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WATER SYSTEM VALIDATION

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ABSTRACT

The purpose of carryout water system validation is to ensure that the remedy process Produce An executive quality of water systemically. The main goal of this discussion is to see the Numerous Factors Of validation that include the treatment of water, qualification of equipment, Documentation, validation, Phase of qualification.

Keywords*:* Validation, water purification

INTRODUCTION:

The water is extensively used substance & raw material within inside manufacturing, Processing & formulation of pharmaceutical &therefore it playcrucialrole in pharmaceutical processing. Purified water is derived from consuming water through a typical water purification system of unit Operation. The validation of water remedy system is essential to acquired water with all quality Characteristics. Validation Requirement: To reduce the batch variations. To acquire an efficient, good & Pure product. Water for Pharmaceutical Purpose: The quality characteristics of water for a specific utility Dictated by the requirement of its usage. Sequential processing steps accompanied for treating water for Distinctive reason

Installation Material of Construction & Component selection: The installation technique is essential Because they can affect the mechanical, sanitary, corrosive of the system. Valve installation characteristics Should promote gravity drainage. Pipe support provide suitable slope for drainage &must be designed to Assist the piping appropriately under worst case thermal conditions. Methods of connecting device Component including unit of operation, tank & distribution piping required careful attention to Prevent potential problem. Stainless steel welds must provide dependable joint which are internally Smooth & corrosion free. Low carbon stainless, compatible with filter, wherein necessary inert gas, Automatic welding machine & regular inspection, documentation assist to ensure the acceptable weld Quality. Follow up cleaning & passivation are necessary for removing contamination & corrosion product To re-set up the passive corrosion resistant surface. Plastic material should be fused in some cases & also Required smooth, uniform internal surface. Adhesive should be avoided due to the potential for voids & Chemical reaction. Mechanical technique of joining such as flange fitting, required care to avoid the Creation of offset, gap, penetration & void control measure include good alignment, properly sized gasket Appropriate spacing, uniform sealing force

Material Of Construction: It must be selected to be well suited with control measure consists of cleaning, Sanitizing, passivating. Temperature score is a essential factor in selecting suitable material due to the Fact surface can be required to improve operating & sanitization temperature. Material must be able to Handling turbulent flow &improve velocities without wear on the corrosive barrier effect such as Passivation related chromium oxide surface of stainless steel. Validation & Qualification of Water Purification, Storage & Distribution System: Establishing the dependability of pharmaceutical water Purification, storage, distribution system required on suitable duration of monitoring & observation.

Simply few problems are encountered in preserving the chemical purity of purified water & water for Injection. However, it is more difficult to fulfill established micro- biology quality criteria consistently. A Usual program involve extensive day by day sampling &checking out by major process point for at least One month after operational criteria have been established for every sampling point. Validation is the Processor acquiring & documenting substantiation to a excessive stage of assurance that a Particular system will continuously produce a product confirming to an installed set of quality Characteristics. The validation defines essential procedure parameter & their operating ranges.

A Validation plan for a water system usually consists of subsequent steps,

•Establishing standard for quality characteristics &working parameter.

• Defining system &sub-system able to produce the desired quality attribute from the available source water.

• Selecting device, control & monitoring technologies.

• Developing a set up qualification level such as tool calibration, inspection to confirm that the drawing appropriately depicts the as Constructed configuration of the water system &wherein important, unique assessment to confirm that the set up neet the layout requirement.

• Developing an operational qualification stage consisting test & inspection to confirm that the equipment, system alert & control are working are reliably & that appropriate alert & action stage are established. This stage of qualification may also overlap with element of the subsequent step.

• Developing a performance qualification level to verify the appropriateness of critical parameter operating range. A concurrent or retrospective performance qualification is accomplished to illustrate system reproducibility over an appropriate time period. During this phase of validation, alert & action level for key quality characteristics &working parameter verified.

• Supplementing a validation renovation program that include mechanism to control modification to the system & establish & carry out preventive maintenance consisting of recalibration of instrument. In addition, validation renovation consists a monitoring program for essential procedure parameter & a corrective action program.

Validation Sequence:

•Design qualification – The design qualification will list the activities important to regular manufacturing of the stipulated grade of water. It will comprise a complete description of the system specifying its Reputation working range &restriction. It will deliver complete schematic of the electrical, mechanical & Water flows for next verification of their proper installation. It will confirm the particular sampling plans & ports for chemical & microbial testing, stipulated sanitizing technique & defined process for the analysis &plating of data. Design qualification is prepared according to the URS & Pharmacopoeial standard

• Installation qualification –System & equipment must be efficiently set up in accordance with a set up Plan & installation qualification protocol.

• Operation qualification –It must provide documented evidence that utilize, system or equipment & all Its factor operate in accordance with operational specification. Tests must be designed to illustrate pleasant operation over the regular operating range as well as at limit of its operating circumstance

• Performance qualification – The reason of performance qualification is to provide rigorous checking out of demonstrate the effectiveness & reproducibility of the total incorporated process.

Phase 1 (investigational phase) Test duration must be 2-4(14 day minimum) week for monitoring the System intensively. During this period the system must be performed constantly without failure or Performance deviation.

Phase 2 (verifying control) Test duration must be 2-4 week (30 day) it must be spent carrying out further Intensive monitoring, while developing all thedelicateSOP's after the excellent completion of phase1.

Preventive maintenance: This element is often considered to be obligation of the site renovation & Operation department &frequently it gives a low precedence inside an engineering design team. There is Apparent requirement to maintain a facility in a state of qualification. It is an important aspect of schedule of work to acquire this objective.

The role of vendor & supplies is essential in this area. Operation &renovation manual must be considered as a carried out during the layout the phase & the documentation required must be included in the Requisition.

Change control: The change control must be managed with a SOP as modification may also an effecton a Certified utility, system or pieces of equipment & a validated technique &process. The process must Describe the action to be taken, such as the need for extent of

qualification or validation to be done. Changes must be officially requested, documented &accredited before implementation

Revalidation: Revalidation must be carried out only when there has been a substantial alternate to the System or to the operational parameter. Routine monitoring & inspection will continue under the same Condition as those that exists during the original validation. Routine renovation or replacement of Component must have A particular written procedure, which should be validated at the time of original Validation II.

CONCLUSION:

It can be concluded that the system is efficient in removing the organic, inorganic and Microbial contamination. Validation and qualification of the system must be performed over a period of Time so as to prove its reliability and robustness of the system for producing water of specified quality with a high degree of assurance.

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