on any ***two*** : *5×2=10*

   (a) Expiry dates and Expiration dating

   (b) Drugs Technical Advisory Board (DTAB)

   (c) Labelling and Packing of Medicines

   (d) Poison Act

No. of Printed Pages : 2

MVE-005

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

00154 **Term-End Examination**

June, 2014

MVE-005 : INTRODUCTION TO MANAGEMENT

Time : 3 hours *Maximum Marks : 75*

Note : *Attempt any **five** questions. All questions carry equal marks.*

1. (a) Describe briefly the tasks of the Top Manager in terms of meeting the challenge of increasing competition and managing innovation. *8*

(b) What steps are required to postpone managerial obsolescence ? *7*

2. How are interpersonal skills developed ? Describe using the Johari Awareness Model of Interpersonal process. *15*

3. What do you understand by 'Leading Skills' ? Explain these skills. *15*

4. (a) What are the steps required in formulating 'PLAN' of an organisation ? Explain. *8*

(b) Discuss the decision making under certainty and decision making under uncertainty. *7*

5. (a) What is Managerial Ethos ? Describe its characteristics. *8*

(b) "A manager gets more strain by stress than by work." Discuss. *7*

6. (a) Describe the three-phase model in decision-making. *8*

(b) What are the Manpower demand forecasting techniques used at the macro level ? Explain. *7*

7. (a) Discuss the process which is essential for executive development. *8*

(b) What do you understand by group dynamics ? How is a group formed ? Explain. *7*

8. Write short notes on any ***two*** of the following : $7\frac{1}{2}\times 2=15$

(a) Difference between Training and Development

(b) McGregor's X and Y Theories

(c) Steps to manage stress

(d) Functions of First Level Manager of the organisation

No. of Printed Pages : 3

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

00274

Term-End Examination

December, 2014

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Attempt any **five** questions.*

1. (a) What are the functions of the Review Committee on Genetic manipulation ? *6*

(b) Describe the evolution of Indian Pharmaceutical Industry. *4*

2. (a) Why is the task-force formulated for DOBT ? Name any three task-forces of DOBT. *4*

(b) Discuss the procedure for fixing the Pricing of Formulations by NPPA. *6*

3. (a) What do you mean by LD 50 ? Give the procedure for obtaining permission to start a clinical trial. *6*

(b) Write down the essential composition of an ethics committee. *4*

4. (a) Give the full form of any ***four*** of the following : *4*

(i) RDAC

(ii) ICMR

(iii) IBSC

(iv) GEAC

(v) DLC

(vi) SBCC

(vii) VRBPAC

(b) What is the process of approval of vaccines or other biologicals ? *6*

5. (a) Give an overview of drug approval process. *4*

(b) What is the mandatory information that is supposed to be provided when filing the New Drug Application ? *6*

6. (a) Discuss the constitution of Pharmacy Council of India. *6*

(b) Discuss the Genesis of Drugs in 1940. *4*

7. (a) What are the factors affecting the potency of drugs during storage ? *5*

(b) Discuss the labelling and packaging of medicines under Drugs and Cosmetics Acts and Rules. *5*

8. Write short notes on any ***two*** of the following : *2×5=10*

(a) Narcotic Drugs and Psychotropic Substances (NDPS) Act

(b) Drugs and Magic Remedies Act

(c) Drugs Prices Control Order

No. of Printed Pages : **2**

MVE-004

(0045)

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2015

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Attempt **any five** questions.*

1. (a) Discuss the current status of pharmaceutical industry. 5
   (b) What were the changes and reforms in pharma industry after 1995 ? Explain any one in brief. 5

2. (a) Write any five functions of National Pharmaceutical Pricing Authority. 5
   (b) Give the procedure for fixing the pricing of formulations. 5

3. (a) Describe the 'sources of drug' step followed during the preclinical evaluation of drugs. 6
   (b) What is meant by blindness in clinical trial ? Describe in brief its two types. 4

4. (a) Discuss the regulations applicable to the biologicals produced by rDNA technology. 5
   (b) What are the rules that govern approval and prohibitions of novel diagnostic agents ? 5

5. (a) Give the full form of the following : **(Any four)** 4

   (i) NDA

   (ii) GEAC

   (iii) DLC

   (iv) SBCC

   (v) RDAC

   (b) Give an overview of new drug approval process. 6

6. (a) What are the aims of Pharmacy Act 1948 ? 5

   (b) Describe the 'Education Regulations' of Pharmacy Council of India. 5

7. Write short notes on (**any two**) of the following : 10

   (a) Storage of medicines in cold conditions

   (b) Shelf life

   (c) Modern trends in labelling of medicines

8. (a) Discuss the Medicinal and Toilet Preparations Act 1995. 5

   (b) What is the Medical Termination of Pregnancy (MTP) Act ? Give any three reasons for MTP. 5

