PHARMACY INDIA

# COMMON INTERVIEW QUESTIONS & ANSWERS

## FOR QUALITY CONTROL

## PHARMA GRADUATES & POST-GRADUATES

Quality Control Interview Questions & Answers

**Q1. What is quality control?**

The term quality control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical product. It involves in chemical, physical and sometime microbiological testing of a pharmaceutical product.

Quality control involves testing of pharmaceutical products against the specifications.

The other responsibilities of quality control are sampling of raw & packing material, Testing of raw material, packing material, in-process, finished product & stability batches, sampling & testing of water, calibration of instruments, preparation of specification of raw, packing, in-process & finished products, preparation of standard test procedure of raw, packing, in-process & finished products and reporting of result after analysis & preparation of COA.

**Q2. What is disintegration test?**

It is the time required for the tablet/ capsule to break into particles, the disintegration test is a measure of the time required under a given set of conditions (temperature) for a group of tablets/capsules to disintegrate into particles.

Cycle of shaft holding the tube basket limit is 29-32 cycles per minutes and distance covered by shaft basket is 50-60 mm and beaker temperature is 35 to 39ºC.

Disintegration is to be performed to determine whether tablets or capsules disintegrate within the prescribed time when placed in a liquid medium at the experimental conditions.

**Q3. What is the disintegration time of tablets?**

- Uncoated Tablet 15 min as per BP
- Uncoated Tablet 30 min as per USP
- Sugar Coated Tablet 60 min as per BP
- Film Coated Tablet 30 min as per BP
- Plain Coated Tablets DT in specific medium for 30 min as per USP
- Enteric Coated Tablets DT in simulated gastric fluid (0.1 M HCl) for 1 hr and then in simulated intestinal fluid (Phosphate buffer 6.8 pH) until disintegrate as per USP.
- Dispersible Tablets 3 min (15- 25º C) as per BP.
- Effervescent Tablets 1 tablet in 200 mL water for 5 min (15- 25º C)
- as per BP
- Buccal Tablets 4 hrs as per USP.
- Soluble Tablets 3 min (15- 25º C) as per BP.
- Chewable Tablets are not required to comply with test

**Q4. What is the disintegration time of capsules?**

- Gastro resistant capsule DT 2 hrs without disk in 0.1 M HCl and phosphate buffer pH 6.8 for further 60 min as per BP.
- Hard and Soft gelatine capsule DT 30 min as per BP & USP.

**Q5. What is friability test of tablet & friability calculation?**

Friability is defined as the percentage of weight loss of powder from the surface of the tablets due to mechanical action and the test is performed to measure the weight loss during transportation.

Friability (%) $=W_1 - W_2/W_{1X100}$

Where,
$W_1$ = Weight of Tablets (Initial / Before tumbling)
$W_2$ = Weight of Tablets (After Tumbling or friability)

**Limit:** Friability (%) = Not More Than 1.0 %

Tablets with individual weight equal to or less than 650 mg then take the sample of whole corresponding to as near as 6.5 gram equivalent and tablets with individual weight more than 650 mg then take sample of 10 whole tablets to perform friability test. Tablets must be de-dusted prior to and after use.

**Q6. What is incident?**

Any unplanned or uncontrolled event in the form of non-compliance to the designed systems or procedures at any stage of testing, and storage of drug product due to system failure or equipment breakdown or manual error.

A laboratory Incident is an event in the laboratory that occurs for two primary reasons either due to analyst error or instrument error.

**Q7. What is calibration?**

The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a traceable standard over an appropriate range of measurements.

**Q8. What is qualification?**

The action of proving that any equipment or process work correctly and consistently and produces the expected result. Qualification is part of, but not limited to a validation process, i.e., Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ).

The act of planning, carrying out and recording the results of tests on equipment to confirm its capabilities and to demonstrate that it will perform consistently as intended use and against predefined specification.

**Q9. What is deviation?**

Any unwanted event that represents a departure from approved processes or procedures or instruction or specification or established standard or from what is required. Deviations can occur during manufacturing, packing, sampling and testing of drug products.

**Examples of Deviations:** Temperature and RH of area goes out of limit during manufacturing, typographical error observed in approved documents, standard operating procedure not followed, breakdown of equipment, spillage of material during unloading, instrument calibration results go out of limit etc. Deviations are of three types minor, major and critical.

