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Roll No

BP-804T(B)/PY-804 (B)-CBGS

**B.Pharmacy VIII Semester (PCI Scheme)/
(Non-PCI Scheme)**

Examination, June 2020

Choice Based Grading System (CBGS)

Pharmacovigilance

Time : Three Hours

Maximum Marks : 75

Note: i) Attempt any five questions.

ii) All questions carry equal marks.

1. Explain in detail about history and development of Pharmacovigilance with special reference to Pharmacovigilance Program of India (PvPI).
2. Enumerate the different types of information resources available in Pharmacovigilance with Drug Dictionaries and coding used in Pharmacovigilance.
3. What is Vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance.
4. What is the organization and objective of ICH guidelines in Pharmacovigilance? Explain in detail good clinical practices in Pharmacovigilance studies.

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5. Explain in detail different Pharmacovigilance evaluation methods used for drug safety in special populations.
6. Define and classify Adverse Drug Reaction (ADRs) with methods used for causality assessment of ADRs.
7. Explain in detail methods used for effective communication in Pharmacovigilance with special reference with regulatory agencies.
8. Write short notes on (any two).
 - a) CIOMS
 - b) CDSCO and Pharmacovigilance
 - c) MedDRA

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