No. of Printed Pages : 2

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2015

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*

*(ii) **All** questions carry **equal** marks.*

1. (a) Give the full forms of **any five** : **5**

(i) UNISEF

(ii) DPCO

(iii) TRIPS

(iv) GATT

(v) IPA

(vi) CRAMS

(vii) OTC

(b) What are the major sectors of Indian pharmaceutical industry ? **5**

2. (a) What do you understand by the Regulatory authorities ? **5**

(b) Discuss the different functions of National Pharmaceutical Pricing Authority (NPPA). **5**

3. (a) What is preclinical evaluation of drugs ? **5**

(b) (i) What is acute toxicity study ? **2.5**

(ii) What is placebo ? **2.5**

4. Discuss in brief : **5x2=10**

(a) What is the process of approval of vaccines ?

(b) What are the composition of Institutional Bio-Safety Committee (IBSC) ?

5. Explain **any one** in detail : **10**

(a) What is the mandatory information that is supposed to be provided when filing the Investigational New Drug Application ?

(b) Discuss the Requirement of permission to import and manufacture fixed dose combinations.

6. (a) Discuss the constitution of Pharmacy Council of India. **5**

(b) Discuss the Pharmacy Act. **5**

7. (a) What is Drug Technical Advisory Board (DTAB) ? Give its Constitution. **5**

(b) What are the powers of Drug Inspectors as per Drugs and Cosmetics Act ? **5**

8. Explain **any two** : **5x2=10**

(a) What are drugs and magic Remedies Act ?

(b) What are the Poison Act, 1919 ?

(c) What is medicinal and toilet preparation (Excise duty) act ?

No. of Printed Pages : 2

MVE-004

00718

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2016

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer any five questions.*

(ii) All questions carry equal marks.

1. (a) Give the full forms of any five : **1x5=5**

(i) DGTD
(ii) IPI
(iii) NDP
(iv) OTC
(v) CRAMS
(vi) IPA
(vii) UNISEF

(b) What are Over the Counter Medicines ? **5**

2. (a) Give an overview of the governing body of the Indian Council of Medical Research (ICMR). **5**

(b) Discuss the role and responsibility of CDSCO. **5**

3. (a) What is carcinogenicity and teratogenicity ? **5**

(b) (i) What is acute toxicity study ? **2.5**

(ii) Define informed consent. **2.5**

4. Discuss **any two** in brief : **5x2=10**
   (a) What is the process of approval of vaccines ?
   (b) Discuss the role and constitution of State Biotechnology Co-ordination Committee (SBCC).
   (c) Discuss the structure of IBSC committee.

5. Explain **any one** in detail : **10**
   (a) What are the different phases of clinical trials and what is their importance ?
   (b) Give the functions of National Pharmaceutical Pricing Authority.

6. (a) Discuss various drugs legislations during the British Rule. **5**
   (b) Discuss the genesis of drugs act 1940. **5**

7. (a) Discuss the salient features of adulterated drugs. **5**
   (b) Discuss the various storage conditions of medicines. **5**

8. Explain **any two** : **5x2=10**
   (a) Narcotic Drugs and Psychotropic Substances (NDPS) Act.
   (b) Medical Termination of Pregnancy (MTP) Act, 1971.
   (c) Drug Price Control Order.

No. of Printed Pages : 2

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2016

(00014)

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Attempt **any five** questions.*

1. (a) What do you mean by generic and OTC product ? Describe in brief. 5

(b) Write the different phases involved in evolution of Indian pharmaceutical Industries, indicate in tabular form. 5

2. (a) Describe the different tasks performed by CDSCO. Enlist the major responsibilities of Dept. of Science and Technology (DST). 5

(b) What does MAPE stands for ? How are the retail prices of formulations calculated ? 5

3. (a) What are the different phases in clinical evaluation of a drug in human beings ? Describe phase III clinical trial in brief. 5

(b) Define **any two** : 5

(i) Informed consent

(ii) Placebo

(iii) Ethics committee

4. (a) What are the processes of approval of vaccines and other biologicals ? 6

(b) Write the full forms and functions of following committee. (**Any two**) : 4

(i) GEAC
(ii) RDAC
(iii) IBSC
(iv) CBER

5. (a) What are functions of DTAB and DCC ? 5

(b) Define misbranded, adulterated and spurious drugs. 5

6. (a) What do you understand by expiry date of a Drug ? 5

(b) Define the terms "Drug" and "cosmetics". 5

7. (a) What are the details to be shown on the label of a medicine ? 5

(b) Discuss the different factors affecting the potency of drug during storage. 5

8. Write short note on **any two** of the followings : 2x5=10

(a) Medical Termination of Pregnancy Act.
(b) Drugs and Magic Remedies Act.
(c) Drug prices control order.
(d) Paison Act.

