Question 1. What Is An Sop ?

Answer :

Standard Operating Procedure (SOP) is a certain type of document that describes in a step-by-step

Question 2. What Is 21 Cfr Part 11 ?

Answer :

Title 21 CFR Part 11 of the Code of Federal Regulations deals with the Food and Drug Administration (FDA) guidelines on electronic records and electronic signatures in the United States. Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records.

Question 3. What Are User Requirements ?

Answer :

User Requirements Specification describes what users require from the System. User requirement specifications are written early in the validation process, typically before the system is created. It is written by the System Owner and End Users, with input from Quality Assurance. Requirements outlined in the URS are usually tested in the Performance Qualification. User Requirements Specifications are not intended to be a technical document; readers with only a general knowledge of the system should be able to understand the requirements outlined in the URS.

Question 4. What Is A Validation Plan ?

Answer :

Validation Plans define the scope and goals of a validation project. Validation plans are written before a validation project and are specific to a single validation project.

Validation Plans can include:

Deliverables (Documents) to be generated during the validation process

Resources/Departments/Personnel to participate in the validation project

Time-Line for completing the validation project

[Medical Terminology(Adaptive\*) Tutorial](https://www.wisdomjobs.com/e-university/medical-terminology-adaptive-tutorial-119.html" \o "Medical Terminology(Adaptive*) Tutorial)

Question 5. What Is An Iq Document ?

Answer :

Installation Qualifications are a collection of test cases used to verify the proper installation of a System. The requirement to properly install the system was defined in the Design Specification. Installation Qualifications must be performed before completing Operational Qualification and Performance Qualification.

[Pharmacology Interview Questions](https://www.wisdomjobs.com/e-university/pharmacology-interview-questions.html" \o "Pharmacology Interview Questions)

Question 6. What Is An Oq Document ?

Answer :

Operational Qualifications are a collection of test cases used to verify the proper functioning of a System. The operational qualification tests requirements defined in the Functional Requirements. Operational Qualifications are usually performed before the system is released for use.

Question 7. What Is A Pq Document ?

Answer :

Performance Qualifications are a collection of test cases used to verify that a System performs as expected under simulated real-world conditions. The performance qualification tests requirements that were defined in the User Requirement Specification (or possibly the Functional Requirements). Due to the nature of performance qualifications, these tests are sometime conducted with power users as the system is being released.

[Pharmacology Tutorial](https://www.wisdomjobs.com/e-university/pharmacology-tutorial-128.html" \o "Pharmacology Tutorial) [Clinical Research Interview Questions](https://www.wisdomjobs.com/e-university/clinical-research-interview-questions.html" \o "Clinical Research Interview Questions)

Question 8. What Is A Validation Summary Report ?

Answer :

Validation Summary Reports provide an overview of the entire validation project. When regulatory auditors review validation projects, they typically begin by reviewing the summary report.

The validation summary report should include:

A description of the validation project

All test cases performed, including if those test cases passed without issue

All deviations reported, including how those deviations were resolved

Question 9. What Is A Change Request ?

Answer :

Change Control is a general term describing the process of managing how changes are introduced into a controlled System. In validation, this means how changes are made to the validated system. Change control is required to demonstrate to regulatory authorities that validated systems remain under control after system changes. Change Control systems are a favorite target of regulatory auditors because they vividly demonstrate an organization capacity to control its systems.

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Question 10. Why Water For Pharmaceutical Use Is Always Kept In Close Loop In Continuous Circulation?

Answer :

Water is a best medium for many microorganisms, microorganism can be a highly pathogenic which causes serious diseases(many diseases are  water born), these pathogens infect after consumption of contaminated water, microorganisms tend to settle on a surface if water is allowed to stand in a stagnant position for few hours, these settled microorganism form a film over the surface of vessel and piping, such film formed by microorganisms is also called as biofilm, biofilms are very difficult of remove, once a biofilm is formed at a particular point then that point may form a biofilm again even after cleaning very easily as seed from this point is may not completely get removed effectively.

Question 11. Biofilms Then Can Become A Source Of Microbial Contaminations; Therefore Purified Water After Collection In A Distribution System Is Always Kept In A Closed Loop In A Continuous Circulation.

Answer :

Water is a best medium for many microorganisms, microorganism can be a highly pathogenic which causes serious diseases(many diseases are  water born), these pathogens infect after consumption of contaminated water, microorganisms tend to settle on a surface if water is allowed to stand in a stagnant position for few hours, these settled microorganism form a film over the surface of vessel and piping, such film formed by microorganisms is also called as biofilm, biofilms are very difficult of remove, once a biofilm is formed at a particular point then that point may form a biofilm again even after cleaning very easily as seed from this point is may not completely get removed effectively.

