LIITHMR UNIVERSITY

Institute of Health Management Research

MBA Pharmaceutical Management

Batch-08th (2016-2018) First Year

Regulatory Environment for Pharma Business

Term Examination

EXAMINATION CELL IIHMR UNIVERSITY

Time - 2 Hours M.M.-70

Roll Number				
Batch	
Stream	
Date	d	d	m	m	y	y
Day	

Signature of Invigilator _____

Marks obtained

Signature of Examiner _____

Note: **1.** Term Paper includes section A and B. Ensure there should be 9 pages (both-side)
2. Section A contains 30 questions each carries equal 1.5 marks (Attempt all questions in Section-A)
3. Overwriting and tick marks are not allowed, mention your answer in given bracket.

(Section-A)

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) Q2Validation: 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 ( )

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 ( )

Q. 19. Methods used for the examination of pharmaceutical material may be broadly classified as follows:
a) Methods used to determined quantitatively the conc. of bulk drug or major ingredient in finished dosage form.
b) Methods used to determined impurities in finished dosage form.
c) Methods used to determined physical of in finished dosage form.
d) Methods used to determined 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 ( )

Q. 21. _____ and _____ is vital importance to manufacturer.
a) Documentation and standardization
b) Quality and consistency
c) QC and QA
d) Research and development ( )

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 ( )

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 ( )

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 ( )

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 ( )

Q. 27. The requirements for NDA registration need (except one):
a) Animal pharmacology
b) Clinical studies
c) In-vivo studies
d) In-vitro studies ( )

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 ( )

(Section-B)

Attempt any two question, each carry equal 12.5 marks.

Q. 1. If company x pharmaceutical wants to make changes in (Manufacturing site, labelling etc.) regarding ANDA approved drug for oncology purpose in US than what are the procedures they must follow for getting marketing approval?

Ans.

Q. 2. As you know documentation in Pharmaceutical operations is important part, discuss in detail and also elaborate validation process in Pharmaceuticals?

Ans.

Q. 3. Write short notes on: (any 3)

a) SUPAC
b) DMF
c) IND
d) Regulatory pertaining to biosimilar

Ans.