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Validation of Water Purification System for Pharmaceuticals

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ABSTRACT: Water purification systems must be validated to insure that the specified quality of water is consistently produced for use of all purpose as well as formulation, production, analysis, drinking cleaning and to solve the problems arising in the purification system. Validation of water purification system was performed in three phases by applying various chemical and microbiological tests as specified in U.S.P, Ph.Eur. and Int.Ph. Bacteria were isolated, characterised after each treatment, the minimum inhibitory concentration of the main chemical agent used for disinfection over the isolated and identified bacteria was studied.
The results were found to be shown satisfactory and within the specified limit.
KEYWORD: Water purification, validation.

INTRODUCTION

Water is essential for industrial, pharmaceutical and hospital purposes, in the preparation and processing of medicines and other health products and for cleaning and hygiene purposes. There is no pure water in nature, as it can contain up to 90 possible unacceptable contaminants. Every industrial or pharmaceutical plant related to health products must rely on appropriate water purification systems, allowing it to meet its particular requirements, especially as to the problems related to storage and internal distribution. Purified water is obtained from drinking water[1] through a typical water purification system of unit operations. In the year 1978/1990 Brazilian Ministry of Health issued directives to meet the set standard of water purification system. Purified water systems for water must be validated in order to meet the requirements[2] for the purity (ionic and for total organic compounds), even the microbial content. The present work was under taken to examine the efficiency of each treatment stage, to characterize the isolated bacteria.

EXPERIMENT

Materials:

Water purification system, model: Prevue by US Filter.
pH meter, model: Inolab 730 by WTW GmbH.
All other chemicals and reagents used were of Analytical grade.
The Water purification system for validation has got following sampling and distribution points.
Point 1: Storage Tank (feed water)
Point 2: Two multimedia Filters (primary filtration with 1µm cellulose filter for removal of non-dissolved ions)
Point 3: Two water softeners (hardness reduction)
Point 4: One filter of activated carbon bed (for removal of chlorine and low molecular weight organic compound)
Point 5: One 5.0 µm filter (removal of particle materials)
Point 6: One reverse osmosis membrane system (removal of organic and inorganic substances)
Point 7: One continuous deionization column (removal of dissolved minerals and salts)

Point 8: One storage tank (After ozone treated water)
Point 9: Light UV: 254 nm (reduce TOC)
Point 10: Three 0.05 µm filters in parallel (removal of particles and bacteria)
Points 11, 12, 13: Loop of distribution of purified water for consumption

Methodology:

The Validation of water systems Purification was carried out in three phases,

Phase 1 (Investigational Phase) with Duration 2 – 4 weeks, the Design Qualification, Installation Qualification and Operational Qualification were carried out following the standard procedure. The operational parameters and cleaning and sanitization procedures and frequencies were developed.

Sampling was done daily at each point of used and SOPs was prepared for the water system

Phase-2(verifying control) carried out for 4-5 weeks, to ensure the integrity of the system and

Sampling was carried out as in phase 1

Phase-3(verifying long-term control) lest for 1 year, during which the Performance Qualification was demonstrated.

the sampling was done Weekly, Microbiological testing were carried for all the sampling point by ones in a week and Physico-chemical testing were performed for Point 13(Return loop) once in a week.[3]

The sampling was done in sterilised cleaned bottle and care was taken to prevent entry of contamination[4]. The samples were subjected to varies qualitative chemical tests (test for acidity, alkalinity, ammonium, calcium, magnesium, heavy metals, Chloride, Nitrate, Sulphate), Quantitative Chemical Tests (Oxidisable substances, pH, Total organic carbon, Conductivity, Residue on evaporation), were carried out following U.S.P[5], Ph.Eur.[6] and Int.Ph.[7], and microbial limit test as specified in U.S.P[5],and Int.Ph.[7]

The microorganisms were isolation by strict plate method and test were carried out to detect the presence of pathogens likes E. coli, Salmonella, Pseudomonas and Staphylococcus[5, 7].

RESULTS AND DISCUSSION

By analyzing thirteen points of water system (in phase-1, phase-2and ongoing phase-3), in respective intervals we found that the all result are complies with in the limits (fig-1 and fig-2).

In point 2, two multimedia filters parallel to each other offers a highly efficient removal of suspended fragmented matter from the water. So by this process foreign particles are removed from the water.

In point 3, two water softeners of an alternated sodium resin which remove hard minerals from the water.

In point 4, one filter of activated carbon is used to remove chlorine, chloramines, and dissolved organic substances from the water.