[Medical School Interview Questions](https://www.wisdomjobs.com/e-university/medical-school-interview-questions.html" \o "Medical School Interview Questions)

Question 12. Water For Pharmaceutical Use Shall Be Free Cations,anions And Other Impurities Why ?

Answer :

Water for pharmaceutical must be free from inorganic as well as organic impurities, minerals, and heavy metals. Some impurities like calcium, magnesium, ferrous are responsible for degradation of drug molecule, many cations like ferrous and calcium magnesium act as catalysts in degradation reaction of drug molecule, anions like chloride are highly active they participate in nucliophylic substitution reactions, where in they break a double bond between -C=C- in to a single bond as CL –CH-CH2- , which a reason why we observe that color dies tend to fed in presence of chlorine as most of the dies used are diazo compounds which has plenty of places for nucliophylic substitution reactions, which is also a reason why stability of drug is drastically affected in presence of cations and anions from mineral origin present in water.

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Question 13. Water For Pharmaceutical Use Shall Be Free Heavy Metals Why ?

Answer :

Heavy metals like lead and arsenic are highly cumulative neurotoxic metals, heavy metals are not eliminated out of our body easily like other drugs and molecules but heavy metals bind with proteins and tend to get accumulated in fatty tissues, nerve tissue is most likely to get damaged by heavy metals, heavy metal causes nervous tissue damage there for water must be free from heavy metals.

Question 14. Brazil Falls Under Which Climatic Zone ?

Answer :

Zone IVB (30 degree celsius and  75% relative humidity)

Question 15. Change In The Size Or Shape Of The Original Container Requires Any Stability Study?

Answer :

Change in the size or shape of the original container may not necessitate the initiation of new stability study.

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Question 16. Forced Degradation(stress Testing) And Accelerated Stability Testing Are Same?

Answer :

Forced degradation and stress testing are not same. Stress testing is likely to be carried out on a single batch of the drug substance. The testing should include the effect of temperatures (in 10°C increments (e.g., 50°C, 60°C) above that for accelerated testing), humidity (e.g., 75 percent relative humidity or greater) where appropriate, oxidation, and photolysis on the drug substance. The testing should also evaluate the susceptibility of the drug substance to hydrolysis across a wide range of pH values when in solution or suspension. Photo stability testing should be an integral part of stress testing.

Question 17. According To Who Guidelines What Is The Storage Condition Of Climatic Zone Iva And Zone Ivb?

Answer :

 Zone IV a: 30°C and 65% RH (hot and humid countries)

Zone IV b: 30°C and 75% RH (hot and very humid countries

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Question 18. Countries Comes Under Climatic Zone Ivb?

Answer :

Brazil,Cuba,China,Brunei,Cambodia,Indonesia,Malaysia,Myanmar,Philippines,Singapore,Thailand

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Question 19. What Is The Purpose Of Stress Testing In Stability Studies?

Answer :

Stress testing of the drug substance can help identify the likely degradation products, which can in turn help establish the degradation pathways and the intrinsic stability of the molecule and validate the stability indicating power of the analytical procedures used. The nature of the stress testing will depend on the individual drug substance and the type of drug product involved.

Question 20. What Is Dead Leg?

Answer :

A dead leg is defined as an area in a piping system where liquid can become stagnant and not be exchanged during flushing.

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Question 21. What Is The Recommended Bio Burden Limits Of Purified Water & Wfi?

Answer :

Purified water has a recommended bioburden limit of 100 CFU/mL, and water for injection (WFI) has a recommen

Question 22. Brief About Ich Stability Guidelines?

Answer :

Q1A- Stability testing of new drug substance & products

Question 23. What Is Significant Changes In Stability Testing?

Answer :

A 5% change in assay for initial value.

Question 24. If Leak Test Fail During In Process Checks What Needs To Be Done ?

Answer :

Immediately stop packing process and check for:

Sealing temperature

Verify for any possible changes like foil width,knurling etc.

Check & quarantine the isolated quantity of packed goods from last passed inprocess.

Collect random samples & do retest.

Blisters from the leak test passed containers shall allow to go further and rest must be deblistered/defoiled accordingly.

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Question 25. How Many Tablets Shall Be Taken For Checking Friability?

Answer :

For tablets with unit mass equal or less than 650 mg, take  sample of whole tablets corresponding to 6.

Question 26. What Is The Pass Or Fail Criteria For Friability Test?

Answer :

Generally the test is run for once.If any cracked,cleaved or broken tablets present in the tablet sample after tumbling,the tablets fails the test.If the results are doubtful,or weight loss is grater than the targeted value,the test should be repeated twice and the mean of the three tests determined.A  mean weight loss from the three samples of not more than 1.0% is considered acceptable for most of the products.

Question 27. What Is The Standard Number Of Rotations Used For Friability Test?

