**FINAL YEAR UNIVERSITY EXAMINATION 2019-2020**
**Final Year B.Pharm. Semester VIII**
**Pharmaceutical Regulatory Affairs**
**MULTIPLE CHOICE QUESTIONS: PRACTICE QUESTION BANK**

1. Select the responsibility/s of RA personnel
    a. To analyze the content of the active ingredient in the formulation
    b. Work with federal, state and local governing agencies to get the approval for drug
    c. To undertake stability studies of the drug products
    d. To supervise the production of the formulation
2. Central drug Testing Laboratory is located at _____
    a. Kasauli
    b. Delhi
    c. Bangalore
    d. Lucknow
3. List of approved drugs and their associated IPR is available in _____
    a. Pink book
    b. Orange book
    c. Red book
    d. Black book
4. Identify the relevant regulatory body in USFDA for approval of drugs.
    a. BLA
    b. IND
    c. CBER
    d. CDER
5. To submit a BLA, applicants are required to submit a Form FDA 356h to …… regulatory body
    a. CDER
    b. CBER
    c. CDSCO
    d. MHRA
6. Change in process from dry granulation to wet granulation is which type of variation as per US regulation
    a. Minor
    b. Major
    c. Moderate

d. No change

7. …….. are the committees related to EU Regulations
    a. TGA
    b. CDER
    c. CBER
    d. COMP
8. ASMF is physically divided into two separate parts, namely ….....
    a. Applicant Part and the Restricted Part
    b. Application part and report part
    c. Applicant part and Report part
    d. Addendeum part and report part
9. Schedule ….....of the D&C Act 1940 and Rules 1945 deals with the guidelines for Good Manufacturing Practices
    a. Y
    b. M
    c. P
    d. X
10. CTD is divided into …..modules
    a. 3
    b. 4
    c. 5
    d. 6
11. Validation of Analytical Procedures: Text and Methodology is given under the ….....guidelines of ICH
    a. Q2(R1)
    b. Q2(R2)
    c. Q2(R3)
    d. Q2(R4)
12. The entry in Batch Manufacturing Record is done by
    a. Quality control department
    b. Quality assurance department
    c. Warehouse department
    d. Production department
13. BCS classification for Class III drugs is
    a. High solubility high permeability
    b. Low solubility high permeability

c. High solubility low permeability
d. Low solubility Low permeability

14. As per ANDA requirements the bioequivalence of test to reference formulation is _____
    a. 80-120%
    b. 100-150%
    c. 70-130%
    d. 70-80%
15. The headquarter of the WTO is located at _____
    a. Geneva
    b. Belgium
    c. Austria
    d. Czech
16. Which of the following is regulatory authority of Australia
    a. Pharmaceutical and Medical Devices Agency
    b. Therapeutic Goods Administration
    c. Medicines and Healthcare Products Regulatory Agency
    d. Central Drug Standard Control Organization
17. Which of the following is an International regulatory authority for drug regulation
    a. CDSCO
    b. US-FDA
    c. WHO
    d. EMA
18. The term "WIPO" stands for…...
    a. World Investment policy organization
    b. Wildlife Investigation and Policing organization
    c. World institute for Prevention of organized crime
    d. World intellectual property organization
19. Which of the following is a branch of CDL-
    a. New Delhi
    b. Kolkata
    c. Faridabad
    d. Bangalore
20. As per ICH guidelines Chloroform is classified as-
    a. Class I solvent

b. Class II solvent
c. Class III solvent
d. Class IV solvent

21. Form 11 licence is issued for-
    a. Export of drugs for examination, test or analysis
    b. Manufacture of drugs for the purpose of examination, test or analysis
    c. Import of drugs for examination, test or analysis
    d. Distribution of drugs for examination, test or analysis

22. Indian Pharmacopoeia Commission headquarter is located at
    a. Delhi
    b. Mumbai
    c. Hyderabad
    d. Ghaziabad

23. Which of the following is responsibility of state authority of CDSCO
    a. Regulatory control over the import of drugs
    b. Approval of new drugs and clinical trials
    c. Meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB)
    d. Regulation of manufacture, sale and distribution of Drugs

24. The 1st edition of Indian Pharmacopoeia was published in the year
    a. 1966
    b. 1955
    c. 1950
    d. 1960

25. The chairman of Indian Pharmacopoeial commission is-
    a. Chairman-Scientific Body
    b. The Drugs Controller General
    c. Directorate General of Health Services
    d. The Secretary, Ministry of Health and Family Welfare