**Q10. What is change control?**

It is an approved procedure which is taken to change in any documents, standard operating procedures, specification, process parameters and change in batch size etc. change control is raised by user department as per requirement and finally the change control is approved by quality assurance. Change control can be raised through software or through manually.

After Final approval of change control, the changes can be made in documents and change control can be closed after completion of required action plan which is mentioned in the change control form.

Change controls are of two types i.e., major and minor.

**Q11. Corrective action & preventive action?**

**Corrective action:** An action taken to eliminate the cause of the existing deviation, incident or problem in order to prevent its recurrence (occurring again).

**Preventive action:** An action taken to eliminate the cause of potential deviation, incident or problem in order to prevent its occurrence (an incident or event).

**Q12. What is chromatography?**

Chromatography is an analytical technique commonly used for separating a mixture of chemical substances into its individual components, so that the individual components can be thoroughly analysed.

Chromatography is a laboratory technique for the separation of a mixture. The mixture is dissolved in a fluid called the mobile phase, which carries it through a structure holding another material called the stationary phase and the separation is based on differential partitioning between the mobile and stationary phases.

**Q13. What is difference between Stationary Phase and Mobile Phase?**

The key difference between stationary and mobile phase is that stationary phase does not move with the sample whereas mobile phase moves with the sample. Stationary phase and mobile phase are two important terms in chromatography, which is a technique of separation and identification of the components in a mixture.

**Q14. What is column in chromatography?**

A Chromatography column is a device used in chromatography for the separation of chemical compounds. A chromatography column contains the stationary phase, allowing the mobile phase to pass through it. The columns are mostly made of borosilicate glass, acrylic glass or stainless steel.

**Q15. Which gas is used in Gas Chromatography?**

In GC Nitrogen, Helium and Hydrogen are considered to be suitable carrier gases but Helium is most widely used due to safety concerns associated with hydrogen and also the fact that nitrogen is much less efficient.

**Q16. What is HPLC in chemistry?**

High performance liquid chromatography (HPLC) is a technique in analytical chemistry which is used to separate, identify, and evaluate each component in a mixture.

**Q17. What is system suitability?**

Before start of analysis of the Chromatographic system like HPLC &GC system suitability has to perform to know that the system is working properly or to know the performance.

System suitability criteria may include such factors as plate count, tailing, retention, and/ or resolution and the above factors are most important as they indicate system specificity, precision, and column stability.

**Q18. What is RT & RRT in HPLC?**

The amount of time it takes for the compound to pass through the column is the retention time (RT). The relative retention time (RRT) is the comparison of the RT of one compound to another.

**Q19. Types of HPLC pumps?**

There are 3 main types of HPLC pumps: Reciprocating pump, Displacement (or syringe) pump and Pneumatic (or constant pressure) pump.

**Q20. What is trailing factor?**

The tailing factor is a measure of peak tailing. It is defined as the distance from the front slope of the peak to the back slope divided by twice the distance from the centre line of the peak to the front slope, with all measurements made at 5% of the maximum peak height.

**Q21. What are the different types of HPLC columns?**

The different types of HPLC columns are normal phase, reverse phase, ion exchange and size exclusion columns.

**Q22. What is good laboratory practice (GLP)?**

Good laboratory practice contains a set of principles that provides a framework within which laboratory studies (activities) are planned, performed, monitored, recorded, reported and archived. GLP help assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be confidence upon when marking risk/safety assessment.

Good laboratory practice contains different principles which are designed to ensure and promote consistency, quality, safety, reliability and integrity of chemicals during non-clinical and laboratory testing.

**Q23. What is working & reference standard?**

A reference standard is the traceable, raw material standard (usually in crystallized form) that we dissolve and volumetrically dilute to make our working standard. The working standard is what we use to “do our work.” and this information makes it traceable and is recorded in the preparation notebook.

A reference standard is prepared for use as the standard in an assay, identification, or purity test and should have a quality appropriate for its use.

**Q24. Why is dissolution test required?**

Dissolution tests are performed to establish drug (active pharmaceutical ingredient) release characteristics of solid oral products, such as tablets and capsules. The rationale for conducting these tests is that for a product to be therapeutically effective, the drug must be released from the product and should generally be dissolved in the fluid of the gastrointestinal (GI) tract. The API in solution form facilitates the absorption of the drug from the GI tract into the systemic (blood) circulation to reach its desired target (site of action) to exert its effect.