Answer :

100 rotations

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Question 28. What Is The Fall Height Of The Tablets In The Friabilator During Friability Testing?

Answer :

6 inches.Tablets falls from 6 inches eight in each turn within the apparatus.

Question 29. Why Do We Check Hardness During Inprocess Checks?

Answer :

To determine need for the pressure adjustments on the tableting machine. Hardness can affect the disintegration time.If tablet is too hard, it may not disintegrate in the required period of time. And if tablet is too soft it will not withstand handling and subsequent processing such as coating,packing etc.

Question 30. What Are The Factors Which Influence Tablet Hardness?

Answer :

compression force

Binder quantity(More binder more hardness)

Moisture content

Question 31. Which Type Of Tablets Are Exempted From Disintegration Testing?

Answer :

Chewable Tablets

Question 32. Which Capsule Is Bigger In Size - Size '0' Or Size '1'?

Answer :

'0' size

Question 33. What Is The Recommended Temperature For Checking Dt Of A Dispersible Tablet?

Answer :

25 ±10C (IP) & 15 – 250C (BP)

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Question 34. What Is Mesh Aperture Of Dt Apparatus ?

Answer :

 1.8 -2.2mm (#10)

Question 35. What Is The Pass/fail Criteria For Disintegration Test?

Answer :

If one or two tablets/capsules fails to disintegrate completely, repeat the test on another 12 additional dosage units. The requirement is meet if not fewer than 16 out of 18 tablets/capsules tested are disintegrated completely.

Question 36. What Is The Recommended Storage Conditions For Empty Hard Gelatin Capsules?

Answer :

15 - 250C & 35 -55% RH

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Question 37. Which Method Is Employed For Checking “uniformity Of Dosage Unit”?

Answer :

Content uniformity

Question 38. What Is The Recommended Upward And Downward Movement Frequency Of A Basket-rack Assembly In A Dt Apparatus?

Answer :

 28 – 32 cycles per minute.

Question 39. When Performing The ‘uniformity Of Weight’ Of The Dosage Unit, How Many Tablet/capsule Can Deviate The Established Limit?

Answer :

Not more than two of the individual weights can deviates from the average weight by more than the percentage given in the pharmacopeia,and none can deviates more than twice that percentage.

Weight Variation limits for Tablets.

Question 40. What Precautions Shall Be Taken While Collecting In Process Samples ?

Answer :

While collecting inprocess samples, avoid contamination of the product being sampled (Don’t collect samples with bare hands) & avoid  contamination of sample taken.

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Question 41. In A Tablet Manufacturing Facility ‘positive’ Pressure Is Maintained In Processing Area Or Service Corridors?

Answer :

In tablet manufacturing facilities, pressure gradients are maintained to avoid cross contamination of products through air. Usually processing areas are maintained under positive pressure with respect to service corridors.

Question 42. If Sticking Observed During Tablet Compression What May The Probable Reason For The Same?

Answer :

If the granules are not dried properly sticking can occur.

Too little or improper lubrication can also leads to sticking.

Sticking can  occur because of too much binder or hygroscopic granular.

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Question 43. What Checks Shall Be Carried Out, While Calibrating Dt Apparatus?

Answer :

While calibrating DT apparatus, following checks shall be performed.

Question 44. What Is In Process Checks?

Answer :

In process checks are  checks performed during an activity,In order to monitor and,if necessary,to adjust the process to ensure that product confirms to its specification.

Question 45. What Is The Difference Between Disintegration And Dissolution?

Answer :

Disintegration is a disaggregation process, in which an oral dosage form falls apart in to smaller aggregates.(Disintegration time is the ‘break up’ time of a solid dosage form).

Where as dissolution is a process by which solid substance enters in the solvent to yield a solution.It is controlled by the affinity between the solid substance and the solvent.

In other word disintegration is a subset of dissolution.

Question 46. Why Do We Calibrate A Qualified Equipment/instrument On Definite Intervals?

Answer :

An equipment or instrument can ‘drift’ out of accuracy between the time of qualification and actual use.So it is recommended to calibrate and recalibrate the measuring devices and instruments on predetermined time intervals, to gain confidence on the accuracy of the data.

Question 47. Why Do We Consider Three Consecutive Runs/batches For Process Validation? Why Not Two Or Four?

Answer :

The number of batches produced in the validation exercise should be sufficient to allow the normal extent of variation and trends to be established and to provide sufficient data for evaluation and reproducibility.

First batch quality is accidental (co-incidental),

Second batch quality is regular (accidental),

Third batch quality is validation(conformation).

In 2 batch we cannot assure the reproducibility of data,4 batches can be taken but the time and cost are involved.

Question 48. Explain About Revalidation Criteria Of Ahu System?