26. Which of the following is a part of 4 M's of quality manufacturing-
    a. Machine
    b. Mechanism
    c. Manufacturing
    d. Modelling

27. International Conference on Harmonisation (ICH) was created in 1990 as an agreement between the _____to harmonize different regional requirements for registration of pharmaceutical drug products
    a. China, USA and EU
    b. Russia, EU, Australia
    c. EU, Japan and the USA
    d. Australia, USA, Brazil
28. The climatic condition for Zone-IV as per ICH guideline is-
    a. 25ºC/ 60%RH
    b. 30ºC/ 70%RH
    c. 21ºC/ 45%RH
    d. 30ºC/ 35%RH
29. Impurity for which a structural characterization has not been achieved and that is solely defined by qualitative analytical properties is known as-
    a. Specified impurity
    b. Unidentified impurity
    c. Unspecified impurity
    d. Identified impurity
30. Quality by design (QbD) is a concept introduced by the international conference on harmonization (ICH) as _____guideline
    a. ICH Q5
    b. ICH Q6
    c. ICH Q7
    d. ICH Q8
31. Marketing Authorization Application (MAA) is an application to the relevant authority to market a drug or medicine in
    a. US market
    b. Europe market
    c. Canadian market
    d. All countries
32. If any organization wishes to market their product only in one EU country then_____ is preferred procedure.
    a. National Procedures
    b. Mutual recognition Procedure

c. Centralized Procedure
d. decentralized Procedure

33. Where the medicinal product has already received a marketing authorization in a member states of EU at the time of application then the registration procedure is
    a. Decentralized procedure
    b. Mutual Recognition procedure
    c. Centralized procedure
    d. National procedure
34. Drug regulatory body of Brazil is
    a. TGA
    b. SFDA
    c. MHLW
    d. ANVISA
35. "Certificate of suitability" is applicable for-
    a. Substances not included in Ph. Eur. (except TSE CEP)
    b. Biologicals and products extracted from animal tissues
    c. Substances described in monographs in the Ph. Eur. Such as Active substances, excipients, herbal drugs
    d. Human tissues derivatives, blood derivatives, vaccines
36. Variations that are the minor variations which have only a minimal impact or no impact at all, on the quality, safety or efficacy of the medicinal product are called as
    a. Type IA variation
    b. Type IB variation
    c. Type II variation
    d. Extension applications
37. Variation approval timeline for II type of variation as per EU guideline is
    a. 30- 90 days
    b. 150- 180 days
    c. 210 days
    d. 120 days
38. Name the type of NDA application that needs to be filed in united states for combination of two or more active moieties
    a. Type 2
    b. Type 4

c. Type 5
d. Type 6

39. The 600 series in the Chapter 1 of 21 CFR deals in
    a. cGMP
    b. Cosmetics
    c. Biological products
    d. OTC drugs
40. _____ product does not require a BLA
    a. Serum
    b. Glucagon
    c. Blood, blood component or derivative
    d. Vaccine
41. A competitor can file for ANDA before its expiry under _____ clause of ANDA certification clause
    a. Para I
    b. Para II
    c. Para III
    d. Para IV
42. Under GAIN Title VIII of the FDA Safety and Innovation Act, FDA can grant an additional _____ years to certain exclusivity periods for products that have been granted a Qualified Infectious Disease Product (QIDP) designation
    a. 6 months
    b. 4 years
    c. 5 years
    d. 7 years
43. CFR stands for
    a. Code of Federal Regulations
    b. Centre of Federal Regulations
    c. Code of Federal Register
    d. Centre of Federal Regulator

## MULTIPLE CHOICE QUESTIONS: ANSWERKEY

| Question No. | Correct Option |
|---|---|
| 1 | b |
| 2 | a |
| 3 | b |
| 4 | d |
| 5 | b |
| 6 | b |
| 7 | d |
| 8 | a |
| 9 | b |
| 10 | c |
| 11 | a |
| 12 | d |
| 13 | c |
| 14 | a |
| 15 | a |
| 16 | b |
| 17 | c |
| 18 | d |
| 19 | b |
| 20 | b |
| 21 | c |
| 22 | d |
| 23 | d |
| 24 | b |
| 25 | d |
| 26 | a |
| 27 | c |
| 28 | b |
| 29 | b |
| 30 | d |
| 31 | b |
| 32 | a |
| 33 | b |
| 34 | d |
| 35 | c |
| 36 | a |
| 37 | a |
| 38 | b |
| 39 | c |
| 40 | b |
| 41 | c |
| 42 | c |
| 43 | a |