No. of Printed Pages : 2

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

00883

Term-End Examination

June, 2017

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : Attempt any five questions.

1. (a) Discuss the present scenario of Indian Pharmaceutical Industry. 5
   (b) What are over the counter (OTC) medicines ? 3
   (c) Write the full forms of **any two** of the following : 2
   (i) GATT (ii) DPCO
   (iii) DST (iv) ICMR

2. (a) Describe the role of National Pharmaceutical Pricing Authority (NPPA) in price fixation of bulk drug and formulation. 5
   (b) What does MAPE stands for ? How is the retail price of formulation calculated ? 5

3. (a) What are the different types of toxicity studies ? Describe acute toxicity study in brief. 4
   (b) What is meant by therapeutic confirmatory trial ? 3
   (c) Describe briefly Post Marketing Surveillance (PMS). 3

4. (a) Describe the function of the Review Committee on Genetic Manipulation (RCGM). 5

(b) What are the general regulations applicable for biologicals ? 5

5. (a) Give an overview of new drug approval process with the help of a flow diagram. 5

(b) What are different categories of filling an Investigational New Drug application ? 5

6. (a) Briefly mention the genesis of modern medicine system in India. 5

(b) Discuss the Constitution of Pharmacy Council of India. 5

7. (a) Write about the various storage conditions of drug and discuss how the potency of drug may be affected by storage condition ? 5

(b) What are the details that should appear on the label of a container of drug ? 5

8. Write the short notes on **any two** of following : **2x5=10**

(a) Medical Termination of Pregnancy Act.

(b) Narcotic Drugs and Psychotropic Substances (NDPS) Act.

(c) The Medical and Toilet Preparation Act.

(d) The Poisons Act.

No. of Printed Pages : **2**

MVE-004

00783

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2017

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : (i) Answer any five questions.

(ii) All question carry equal marks.

1. (a) Give the full form of **any five** : **1x5=5**

(i) DPCO **(ii)** TRIPS

(iii) IPA **(iv)** FDA

(v) ICAR **(vi)** DST

(vii) RDAC

(b) Describe the **phase wise evolution of Indian Pharmaceutical Industry.** **5**

2. (a) Write the **constitution and function of Genetic Engineering Approval Committee (GEAC).** **5**

(b) What are the **FDA requirements for manufacturing of vaccines ?** **5**

3. (a) What are the **different types of toxicity studies ? Describe any one type.** **5**

(b) Name the **four phases of Clinical trials. Briefly describe any one phase.** **5**

4. Write short notes on **any two** : **5x2=10**

   (a) Drugs Consultative Committee

   (b) Shelf life of drugs

   (c) Misbranded drugs

5. Discuss in detail 'Drug and Cosmetic Act '1940. **10**

6. Write short notes on **any four** : **2.5x4=10**

   (a) Informed Consent

   (b) Teratogenicity

   (c) Post-marketing Surveillance

   (d) Adulterated drugs

   (e) Cell hybridization

7. (a) What are the factors affecting the potency of drugs during storage ? Describe briefly. 5

   (b) Describe the responsibilities of Ethics Committee. 5

8. (a) What is Poison Act, 1919 ? Write the power of State government for Sale of Poisons. 5

   (b) Give the functions of National Pharamaceutical Pricing Authority (NPPA). 5

No. of Printed Pages : 2

MVE-004

00528

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

June, 2018

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *(i) Answer **any five** questions.*

*(ii) **All** question carry **equal** marks.*

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1. (a) Give the full form of **any five** : 1x5=5

(i) NPPA (ii) DGTD

(iii) BRCPC (iv) ICMR

(v) IPI (vi) RDAC

(vii) CDSCO

(b) Give a brief summary on evoluation of Indian pharmaceutical industry. 5

2. (a) What are the functions of review Committee on genetic manipulation ? 5

(b) What is the process of approval of vaccines and other biologicals ? 5

3. (a) Give an overview on new drug approval process. 5

(b) Describe Shelf life of drugs. 5

4. (a) Discuss the history of pharmaceutical legislation in India. 5

(b) Describe the role of drugs enquiry Committee. 5

5. Write short notes on **any four** : 2.5x4=10

(a) Carcinogenicity

(b) Drug Technical Advisory Board (DTAB)

(c) Therapeutic Confirmatory trials

(d) Acute Toxicity Study

(e) Mis-branded drugs

(f) OTC drugs

6. Discuss **any two** : 5x2=10

(a) Narcotic Drugs and Psychotropic Substance (NDPS) Act.

