70

SVKM'S NMIMS

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Programme: B. Pharm / B. Pharm + MBA
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Subject: Pharmacovigilance

Year: IV

Semester: VII
Marks: 70
Time: 2.00 pm to 5.00 pm
Duration: 3 hrs.
No. of Pages : 02

Date: 06 December 2019

FINAL EXAMINATION

Instructions: Candidates should read carefully the instructions printed on the question paper and on the cover of the Answer Book, which is provided for their use.

1) Question No. 1 is compulsory.
2) Out of remaining questions, attempt any four questions.
3) **In all five questions to be attempted.**
4) All questions carry equal marks.
5) **Answer to each new question to be started on a fresh page.**
6) **Figures in brackets on the right hand side indicate full marks.**
7) **Assume suitable data if necessary.**

SECTION A

Q. 1 (14)

a) Fill in the blanks
   i. _____ is involved in harmonising existing guidelines from EU, USA and Japan related to development and registration of medicines.
   ii. VAERS is a national system for passive surveillance of adverse events following _____.

b) Answer the following
   i. Enlist any four partners in pharmacovigilance.
   ii. Enlist any two criteria for a valid ADR report.

c) Expand the following acronyms.
   i. AEFI
   ii. MedDRA

d) Give two examples of :
   i. Type A adverse drug reaction
   ii. International organizations involved in Pharmacovigilance

e) Choose the correct option
   i. This incorporates tools for report analysis, and facilitates sending reports to VigiBase
      a. Vigisearch
      b. Vigiflow
      c. Vigimed
      d. All of the above

1/2

ii . Identify the pregnancy category A drug from the following

a. Metformin b. Folic acid

c. Losartan d. Gabapentin

f) Explain the terms:

i. Registries ii. Pharmacoepidemiology

g) Match the following

i. Thalidomide	a. Sweden
ii. Indian pharmacopoeia commission.	b. Torsade de pointes
iii. UMC	c. NCC
iv. Terfenadine	d. Phocomelia

SECTION B

Q.2

a) Discuss special issues in reporting to Pharmacovigilance centers. (7)

b) Mention different scales for causality assessment. Describe WHO-UMC Causality assessment scale. (7)

Q.3

a) Write a note on development of Pharmacovigilance program in India and also explain the ADR data flow in PvPi. (7)

b) What are the different methods of Pharmacovigilance? Explain comparative observational studies and Stimulated reporting. (7)

Q.4

a) Write a note staff requirement for National Pharmacovigilance center. (7)

b) Write a note on WHO Pharmacovigilance program for global monitoring. (7)

Q.5

a) Write a note on reporting of adverse drug reactions to Pharmacovigilance center. (7)

b) Write a note on aims and scope of Pharmacovigilance. (7)

Q.6

a) Discuss practicalities in the organization of a pharmacovigilance center. (7)

b) Write a note on tools used in Pharmacovigilance and limitations of Pharmacovigilance. (7)

Q.7 Write short notes on (any four) (4x3.5=14)

a) Causality assessment of a drug

b) Use of drugs during lactation

c) Types of data available for safety of a medicine

d) Challenges in Pharmacovigilance of Herbal medicine

e) Future measures to strengthen regulations