**Q25. How dissolution test is performed?**

The drug is placed within the medium in the vessels after it has reached sufficient temperature and then the dissolution apparatus is operated. Sample solutions collected from dissolution testing are commonly analysed by HPLC or ultraviolet–visible spectroscopy.

**Q26. What is Q stands for in dissolution?**

'Q' is the amount of dissolved active ingredient specified in the monograph which is required to be released in the stated time, expressed as a percentage of labelled strength, then the batch of the tablet or capsules is acceptable, if each unit is not less than Q+5 %.

If the initial sample analysis, known as S1 or stage 1 testing fails to meet the acceptable value for Q, then additional testing known as stage 2 and 3 testing is required. S3 testing is performed only if S2 testing fails in Q parameter. If there is a deviation from the acceptable Q values at S3, then an OOS (out of specification) investigation is generally initiated.

**Q27. Which tablets are used in calibration of dissolution apparatus?**

Non disintegrating (Salicylic Acid) and disintegrating (Prednisone) tablets are used in the calibration of dissolution test apparatus.

**Q28. What is gas chromatography?**

Gas chromatography is a common type of chromatography which is used for separating and analysing compounds that can be vaporized without decomposition. Particular uses of GC include testing the purity of a particular substance, or separating the different components of a mixture and in some situations, GC may help in identifying a compound.

In gas chromatography, the mobile phase is a carrier gas, usually an inert gas such as helium or an un reactive gas such as nitrogen.

**Q29. What is Karl Fischer titration?**

Karl Fischer titration is a classic titration method in chemical analysis that uses coulometric or volum etric titration to determine trace amounts of water in a sample. It was invented in 1935 by the German chemist Karl Fischer.

**Q30. What is KF reaction?**

The Karl Fischer titration is a titration method for measuring water content in basically all types of substances. The Karl Fischer titration is based on an iodine / iodide reaction and the water reacts with iodine.

The endpoint of the titration is reached when all the water is consumed and the process uses an organic base (B), sulphur dioxide, iodine and an alcohol.

**Q31. What is infrared spectroscopy?**

The infrared spectrum of a sample is recorded by passing a beam of infrared light through the sample and when the frequency of the IR is the same as the vibrational frequency of a bond or collection of bonds, absorption occurs. Examination of the transmitted light reveals how much energy was absorbed at each frequency (or wavelength). This measurement can be achieved by scanning the wavelength range using a monochromator.

**Q32. What is the use of incubator?**

An incubator is a device used to grow and maintain microbiological cultures or cell cultures. The incubator maintains optimal temperature, humidity and other conditions such as the CO2 and oxygen content of the atmosphere inside. Incubators are essential for a lot of experimental work in cell biology, microbiology and molecular biology and are used to culture bacterial cells.

**Q33. What is out of Specification?**

Out of specification (OOS) means the test result that falls outside the specifications or acceptance criteria which has been specified in the official monographs or the blend, in-process, raw material, packing material, stability and finished product specification.

During analysis if any OOS observed then it should be investigated to find out the root cause and required corrective & preventive actions shall be taken to avoid the reoccurrence.

There are two phases of investigation laboratory investigation and production process investigation.

**Q34. What is out of trend?**

Out of trend (OOT) means the test result that is within the specification limit or acceptance criteria as mentioned in the blend, in-process, raw material, packing material, stability and finished product specification but outside the trend of previously tested batches.

Suppose product X has the Specification limit 95 to 105 % & we have tested many batches of product X and the trend result shows is 98 to 102 %. Suppose product X current result is 97.5 % so in this case it is called OOT.

**Q35. What is stability study?**

Stability of a pharmaceutical product means how long it can maintain its original form for the duration of the shelf life assigned to it and should comply the specification without any visible changes under the influence various environmental factors like temperature and humidity.

The pharmaceutical industry conducts this testing to develop a new product and establish the shelf-life of a product.

**Q36. What is bracketing in stability testing?**

The design in which only the extremes are tested at all time points e.g., strength, pack size, container fill etc. are tested.

Bracketing is applicable if the strength is identical or very closely related in composition (e.g., for a tablet range made with the different compression weights of similar basic granulation, or a capsule range made by filling different plug fill weight of the same basic composition in to different size capsule shells. Bracketing can be applied to different container sizes or different fills in the same container closure system).

