

**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*

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

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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

**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*

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

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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
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