Answer :

AHU system shall be revalidated periodically as mentioned in the regulatory standards.

AHU shall be revalidated in following cases also:

When basic design of AHU is changed,

When clean room volume is changed,

When new equipment is installed

When a construction is carried out, that calls for reconstruction of AHU system.

Question 49. What Needs To Be Checked During Ahu Validation?

Answer :

During AHU validation, following tests shall be carried out:

Filter efficiency test,

Air velocity & number of air changes,

Air flow pattern (visualization)

Differential pressure, temperature and RH

Static condition area qualification

Dynamic condition qualification

Non-viable count

Microbial monitoring

Area recovery and power failure study.

Question 50. Position Of Oblong Tablets To Be Placed In Hardness Tester To Determine The Hardness? Lengthwise / Widthwise?

Answer :

Position of oblong tablets should be length wise because the probability of breakage is more in this position.

Question 51. Explain In Detail About Qualification Of Pharmaceutical Water System?

Answer :

Qualification of pharmaceutical water system involves three phases:

Phase -1

Phase -2

Phase -3

Phase -1:

A test period of 2-4 weeks should be spent for monitoring the system intensively. During this period the system should operate continuously without failure or performance deviation.Water cannot be used for pharmaceutical manufacturing in this phase.The following should be included in testing approach.

Under take chemical & microbiological testing in accordance with a defined plan.

Sample incoming feed water daily to verify its quality.

Sample each step of purification process daily.

Sample each point of use daily.

Develop appropriate operating ranges.

Demonstrate production and delivery of product water of required quantity and quality.

Use and refine the SOP’s for operation,maintenance,sanitization and trouble shooting.

Verify provisional alert and action levels.

Develop and refine test failure procedure.

Phase -2:

A further test period of 2-4 weeks. Sampling scheme will be same as  Phase – 1.Water can be used for manufacturing process in this phase. Approach should also

Demonstrate consistent operation within established ranges.

Demonstrate consistent production & delivery of water of required quality and quantity.

Phase - 3:

Phase 3 runs for one year after satisfactory completion of phase-2.Water can be used for manufacturing process during this process.

Objectives & Features of Phase -3:

Demonstrate extensive reliable performance.

Ensure that seasonal variations are evaluated.

The sample locations, sampling frequencies and test should be reduced to the normal routine pattern based on established procedures proven during Phase -1 & phase - 2.

Question 52. What Is The Difference Between Calibration And Validation?

Answer :

Calibration is a demonstration that, a particular

Instrument or device produces results with in specified limits by comparisons with those produced by a reference or traceable standard over an appropriate range of measurements.

Where as Validation is a documented program that provides high degree of assurance that a specific process, method or system consistently produces a result meeting pre-determined acceptance criteria.

In calibration performance of an instrument or device is comparing against a reference standard. But in validation such reference standard is not using.

Calibration ensures that instrument or measuring devices producing accurate results. Whereas validation demonstrates that a process, equipment, method or system produces consistent results (in other words, it ensures that uniforms batches are produced).

Question 53. Briefly Explain About Ich Climatic Zones For Stability Testing & Long Term Storage Conditions?

Answer :

ICH STABILITY ZONES:

Zone: Type of Climate

Zone I: Temperate zone

Zone II: Mediterranean/subtropical zone

Zone III: Hot dry zone

Zone IVa: Hot humid/tropical zone

Zone IVb:

ASEAN testing conditions hot/higher humidity

Long term Storage condition

Climatic Zone

Temperature

Humidity

Minimum Duration:

Zone I:

21ºC ± 2ºC

45% rH ± 5% rH

12 Months

Zone II:

25ºC ± 2ºC

60% rH ± 5% rH

12 Months

Zone III:

30ºC ± 2ºC

35% rH ± 5% rH

12 Months

Zone IV:

30ºC ± 2ºC

65% rH ± 5% rH

12 Months

Zone IVb:

30ºC ± 2ºC

75% rH ± 5% rH

12 Months

Refrigerated

5ºC ± 3ºC

No Humidity

12 Months

Frozen

-15ºC ± 5ºC

No Humidity

12 Months

Question 54. What Are The Common Variables In The Manufacturing Of Tablets?

Answer :

Particle size of the drug substance:

Bulk density of drug substance/excipients

Powder load in granulator

Amount & concentration of binder

Mixer speed & mixing timings

Granulation moisture content

Milling conditions

Lubricant blending times

Tablet hardness

Coating solution spray rate

Question 55. Whether Bracketing & Validation Concept Can Be Applied In Process Validation?

Answer :

Both Matrixing and Bracketing can be applied in validation studies.

Matrixing

Different strength of same product

Different size of same equipment

Bracketing - Evaluating extremes

Largest and smallest fill volumes

Fastest and slowest operating speeds