(b) Drug Price Control Order, 1995.

(c) The Medical Termination of Pregnancy (MTP) Act, 1971.

7. (a) What is Pharmacy Council of India. Give its functions ? 5

(b) State the responsibilities of Department of Science and Technology (DST). 5

8. (a) What are salient features of adulterated drug and spurious drugs ? 5

(b) Discuss the various storage condition prescribed by Indian pharmaceutical manufacturers. 5

No. of Printed Pages : 2

MVE-004

00022

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2018

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

Note : *Attempt any five questions.*

1. (a) Give an account on the reforms and institutional changes post 1995 period and write down the phases of evolution of Indian Pharma Industry. 5

   (b) Write short note on **any two** of the following : 5
   (i) OTC
   (ii) Indian Pharmaceutical Industry
   (iii) DST

2. (a) Describe the role and responsibilities of Indian Council of Medical Research (ICMR). 5

   (b) Discuss the functioning of CDSCO and its Zonal offices in India. 5

3. (a) What are the different types of toxicity studies and describe any one type of study in details. 5

   (b) What are the different phases of clinical trial ? Discuss their importance. 5

4. (a) What are the function of Reviews Committee on Genetic Manipulation (RCGM) ? 5

(b) Discuss the role of Genetic Engineering Approval Committee (GEAC). 5

5. (a) Discuss Rules of Drugs and Cosmetics Act. 5

(b) Write short note on **any one** of the following : 5

(i) Investigational new drug application (IND)

(ii) New Drug Application (NDA)

6. (a) Describe the role of Pharmacy Council of India in Pharmacy education. 5

(b) Discuss History of Pharmaceutical Legislation in India. 5

7. (a) Write the details that appear on the label of container of drugs. 5

(b) List any five conditions of Adulterated drugs as per the Drugs and Cosmetics Act. 5

8. (a) Describe in detail about Narcotics Drugs and Psychotropic Substance (NDPS) Act. 5

(b) Write short note on **any two** of the following : 5

(i) MTP

(ii) Drug Price Control Order

(iii) Poisons Act

00894

No. of Printed Pages : 3

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT

(PGDPSM)

Term-End Examination, 2019

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 Hours] **[Maximum Marks : 50**

Note : Attempt **any five** questions.

1. (a) Discuss the constitution and function of Drug Technical Advisory Board (DTAB). [5]

   (b) What is clinical trial ? Discuss Phase-one of clinical trial. [5]

2. (a) Write short notes on **any two** : [5]

   (i) The Drugs and Magic Remedies Act.

   (ii) Narcotic Drugs and Psychotropic Substance Act.

   (iii) Drug and Price Control Order (DPCO)

(b) Briefly state the Medical Termination of Pregnancy (MTP) Act, 1971. [5]

3. (a) What is the process of approval of vaccines and other biologicals ? [5]

(b) What are the safety criterias to be complied for large scale experiments and manufacture ? [5]

4. Write short notes on **any two** : [5+5=10]

(a) Animal Toxicity Studies.

(b) Pharmacy Act, 1948.

(c) Drug Enquiry Committee.

5. (a) Discuss in detail the procedure for pricing of drug. [5]

(b) State the objective and functions of Central Drugs Standard Control Organisation. [5]

6. (a) Write notes on **any two** : [5]

(i) Spurious Drugs

(ii) Expiry Date of Drugs

(iii) New Drugs

(b) Give an overview of the governing body of ICMR.

7. (a) What are the functions of Recombinant DNA Advisor Committee (RDAC) ? [5]

(b) Discuss the different factors affecting the potency of drug during storage. [5]

8. (a) What are the functions of DTAB ? [5]

(b) Write short notes on **any two** : [5]

(i) Placebo

(ii) Blindness

(iii) Post marketing surveillance (PMS)

(iv) Informed consent

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No. of Printed Pages : 1

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2019

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 hours *Maximum Marks : 50*

*Note : (i) Answer **any five** questions.*

*(ii) **All questions carry equal** marks.*

1. (a) Describe briefly "Over-The-Counter Medicines". 5
   (b) Explain briefly the Historical background of Indian Pharmaceutical Industry. 5

2. (a) Write the functions of National Pharmaceutical Pricing Authority (NPPA). 5
   (b) What are different phases of clinical trial ? Describe any one of them briefly. 5