In point 5, One 5.0 micro polyethylene micro porous depth screen filter is often used ahead of other water purification operations, such as deionization, and reverse osmosis, as a polishing filter for removing resin, carbon fine colloids, and microorganisms.

In point 6, Reverse osmosis (RO) is the finest filtration available, reverse osmosis removes 90% – 99% of particles, colloids, bacteria, pyrogens, dissolved organic and inorganic substances greater than 200–300 molecular weight (MW) range or larger than the membrane's pore size of 150 to 200 angstroms.

In Point 7, one continuous deionization column that removes dissolved minerals and salts, as well as some dissolved organic matter, from the water stream crossing ion exchange resins.

Point 8, is for Ozone treatment to kills bacteria and viruses on contact and kills algae, mold and yeast spores due to it are act is a strong disinfectant.

In point 9, Ultraviolet Light (λ = 254 nm) is used as a final step in the treatment for the purpose of preventing the growth of microorganisms, and reducing total organic carbon (TOC). This system also help to reduce the excess ozone added in previous system.

In point 10, three 0.05 µm filters are set parallel to each other to remove particles, and bacteria, ranging from 0.05 to 0.5 µm contaminants.

Points of use 11, 12, and 13, every point of use is provided with 3 filters of 0.05 am set parallel to each other. From those points, the purified water for consumption is provided by a loop of distribution and is used for the cleaning and washing of critical devices and areas, the preparation of pharmaceuticals.

CONCLUSIONS

In can be concluded that the purification system is efficient in removing organic, inorganic and microbial contamination.

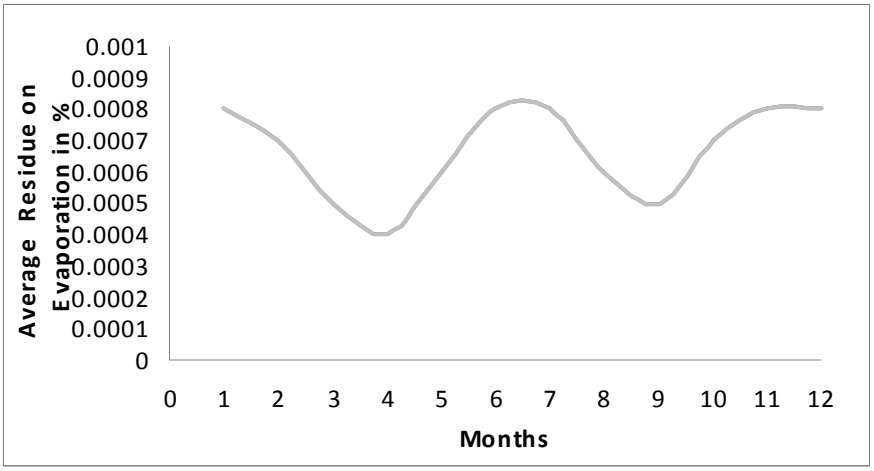

Fig-1: Residue on evaporation of water sample (from may2007 to april2008)

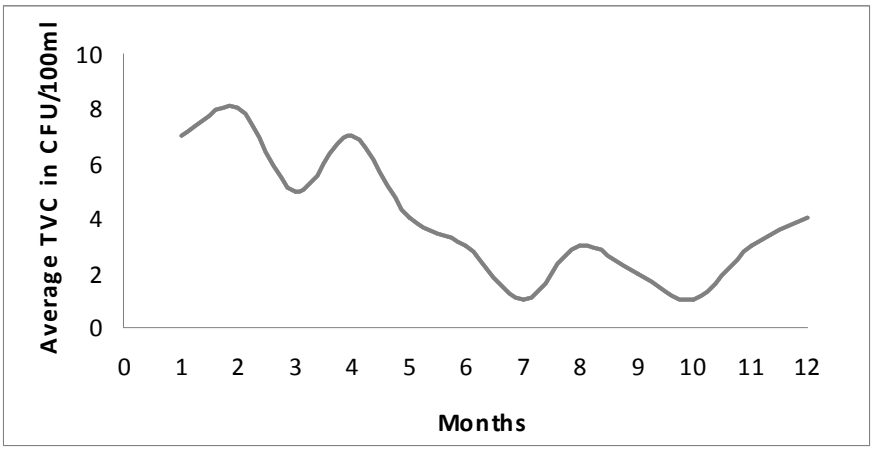

Fig.2: Total viable count of water sample (from may2007 to april2008)

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