



BRAINWARE UNIVERSITY

Term End Examination 2021 - 22
Programme – Bachelor of Pharmacy
Course Name – Quality Assurance
Course Code - BP606T
(Semester VI)

Time allotted : 1 Hrs.30 Min.

Full Marks : 75

[The figure in the margin indicates full marks.]

Group-A

(Multiple Choice Type Question)

1 x 75=75

Choose the correct alternative from the following :

(1) QMS stands for:

- | | |
|----------------------------------|--------------------------------|
| a) a.Quantity Management System | b) b.Quality Management System |
| c) c.Quality Management Standard | d) d.None of these |

(2) IPC means:

- | | |
|----------------------------|-------------------------|
| a) a.In Process Check | b) b.In Process Quality |
| c) c.In Production Control | d) d.In Process Control |

(3) DQ stands for:

- | | |
|---------------------------|--------------------------|
| a) a.Data Quality | b) b.Design Quality |
| c) c.Design Qualification | d) d.Development Quality |

(4) OQ stands for:

- | | |
|--------------------------------|--------------------------------|
| a) a.Operational Qualification | b) b.Outstanding Qualification |
| c) c.In Process Qualification | d) d.other qualification |

(5) The full form of GMP is:

- | | |
|---------------------------------|----------------------------------|
| a) a.Good Laboratory Practice | b) b.Good Manufacturing Practice |
| c) c.Good Manufacturing Process | d) d.None of these |

(6) Foundation in TQM involves:

- | | |
|--------------|--------------------|
| a) a. Ethics | b) b. Integrity |
| c) c. Trust | d) d. All of These |

(7) Roof in TQM involves:

- | | |
|-------------------|---------------------|
| a) a. Ethics | b) b. Communication |
| c) c. Recognition | d) d. Leadership |

(8) Quality Improvement Teams are set up for:

- a) a. 3-12 Months
c) c. 18-24 Months
- b) b. 6-8 Months
d) d. None of these
- (9) The first step of PDSA cycle is:
a) a. Do
c) c. Plan
- b) b. Study
d) d. Act
- (10) The Third Step of PDSA cycle is:
a) a. Act depending on the result
c) c. Implementation of the plan
- b) b. Planning
d) d. Study the data collected
- (11) Guideline Q1 stands for:
a) a. Impurities
c) c. Stability related quality
- b) b. Analytical validation
d) d. Specifications
- (12) STP means:
a) a. Specific Test Protocol
c) c. Stability Test Protocol
- b) b. Safety Test Protocol
d) d. Standard Test Protocol
- (13) Quality Risk Management is in the Guideline:
a) a. Q1
c) c. Q9
- b) b. Q3
d) d. Q7
- (14) QbD was Developed By:
a) a. Dr. Joseph M. Juran
c) c. Kaoru Ishikawa
- b) b. Sadie Shapiro
d) d. None of these
- (15) CPPs stands for
a) a. Critical Process Parameters
c) c. Commercial Process Parameters
- b) b. Control Process Parameters
d) d. None of these
- (16) Tiles not Recommended for Production areas
a) a. Glass
c) c. None of these
- b) b. marble
d) d. Ceramic and Vinyl
- (17) cGMP stands for:
a) a. Quality Good Manufacturing Practice
c) c. Control Good Manufacturing Practice
- b) b. Current Good Manufacturing Practice
d) d. Quantity Good manufacturing Practice
- (18) The second level of training is conducted by:
a) a. Functional area
c) c. One-on-one training
- b) b. HR
d) d. None of these
- (19) OJT means
a) a. Over-the-Job Training
c) c. Both a & b
- b) b. Out-the-Job Training
d) d. On-the-Job Training
- (20) The room pressure in positive pressure rooms:
a) a. Lower than outer rooms
c) c. Higher than outer rooms
- b) b. Equal to outer rooms
d) d. None of these
- (21) FIFO means:
a) a. First Install First Out
c) c. Both a & b
- b) b. First In First Out
d) d. None of these
- (22) Soda-lime Glass is the example of:

- a) a. Type I
c) c. Type III
- b) b. Type II
d) d. Type IV
- (23) Ideal Humidity for storage
- a) a.50%
c) c.40%
- b) b.60%
d) d.30%
- (24) Low temp storage means
- a) a.15-20 °C
c) c.5-6 °C
- b) b.10-12 °C
d) d.2-8 °C
- (25) Powdered Glass Test is done in
- a) a.Type I Glass
c) c.Type NP Glass
- b) b.Type III Glass
d) d.All of these
- (26) Water Attack Test is done in
- a) a.Type I Glass
c) c.Type NP
- b) b.Type III
d) d.Type III
- (27) Temperature for Autoclaving
- a) a.190 °C
c) c.90 °C
- b) b.200 °C
d) d.121 °C
- (28) Whole Container Test is for
- a) a.Paper
c) c.Glass Container
- b) b.Plastic Container
d) d.Carton
- (29) Water Vapour Permeability Test is for
- a) a.Glass Container
c) c.Rubber Closure
- b) b.Plastic Container
d) d.Paper
- (30) Self-seal ability test is done for
- a) a.Plastic Closures
c) c.Rubber Closures
- b) b.Paper Closures
d) d.None of these
- (31) Example of Secondary Packing Material is
- a) a.Paper
c) c.Fibreboard
- b) b. Carton
d) d.All of These
- (32) GLP was First introduced in the year
- a) a.1980
c) c.1930
- b) b.1972
d) d.1950
- (33) ADR means
- a) a.Automatic Drug Reason
c) c.Advance Drug Reaction
- b) b.Advance Dose Reaction
d) d.Adverse Drug Reaction
- (34) PQR means
- a) a.Procedure Quality Report
c) c.Process Quality Review
- b) b.Product Quantity Report
d) d.Product Quality Review
- (35) Validation Concept was first introduced in
- a) a.1970
c) c.1942
- b) b.1950
d) d.1901
- (36) An unequal colour distribution on the surface of the tablet is called