3. (a) What is the process of approval of vaccines and other biologicals ? 5
   (b) What is the essential composition of an ethics committee ? 5

4. Explain **any four** of the following : 4x2.5=10
   (a) Formulation
   (b) Bulk Drug
   (c) New Drug
   (d) Investigational New Drug
   (e) Vaccines

5. (a) Give the Process of New Drug approval ? 5
   (b) Describe acute and chronic toxicity studies. 5

6. (a) Discuss the Constitution of Pharmacy Council of India. 5
   (b) Write the genesis of Drug Act, 1940. 5

7. Write short notes on **any two** : 2x5=10
   (a) Adulterated Drugs
   (b) Drugs Technical Advisory Board
   (c) Poison Act

8. (a) Write Investigative Procedures of NDPS. 5
   (b) Discuss the term of Ceiling and Non-Ceiling prices. 5

No. of Printed Pages : 2

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT(PGDPSM)

Term-End Examination

MVE-004 : DRUGS REGULATORY AFFAIRS

Time : 2 Hours] *[Maximum Marks : 50*

Note: Answer any five questions.

All questions carry equal marks

1. (a) Write the Historical Evolution of Indian Pharma Industry. 5
   (b) Discuss the confirmatory clinical trial phase III. 5
2. (a) Give the major responsibilities of department of Science and Technology (DST). 5
   (b) Write the main function of Department of Biotechnology (DBT). 5
3. (a) Explain the special population studies on Pediatrics. 5
   (b) Discuss the Responsibilities of the Ethics committee. 5
4 (a) Give the full form of any five of following: 1x5=5

i	DLC	ii	RCGM
iii	IBSC	iv	SBCC

v GEAC vi RDAC

vii ICMR

(b) What is the composition of the committee of Genetic Engineering Approval Committee (GEAC)? 5

5. Explain any four of the following: 2.5x4=10

(a) Misbranded drugs

(b) Schedule y

(c) Bulk Drug

(d) Formulation

(e) Bulk drug

6. (a Discuss the aims of Pharmacy act 1948. 5

(b) Give the Genesis of modern medicine and pharmacy. 5

7. (a) What are directions given under Drugs and Cosmetics act for labeling packaging requirement? 5

(b) What are the factors affecting the portending and storage condition of the drugs? 5

8. Write short notes on any two of the following:5x2=10

(a) Narcotic Drugs and Psychotropic Substances act (NDPS).

(b) (MTP) Medical Termination of Pregnancy Act 1971.

(c) "The drugs and magic remedies act."

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No. of Printed Pages : 4

MVE-004

POST GRADUATE DIPLOMA IN PHARMACEUTICAL SALES MANAGEMENT (PGDPSM)

Term-End Examination

December, 2020

MVE-004 : DRUG REGULATORY AFFAIRS

Time : 2 Hours *Maximum Marks : 50*

Note **:** (*i*) *Answer any* ***five*** *questions.*

(*ii*) *All questions carry equal marks.*

1. (a) Give the full form of any ***five*** of the following : 1 each

(i) CSIR

(ii) UNICEF

(iii) DPCO

(iv) COSCO

(v) GCP

(vi) DST

(vii) IBSC

(b) Write the details about Dynamics of Indian Pharmaceutical Industry. 5

2. (a) Define NPPA and write any ***four*** functions of NPPA. 5

(b) What are the types of toxicity studies ? Explain any *one* type. 5

3. (a) List the phases of clinical trials and describe any ***one***. 5

(b) Describe the Informed Consent in the context of ethics committee. 5

4. (a) Explain any ***five*** of the following in one or two sentences each : 1 each

(i) Geriatrics

(ii) Haematology

(iii) Pathogens

(iv) Oxytocin

(v) London proof spirit

(vi) Mis-branded drugs

(b) What are the rules under government notification on approval and prohibition of novel diagnositic agents ? 5

5. Write short notes on any ***two*** of the following : 5×2=10

(i) Drug Technical Adivisory Board (DTAB)

(ii) OTC drugs

(iii) Therapeutic confirmatory trials

(iv) Labelling and packaging of medicines

6. Discuss any ***two*** of the following : 5×2=10

(a) Factors affecting the potency of drug during storage

(b) Responsibilities of investigator of Ethics Committee

(c) Role of drugs enquiry committee

7. (a) What is the significance of "Chopra Committee" in the history of pharmaceutical legislation in India. 5

(b) Give any ***five*** powers of the state government for sale of poisons. 5

8. Describe the following : 5 each

(a) Drug prices control order

(b) Narcotic Drugs and Psychotropic Substances (NDPS) Act