



Term Examination

M.M-70

- 1) This question paper contains 10 printed sides and has two sections.
- 2) Please ensure that your paper has both the sections.
- 3) Attempt all questions on this paper and return it to the invigilator at the end of the exam.

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Signature of Invigilator _____

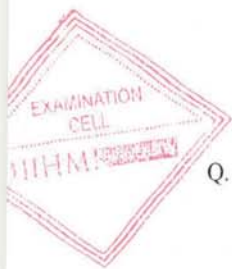
Signature of Examiner _____

Section-A

All questions are compulsory. Each question carries 1.5 marks



- Q. 1. Indian Partnership Act came into:
a) 1942
b) 1932
c) 1948
d) 1949 ()
- Q. 2. Sale of Goods Act shall not apply to:
a) Any contract relating to immovable property
b) Contract of work and skill
c) Patented goods
d) Both a & b ()
- Q. 3. For innovator products proof of _____,
and _____ is needed.
- Q. 4. In a broad sense harmonization means:
a) Harmonization of technical requirements for medicines regulation
b) Harmonization of technical requirements for pharmaceutical operations regulation
c) Harmonization of technical requirements for marketing regulation
d) Harmonization of technical requirements for manufacturing regulation ()
- Q. 5. NMRAs stand for:
a) National Manufacturing Regulatory Authorities
b) National Marketing Regulatory Authorities
c) National Medicines Regulatory Authorities
d) None of above ()
- Q. 6. Agreement to all terms of an offer by words or conduct is known as:
a) Agreement
b) Consideration
c) Acceptance
d) None of above ()
- Q. 7. ICH quality topics include _____ (except one):
a) Q1A-F Stability
b) Q2 Validation: Analytical Procedures
c) Q11 Development and manufacturing of Substances
d) Q4a Microbiological studies ()
- Q. 8. MedDRA is a rich and highly specific standardized _____.



- Q. 9. Focus more on providing the guidelines for toxicity tests and carcinogenicity studies:
- a) Quality topics
 - b) Safety topics
 - c) Efficacy topics
 - d) Multidisciplinary topics
- ()
- Q. 10. Quality Risk Management is:
- a) Q9
 - b) Q10
 - c) Q11
 - d) Q7
- ()
- Q. 11. Efficacy () - related to clinical research in human subjects:
- a) 15 guidelines
 - b) 18 guidelines
 - c) 16 guidelines
 - d) 12 guidelines
- ()
- Q. 12. Consensus build upon
- a) Five parties
 - b) Six parties
 - c) Seven parties
 - d) Four parties
- ()
- Q. 13. Development and manufacture of drug substance pertaining to ICH guideline:
- a) Q10
 - b) Q11
 - c) Q6A
 - d) Q5A
- ()
- Q. 14. Toxicity testing pertaining to ICH guideline:
- a) S6
 - b) S7A
 - c) S4
 - d) S5
- ()
- Q. 15. Validation of Analytical methods is mention under ICH as:
- a) Q2D
 - b) Q2A
 - c) Q2C
 - d) None of the above
- ()

Q. 16. EMEA communicate question on the marketing application to the sponsor by:

- a) 180 days
- b) 190 days
- c) 120 days
- d) 160 days

()

Q. 17. Reference Standard Information includes:

- a) Method of characterization
- b) Method of stability testing
- c) Method of preparation
- d) Both a & c

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Q. 18. _____ is the ability of the procedure to provide analytical results of acceptable accuracy and precision under a variety of conditions.

- a) Robustness
- b) Linearity and range
- c) Accuracy
- d) Precision

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Q. 19. Methods used for the examination of pharmaceutical material may be broadly classified as follows:

- a) Methods used to determine quantitatively the conc. of bulk drug or major ingredient in finished dosage form.
- b) Methods used to determine impurities in finished dosage form.
- c) Methods used to determine physical of in finished dosage form.
- d) Methods used to determine chemical properties of in finished dosage form. ()

Q. 20. The _____ is the process which establishes documented evidence.

- a) Data validation
- b) Analytical validation
- c) Process validation
- d) Qualitative validation

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Q. 21. _____ and _____ is vital importance to manufacturer.

- a) Documentation and standardization
- b) Quality and consistency
- c) QC and QA
- d) Research and development

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Q. 22. Comparison of results obtained by different analysts, by different equipment or carrying out the analysis at different times.

- a) Reproducibility
- b) Repeatability
- c) Robustness



d) Accuracy

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Q. 23. Quality of Pharmaceutical products certified by WHO as:

- a) WHO certificate of analysis
- b) WHO certificate of pharmaceutical products
- c) WHO certificate of GMP
- d) Who certificate of CGMP

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Q. 24. Power to suspend or revoke manufacturer's licenses:

- a) DACA
- b) SA Pharmacy council
- c) MCC
- d) WHO

Q. 25. SMF containing information about _____

- a) Drug standardization process
- b) Manufacturing and distribution process
- c) Manufacturing and marketing process
- d) Manufacturing and control process

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Q. 26. Active ingredient present in the form of salts or hydrates shall be described quantitatively by their:

- a) Total mass
- b) RH of moiety
- c) Volume of moiety
- d) Gravity of moiety

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Q. 27. The requirements for NDA registration need (except one):

- a) Animal pharmacology
- b) Clinical studies
- c) In-vivo studies
- d) In-vitro studies

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Q. 28. Pharmacokinetics investigation should make separate provision for:

- a) Double dose administration
- b) Single dose administration
- c) Quarter dose administration
- d) All of the above

()

Q. 29. There are more than _____ registered herbal medicines in Cambodia

- a) 38
- b) 48
- c) 58
- d) 28

()

Q. 30. ACTD III module contain:

- a) Non clinical data
- b) Clinical data
- c) Quality data
- d) Admin data





Q. 2. As you know documentation in Pharmaceutical operations is important part, discuss in detail about documentation management in Pharmaceuticals?

Ans.

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