- a) a.Cracking
c) c.Picking
- b) b.Chipping
d) d.Mottling
- (37) Filling of pellets in capsule is done by
- a) a.Rotosort
c) c.Accoofil
- b) b.Rotofil
d) d.Pelletofil
- (38) Separation of the tablet into two or more distinct layers is
- a) a.Picking
c) c.Lamination
- b) b.Capping
d) d.Broken
- (39) The storage temperature for soft gelatine capsule shell is
- a) a.21-24 °C
c) c.18-20 °C
- b) b.15-18 °C
d) d.25-27 °C
- (40) NDA stands for
- a) a.New Drug Application
c) c.New Discovery Application
- b) b.New Drug Approval
d) d.New Drug Agency
- (41) Which of the following causes sticking problem
- a) a.Stearic acid
c) c.Lactose Cellulose
- b) b.PVP
d) d.Cellulose
- (42) Type A Gelatine exhibits an isoelectric point at pH
- a) a.2
c) c.9
- b) b.4
d) d.11
- (43) Capping is due to which of the following reasons
- a) a.Air entrapment
c) c.Too rapid expansion
- b) b.Too high compression force
d) d.All of these
- (44) No drug, regardless of its shelf life, can be sold after
- a) a.2 years
c) c.5 years
- b) b.3 years
d) d.7 years
- (45) Gelatine is used as a/an
- a) a.Encapsulating agent
c) c.Viscosity agent
- b) b.Antimicrobial agent
d) d.Tablet glidant
- (46) Disposable Syringe are made of
- a) a.Polypropylene
c) c.Glass
- b) b.Transparent polystyrene
d) d.PTFE
- (47) Which of the below has minimum permissible solid content
- a) a. Distilled Water
c) c. SWFI
- b) b. WFI
d) d. None of the Above
- (48) Test animal used for pyrogen testing is
- a) a. Rat
c) c. Rabbit
- b) b. Mice
d) d. Guinea pig
- (49) Following is/are the integrity test for filter
- a) a. Bubble point Test
c) c. Both
- b) b. Forward Flow Test
d) d. None
- (50) Cool storage means

- a) a. 2-8 °C
c) c.8-15 °C
- (51) Excessive heat means
a) a.Above 40 °C
c) c.20-25 °C
- (52) Deep Freezer means
a) a.-5 to -10 °C
c) c.0 °C
- (53) Very soluble means
a) a.1-10 parts
c) c.30-100 parts
- (54) Freely soluble means
a) a.Less than 1 part
c) c.30-100 part
- (55) Soluble means
a) a.10-30 parts
c) c.100-1000 parts
- (56) Practically insoluble means
a) a.30-100 parts
c) c.100-1000 parts
- (57) CIP means
a) a.Clean in Place
c) c.Both
- (58) SIP means
a) a.Store in Place
c) c.Both
- (59) ELISA is done to detect
a) a.Typhoid
c) c.AIDS
- (60) All metal syringe are sterilized by
a) a.Moist heat
c) c.Gamma radiation
- (61) BMR stands for
a) basic manufacturing record
c) basic material review
- (62) Drug and cosmetics Act is established in
a) a.1950
c) c.1990
- (63) Patent Act is established in
a) a.1970
c) c.1980
- (64) SME stands for
- b) b.20-25 °C
d) d.-18 °C
- b) b.30-40 °C
d) d.25-30 °C
- b) b.-2 to -8 °C
d) d.Below -18 °C
- b) b.Less than 1 parts
d) d.100-1000 parts
- b) b.10-30 part
d) d.1-10 parts
- b) b.30-100 parts
d) d.More than 1000 parts
- b) b.More than 10,000 parts
d) d.1000-10,000 parts
- b) b.Close in Place
d) d.None
- b) b.Sterile in Place
d) d.None
- b) b.Leprosy
d) d.Syphilis
- b) b.Ethylene Oxide
d) d.Dry heat
- b) batch manufacturing review
d) batch manufacturing record
- b) b.1940
d) d.1920
- b) b.1971
d) d.1985

- a) subject matter expert
c) social matter expert
- b) subject material expertise
d) site manufacturing expertise
- (65) Drug price control order act is established in
a) a.1991
c) c.1995
- b) b.1920
d) d.1993
- (66) FTA stands for
a) false tree analysis.
c) failure tree analysis
- b) fault tree analysis
d) false trem analysis
- (67) The All India Council for Technical Education Act is established in
a) a.1992
c) c.1994
- b) b.1957
d) d.1958
- (68) Drug and Magic Remedies Act is established in
a) a.1954
c) c.1998
- b) b.1962
d) d.1945
- (69) fish bone is tools of
a) QMS
c) production
- b) analysis
d) Route cause identifications in risk assesme
nts
- (70) Standard for cosmetics comes under
a) a.Sch P
c) c.Sch D
- b) b.Sch S
d) d.Sch A
- (71) Standard for GMP comes under
a) a.Sch Q
c) c.Sch W
- b) b.Sch P
d) d.Sch M
- (72) Disintegration Time for Coated tablet
a) a. NMT 15 min
c) c. NMT 45 min
- b) b. NMT 30 min
d) d. NMT 60 min
- (73) Basket type Dissolution Apparatus is the example of
a) a.USP III
c) c.USP II
- b) b.USP IV
d) d.USP I
- (74) TGA is the regulatory authority of
a) japan
c) Australia
- b) america
d) china
- (75) Head quarter of ICH is located at
a) india
c) switzerland
- b) tiwan
d) berlin