**Q37. What is shelf life?**

The period of time during which a drug product, if stored correctly, is expected to comply with the specifications determined by stability studies on a number of batches of the product. The shelf life is used to establish the expiry date of each batch.

**Q38. In stability how many conditions are there?**

There are three stability condition long term or controlled room temperature (CRT), accelerated and intermediate.

**Q39. What is significant changes in stability study?**

**At long term and intermediate condition:** Failure to meet the specification is considered as significant change.

**At accelerated condition:** Following changes are considered as “Significant change”.

A 5% change in assay from its initial value, any degradation product exceeding its acceptance criterion. Failure to meet the acceptance criteria for appearance, physical attributes. Failure to meet the acceptance criteria for dissolution.

**Q40. What is limit of detection (LOD)?**

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. Several approaches for determining the detection limit are possible.

Based on visual evaluation the detection limit is determined by the analysis of samples with known concentrations of analyte and by establishing the minimum level at which the analyte can be reliably detected.

**Q41. What is limit of quantification (LOQ)?**

The quantification limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy. The quantification limit is a parameter of quantitative assays for low levels of compounds in sample matrices, and is used particularly for the determination of impurities and/or degradation products.

Based on visual evaluation: The detection limit is determined by the analysis of samples with known concentrations of analyte and by establishing the minimum level at which the analyte can be quantified with acceptable accuracy and precision.

**Q42. Define pH? What is the pH of the blood?**

pH is the negative logarithm of H+ Concentration. The pH of the blood ranges from 7.35 to 7.45.

**Q43. Explain the terms aliquot and diluent?**

**Aliquot:** Aliquot is a measured sub-volume of the original sample.

**Diluent:** the component used to dilute the sample.

**Q44. Explain what is titration?**

Titration is also called volumetric analysis. It is a quantitative chemical analysis used to determine the concentration of an analyte that has been identified. The titrator is a reagent that is prepared as a standard solution with a known concentration and volume. The titrant reacts with the analyte solution to determine the concentration of the analyte. The titration volume is the amount of titrant that reacts with the analyte.

**Q45. Types of titrations?**

There are basically four types of titrations, acid-base titration, complexometric titration, precipitation titration, and redox titration.

**Q46. Explain the four types of titrations.**

**Acid-base titration:** this acidic or basic titrant reacts with an analyte that is a base or an acid.

**Complexometric titrations:** involving metal-ligand complexation reactions

**Precipitation titrations:** When the analyte and titrant react, a precipitate is formed.

**Redox titrations:** Where the titrant is oxidizing agents or reducing agents.

**Q47. What is the Ultraviolet (UV) and visible spectroscopy range?**

The range of UV Spectroscopy is 200-400 nm, and visible spectroscopy ranges from 400- 800 nm.

**Q48. What is the use of UV Spectroscopy?**

Spectroscopy can be used to detect functional groups, and impurities, and perform qualitative and quantitative analyses.

**Q49. What is meant by the solution?**

A solution is a mixture of liquids, gases, and solids, the solution consists of many different types of solutes like salts, oxygen, and organic molecules.

**Q50. Describe the saturated and unsaturated solutions**

A saturated solution is defined as a solution in which a solvent is not capable of dissolving any more solute at a given temperature.

At a given temperature, an unsaturated solution is one in which the solvent is Capable of dissolving any extra solute.

**Q51. What is the difference between qualitative and quantitative analysis?**

Qualitative analysis involves the identification of the compound or chemical based on their chemical (absorption, emission) or physical properties, e.g., melting point and boiling point.

Quantitative analysis: this involves estimation or determination of the concentration or amount of the chemical compounds or components.

**Q52. Explain the principle of ultraviolet spectroscopy?**

Ultraviolet spectroscopy uses light in the UV part of the electromagnetic spectrum. UV absorption spectra form when the outer electrons of a molecule or an atom absorb energy and move from a lower to a higher energy level. The wavelength absorbance of each molecule is unique.

**Q53. Define Molarity?**

A number of moles of solute per litre solution. molarity is denoted with a capital “M”.

**Q54. Define molality?**

The number of moles of solute per kilogram solvent. it is denoted with a small “m”.

**Q55. Define normality?**

The number of moles equivalent per litre solution.

**Q56. What are buffer solutions?**

A buffer solution is an aqueous solution consisting of a mixture of a weak acid and its conjugate base or vice versa.

When a minimal amount of strong acid or base is introduced to it, the pH changes ve-ry little.

