1. Service to customer is described in which clause of ISO 17025:2005
   a) 3.2
   b) 4.2
   c) 4.8
   d) 4.7
2. Sample preparation for testing of medical devices is described in :
   a) ISO 10993-14
   b) ISO 10993-12
   c) ISO 10993-15
   d) ISO 10993-18
3. In the categorization of medical devices as per ISO 10993 the following is not correct with regard to contact with implant devices
   a) Contact with tissue
   b) Contact with bone
   c) Contact with blood
   d) Contact with skin .
4. High density polyethylene is used as a ..... for In vitro cytotoxicity test
   a) Positive control
   b) Negative control
   c) Cannot be used as a control
   d) Can be used as either negative or positive control
5. Erythema and oedema are indications in which test under biocompatibility
   a) Implantation test
   b) Pyrogen test
   c) Sensitization test
   d) Hemolytic property
6. The Good Laboratory Practice (GLP) regulations in the European Union are regulated through
   a) OECD
   b) 21CFR58
   c) ISO
   d) ASTM
7. The following test is suitable to analyse crystallinity
   (i) XRD (ii) SEM (iii) AFM (iv) DSC
   a) (i) and (iii)
   b) (i) and (iv)
   c) (i), (ii) and (iii)
   d) All the four

8. Liquid that results from extraction of the test sample or control is called an
   a) Extract
   b) Medium
   c) Leachable
   d) Chemical constituent
9. The following is not the reactivity grades for in vitro cytotoxicity
   a) 0 - None
   b) 1- Slight
   c) 2- Mild to moderate
   d) 4 - Severe
10. When a customer is dissatisfied on the service offered and wishes to make a complaint, the following is allowed as per ISO 17025
   a) The customer is put into comfort and asked not to raise a complaint
   b) The customer shall be allowed to raise a complaint
   c) The customer shall be offered with a better service the next time
   d) None of the above
11. The following graph is an output of DSC analysis
   a) Temperature Vs time
   b) Temperature Vs heat flow
   c) Temperature Vs Mass loss
   d) Oven temperature Vs difference in temperature (sample & reference)
12. The best way to ensure the effectiveness of customer service is
   a) Conduct internal audits
   b) Conduct review meetings
   c) Implement the Quality system
   d) Conduct customer surveys
13. The relative molecular weight of samples is analysed by
   a) GPC
   b) FTIR
   c) DTA
   d) None of the above
14. If the in vitro genotoxicity test is positive then
   a) Implantation is performed
   b) The material shall be considered as mutagenic
   c) Either in vivo mutagenic test is carried out or the material shall be considered as mutagenic
   d) None of the above
15. Which among the following is incorrect about Young's modulus of elasticity
   a) Ratio of stress and strain
   b) Indicates elasticity of a material
   c) It's unit is N/m
   d) Named after Thomas Young
16. What does GHTF stand for
   a) Global Human Task Force
   b) Global Harmonization Translation Force
   c) Global Harmonization Task Force
   d) Good Human Translation Force
17. Biodegradation tests shall be done in the following cases:

(i) The device is designed to be biodegradable
(ii) The device is intended to be implanted for longer than 30 d
(iii) An informed consideration of the material(s) system indicates that toxic substances might be released during body contact

a) If (i), (ii) or (iii) is true
b) If (i) is true
c) If (i) and (ii) are true
d) If (i), (ii)and (iii) are true

18. CRM is a term usually referred to in Customer Service. What does that stand for:
a) Customer Relationship Management
b) Customer Retention Management
c) Customer Realisation Management
d) None of the above

19. Physiological saline is a
a) Non polar extraction vehicle
b) Polar extraction vehicle
c) Neither polar nor non polar
d) It is not an extraction vehicle

20. The following are evaluated in a quantitative evaluation of cytotoxicity
a) Measure cell death
b) inhibition of cell growth
c) cell proliferation or colony formation
d) All the above

21. The Goods & Services Tax (GST) became effective in India on
a) 1st January 2017
b) 1st April 2017
c) 30th March 2017
d) 1st July 2017

22. Study of blood that includes quantification of cellular and plasma components of blood is called .....
a) Thrombosis
b) Thromboembolization
c) Coagulation
d) Haematology

23. ISO 17025:2017 stands for
a) General requirements for competence, impartiality and consistent operations of laboratories
b) General requirements for competence of testing & calibration laboratories
c) General requirements for competence, impartiality of laboratories
d) General requirements for consistent operations of laboratories

24. The unaligned forces pushing one part of a body in one specific direction, and another part of the body in the opposite direction is called
a) Shear
b) 3 point bending
c) Stiffness
d) Flexure

25. The following test is essential for the product release
a) Genotoxicity
b) Implantation

c) Sterility
d) Bioburden

26. Whenever a non conformity occurs under a Quality Management System (QMS) which among the following is the most ideal:
    a) Do a corrective action and also generate a preventive action
    b) Carry out a corrective action
    c) See to it that the non conformity do not occur again
    d) A non conformity is difficult to arise under a QMS
27. The control and supervision of experiments on animals in India is controlled by
    a) Ethics committee
    b) CPCSEA
    c) CDSCO
    d) ISO
28. Necropsy is a term associated with
    a) Irritation
    b) Sterility
    c) Histopathology
    d) Genotoxicity
29. Which of the following tests would evaluate absorption, distribution, metabolism and excretion (ADME) of a chemical that is known to be toxic or whose toxicity is unknown
    a) Subchronic toxicity
    b) Subacute toxicity
    c) Toxicokinetic
    d) Pyrogen
30. IEC stands for
    a) International Electrotechnical Committee
    b) International Electronic Committee
    c) International Ethics Committee
    d) International Committee for Electronics
31. In the categorization of medical devices by duration of contact, permanent contact devices means whose cumulative single, multiple or repeated long-term use or contact exceeds
    a) 24 hours but not 30 days
    b) 25 days
    c) 30 days
    d) 60 days
32. ..... is the conformation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled
    a) Quality
    b) Standardisation
    c) Verification
    d) Validation
33. ICP OES stands for
    a) Inductively Coupled Plasma Optical Emission Spectrometry
    b) Induced Coupled Plasma Optical Emission Spectrometry
    c) Inductively Coupled Plasma Optical Electron Spectrometry
    d) None of the above
34. ISO 5725 refers to
    a) Spectroscopy analysis

b) Document management system
c) Uncertainty estimation
d) Sterility testing

35. While carrying out customer service in a Quality Management System the utmost importance is given to
    a) Document management
    b) Audit procedures
    c) Customer communications
    d) Management reviews
36. Application of risk management to medical devices is referred in
    a) ISO 17025
    b) ISO 13485
    c) ISO 9001
    d) ISO 14971
37. When reference materials are used
    a) in biological tests as control materials to demonstrate the suitability of procedure to yield a reproducible response
    b) in the same material class as the test sample,
    c) shall meet the established quality assurance procedures of the manufacturer and test laboratory
    d) All the above are correct
38. The analysis relating to shape, contours and micro structural organization of materials is termed as
    a) Morphological
    b) Topographical
    c) Physico-chemical
    d) None of the above
39. The twisting force applied on materials is called
    a) Shear
    b) Flexural
    c) Torsion
    d) Tensile
40. The following is not helpful in determining the accelerated ageing duration
    a) Ambient storage temperature
    b) Accelerated ageing test temperature
    c) Humidity of the chamber
    d) Accelerated ageing test temperature
41. The patency, occlusion and other adverse events in stents are usually studied by a
    a) In vitro Functional evaluation
    b) Safety evaluation
    c) In vivo functional evaluation
    d) Physico-chemical evaluation
42. Which among the following is not true in the case of rise in temperature
    a) Modulus of elasticity increases
    b) Yield strength decreases
    c) Tensile strength decreases
    d) Ductility increases with temperature
43. The following is critical in handling of test items
    a) Storage condition
    b) Transportation

c) Retention
d) Disposal

44. Long term application of load that are below the elastic limit, on the material is referred as
a) Stress
b) Fatigue
c) Strain
d) Creep

45. When it becomes necessary to issue a completely new report in case of amendments
a) Such amendments are not possible
b) The older report should be referred to
c) The report can be an independent one
d) Only addendums are possible

46. The following is not a standard making body
a) ASTM
b) USP
c) IEC
d) OECD

47. The following is referred as Agar diffusion method in vitro cytotoxicity
a) Test on extract
b) Indirect contact
c) Direct contact
d) None of the above

48. The method used for the separation of a mixture is called
a) Chromatography
b) Spectroscopy
c) Profilometry
d) None of the above

49. ISO 10993-1 refers to
a) Animal welfare requirements
b) Tests for genotoxicity, carcinogenicity and reproductive toxicity
c) Evaluation and testing within a risk management process
d) Framework for identification and quantification of potential degradation products

50. ..... is the crucial step in biological evaluation process
a) Implantation
b) In vitro cytotoxicity
c) Functional evaluation
d) Material characterization

MFCP -Technical Assistant (Instruments) Customer Service Cell

Answer key

1.	d
2.	b
3.	d
4.	b
5.	c
6.	a
7.	d
8.	a
9.	c
10.	b
11.	b
12.	d
13.	a
14.	c
15.	c
16.	c
17.	a
18.	a
19.	b
20.	d
21.	d
22.	d
23.	a
24.	a
25.	c
26.	a
27.	b
28.	c
29.	c
30.	a
31.	a
32.	d
33.	a
34.	c
35.	c
36.	d
37.	d
38.	a
39.	c
40.	c
41.	c
42.	a
43.	a
44.	d
45.	b
46.	d
47.	b
48.	a
49.	c
50.	d