**Q57. What is valency?**

Valency is simply the combining power of elements. the valency determines the chemical formula of a compound. When compounds react to form new compound (s) they tend to change their valences.

**Q58. What is aqua regia?**

A mixture of concentrated nitric acid and hydrochloric acids (1:3). It's a highly corrosive liquid that can harm gold and other hardened materials.

**Q59. What is bleaching powder's chemical name?**

Calcium hypochlorite, also known as $CaOCl_2$, is an inorganic chemical compound having the formula $CaOCl_2$. Calcium oxychloride is another name for them.

**Q60. What is polarity?**

Polarity is the electronegativity difference between the atom or molecule or the ability of an atom to attract shared electrons in a covalent bond.

**Example:** Water is a good example of a polar molecule due to the difference in electronegativity between the oxygen atom and the hydrogen. Oxygen is a highly electronegative atom compared to hydrogen. Because fats, petrol, and gasoline do not dissolve in water, they are classified as non-polar molecules. Nonpolar means "insoluble in water."

**Q61. Explain the beer lamberts law?**

It states that the intensity of nonchromatic light absorbed by a substance dissolved in a fully transmitting solvent is directly proportional to the substance concentration and the path length of the light through the solution.

**Q62. What is an indicator in chemistry?**

Indicators are substances that show a change in colour when brought in contact with acid or base. The most commonly used indicators are litmus, methyl orange, and phenolphthalein which change colour as follows.

| Indicator | Acid Solution | Basic Solution | Neutral Solution |
|---|---|---|---|
| Blue Litmus Solution | Red | No change in colour | No change in colour |
| Red Litmus Solution | No change in colour | Blue | No change in colour |
| Methyl Orange | Red | Yellow | Orange |
| Phenolphthalein | Colourless | Red | Colourless |

**Q63. Explain the infrared spectroscopy principle?**

When a molecule absorbs infrared radiation, it vibrates and gives rise to a packed infrared absorption spectrum. This IR spectrum is specific for every different molecule absorbing the IR radiation, useful for identification.

**Q64. What is the common alum?**

Potassium alum, potash alum, or potassium aluminium sulphate is a chemical compound Chemical formula of common alum is $KAI(SO_4)_2.12H_2O$. Use water purification.

**Q65. What is a covalent bond?**

A covalent bond also called a Molecular bond is a chemical bond that involves the sharing of electron pairs between atoms.

**Q66. Mention the formula to calculate the pH of a solution?**

Formula to calculate pH = -log [H+] or pH = -log [$H_3O$+]

**Q67. What is PPM?**

PPM is parts per million (such as % means parts per 100)

**Q68. What is the HPLC principle?**

It's a technology used for separating the mixture of compounds into individual components based on absorption, partition, ion exchange, and size exclusion principles. The stationary phase and mobile phase are used in it. HPLC is used for the identification, quantification, and purification of components from a mixture.

**Q69. Explain what is dextro-rotatory and laevorotatory?**

Laevorotation and Dextrorotation are referred to as the properties of plane-polarized light when light rotates clockwise when it approaches the observer then known as dextro-rotatory, and when light rotates anticlockwise then it's referred to as laevorotatory.

**Q70. Difference between humidity and relative humidity?**

**Humidity –** Measure of amount of water vapour present in the atmosphere.

**Relative humidity –** Water vapour amount exists in air expressed as a percentage of the amount needed for saturation at the same temperature.

**Q71. What is dissolution?**

Dissolution is nothing but the time required to dissolve the active drug substance into a medium in a given set of conditions.

**Q72. What is a stability chamber?**

Stability chambers are the chambers to store the stability sample at different storage conditions to understand the impact of the different climatic conditions on the drug substance or drug product.

**Q73. What is a significant change as per ICH?**

According to ICH significant change in the drug product is defined as;

1. A 5% change in assay from the initial value; or failure to meet the acceptance criteria for potency when using biological or immunological procedures.

2. Any degradation product exceeding its acceptance criterion.

3. Failure to meet acceptance criteria for appearance, physical attributes, and functionality test, (e.g., colour, phase separation, resuspendibility, caking, hardness, dose delivery per actuation). However, some changes in physical attributes, (e.g., softening, suppositories, melting of creams) may be expected under accelerated conditions.

4. Failure to meet acceptance criterion for pH.

5. Failure to meet the acceptance criteria for dissolution for 12 dosage units.

**Q74. What is the stability guideline as per ICH?**

According to ICH, Q1 is a Stability guideline.

**Q75. Total how many ICH quality guidelines?**

Total 14 quality guidelines as per ICH.

**Q76. What are the 14 ICH quality guidelines?**

ICH Q1- Stability

ICH Q2- Analytical Validation

ICH Q3- Impurity

ICH Q4- Pharmacopeia

ICH Q5- Quality of Biotechnological Product

ICH Q6- Specification

ICH Q7- Good Manufacturing Practices

ICH Q8- Pharmaceutical Development

ICH Q9- Quality Risk Management

ICH Q10- Pharmaceutical Quality System

ICH Q11- Development and Manufacture of drug substances

ICH Q12- Lifecycle Management

ICH Q13- Continuous Manufacturing of drug substances and drug products

ICH Q14- Analytical Procedure Development

**Q77. How many types of dissolution as per USP?**

Total 7 types of dissolution as per USP.

**Q78. What are the 7 apparatus of dissolution as per USP?**

Apparatus 1 – Basket

Apparatus 2 – Paddle

Apparatus 3 – Reciprocating cylinder (Not accepted by Japanese Pharmacopoeia)

Apparatus 4 – Flow through cell

Apparatus 5 – Paddle over a disc

Apparatus 6 – Rotating cylinder

Apparatus 7 – Reciprocating Disc

**Q79. What is S1, S2, and S3 as per USP?**

The dissolution test is performed in three stages that are S1, S2, and S3.

**Q80. What is dissolution acceptance criteria as per USP?**

| Stage | No. of Units to be tested | Acceptance criteria |
|---|---|---|
| S1 | 6 | No unit is less than Q+5% |
| S2 | 6 | An average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15% |
| S3 | 12 | An average of 24 units (S1+S2+S3) is equal to or greater than Q, and not more than 2 units are less than Q-15% and no unit is less than Q-25% |

**Q81. Why KBr used in IR?**

1. KBr is an inactive substance in IR range.
2. KBr dipole moment is zero.
3. KBr is a temperature stable substance.

**Q82. Why is water not used in IR spectroscopy?**

1. Water is a strong polar solvent.
2. In the IR region water shows two strong peaks.

**Q83. What is a correction?**

Any repair, modification, adjustment, relabelling, destruction or inspection of a combination product without its physical removal from its point of use to some other location.

**Q84. What is recall?**

Recall is an action to remove of specific products or batches of the product from the market.

**Q85. What is mock recall?**

Tracing specific batches of the product in the market to access the preparedness and efficacy of the distributor/carry and forwarding agents/global distribution centre to get back details of the product in the shortest possible time.

**Q86. What are quality defects in pharmaceutical?**

Attributes of the medicinal product or component (which may affect the quality, safety, and efficacy of the product) which are not in line with the approved product specifications.

**Q87. What is the full form of NDA, ANDA, and IND?**

NDA- New Drug Application

ANDA- Abbreviated New Drug Application

IND- Investigational New Drug

**Q88. What is 21 CFR?**

21 CFR is Code of Federal Regulation Title 21 which represents “Food and Drugs”.

**Q89. What is data integrity?**

Data integrity is the complete, consistent, and accuracy of the data throughout the lifecycle.

**Q90.What is audit trail?**

Audit trail is nothing but secure, time-stamped, computer-generated electronic records that allows for reconstruction of the course of events relating to the creation, modification or deletion of electronic records. It is a chronological record of the activity that happened such as what, when, why, where etc.

**Q91. What is 21 CFR part 11?**

FDA 21 CFR Part 11 represents “Electronic signature and Electronic Records”

**Q92. What is validation?**

Validation is a process of establishing documentary evidence demonstrating that a process, procedure or activity carried out in the testing and then production maintains the desired level of compliance at all stages.

OR

Process validation is defined as the collection and evaluation of data from the process design stage throughout the production, that establishes the scientific evidence that a process is capable to produce consistently delivering quality products.

**Q93. What are the types of validation?**

I. Prospective Validation

II. Retrospective Validation

III. Concurrent Validation

IV. Revalidation

**94. What is Alcoa Plus?**

Alcoa plus is an acronym of

A- Attributable
L- Legible
C- Contemporaneous
O- Original
A- Accurate
C- Complete
C- Consistent
E- Endurance
A- Available