Review Article

A REVIEW: APPLICATION OF WATER IN PHARMACEUTICALS

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ABSTRACT

Water is one of the major commodities used by the pharmaceutical industry. It is present as an excipient, or used for reconstitution of products during synthesis, during production of the finished product or as a cleaning agent for rinsing vessels, equipment, primary packaging materials etc. Water used in pharmaceutical purposes purified water, water for injection, sterile water for injection, bacteriostatic water for injection, sterile water for irrigation according to IP and USP. Two types of water Non pharmaceutical or Natural Water. Naturally occurring waters contain dissolved minerals indigenous to the region. Such waters are described as mineral water, Lithia waters, sulfur waters, and so on. Other is Pharmaceutical water- that has undergone carbon filtration, distillation, deionization, reverse osmosis, ultraviolet sterilization, or some combination of these processes to remove almost all minerals and chemical elements. Different grades of water quality are required depending on the different pharmaceutical uses.

Keywords: Pharmaceutical water, Non pharmaceutical water, safe drinking water act, Maximum contaminants levels (MCLs), treatment of water.

INTRODUCTION

Water is a chemical compound needed all plants and animals on earth in order to sustain life. Pure water is a tasteless, odorless, transparent liquid. In small amounts it is colorless, but it takes on a bluish tint in larger amounts Water is an excellent solvent and as a result it usually contains wide variety of dissolved minerals and other chemicals[1,2]. Water is use in water therapy to improve health. It helps in cure of many diseases as like kidney stone, gastro-enteritis, constipation, hyper-acidity, dysentery and urogenital diseases etc. The objective of this series is to discuss some misconceptions regarding grades of water purity[3] and the acceptable methods of water processing.

Pharmaceutical Water

Distilled water has been purified by an evaporation condensation process that removes most but not all impurities. Deionized water has been purified by an ion-exchange process, which removes both positive ions, such as calcium and sodium, and negative ions, such as chlorides and bicarbonates. It is sometimes called de-mineralized water[4]. The specification must take into account the intended use of the water; i.e. water used to formulate a product should contain no organisms capable of growing in the product. Action or alert limits must be based upon validation data and must be set low enough to signal significant changes from normal operating conditions.

Non Pharmaceutical water

Non pharmaceutical waters contain dissolved minerals indigenous to the region. Such waters are described as mineral water, Lithia waters, sulfur waters, and so on. Owners of springs or other source of such waters often claims have not been substantiated[5]. The dissolved bicarbonate constitutes temporary hardness whereas sulfate and chloride constitute permanent hardness. Hard water contains high amounts of calcium and magnesium salts. This causes soap to form curds. Mineral waters can be divided into five main classes: saline, alkaline, ferruginous, sulphurous and potable.

Pure Water

One means of establishing and assuring the purity and safety of water is to set a standard for various contaminants[6,7]. A standard is a definite rule, principle, or measurement which is established by governmental authority. According to the FDA, water that has been produced by distillation, deionization, reverse osmosis or other suitable processes and that meets the definition of Purified Water.

Water used in Pharmaceutical

It is present as an excipient or used for reconstitution of products during synthesis, during production of the finished product or as a cleaning agent for rinsing vessels, equipment, primary packaging materials etc.

The CPMP/CVMP Quality Working Party and Inspectors Working Party have recently reconsidered the use of RO water for the preparation of WFI[8]. They have concluded on the available evidence, that robustness of distillation and concerns remain about the potential risks associated with. Validation and qualification of water purification, storage and distribution systems are a fundamental part of GMP and form an integral part of the GMP inspection [9, 10]. Water is the most commonly used excipient in medicinal products: the minimum quality of water selected depends on the intended use of the product. For convenience the pharmaceutical industry often uses WFI for the preparation of ophthalmic, sterile nasal/ear and

cutaneous preparations[11]. In such situations, Highly Purified Water represents a useful alternative with the added advantage of satisfying the industry's need for large volumes.

Safe drinking water Act

The Federal Safe Drinking Water Act (SDWA) (P.L. 93-523) was signed into law in 1974 and amended several times thereafter[12]. The act authorized the U.S. Environmental Protection Agency (USEPA) to establish a cooperative program among local, state, and federal agencies for drinking water. The primary role of the federal government was to develop national drinking water regulations that protect public health and welfare. A public water system is either a community water system or a noncommunity water system. A Community Water System means a public water system which serves at least 15 service connections used by permanent residents or regularly serves 25 permanent residents[13]. A Noncommunity Water System means a public water system that is not a community water system. Examples include separate water systems which serve motels, restaurants, campgrounds, churches, lodges, rest stops along interstate highways, and roadside service stations.

The New Jersey Safe Drinking Water Act became law in September 1977. The A-280 amendments state that the MCLs for carcinogens shall permit cancer in no more than one in a million persons ingesting that chemical for a lifetime.

Health effects of drinking water contaminants

An acute effect usually follows a large dose of a chemical and occurs almost immediately. Examples of acute health effects are nausea, lung irritation, skin rash, vomiting, dizziness, and, in the extreme, death[14]. They are more likely to cause chronic health effects, effects that occur after exposure to small amounts of a chemical over a long period. Examples of chronic health effects include cancer, birth defects, organ damage, disorders of the nervous system, and damage to the immune system.

Maximum contaminant level

An MCL is the highest amount of a specific contaminant allowed in the water delivered to any customer of a public water system. May be expressed in milligrams per liter (mg/l), which is the same for the purposes of water quality analysis as parts per million (ppm)[15,16].

The process of settling primary standards (MCLs) for drinking water contaminants is based on three criteria:

(1) The contaminant causes adverse health effects;

(2) Instruments are available to detect it in drinking water; and

(3) It is known to occur in drinking water.

Preparation of pharmaceutical waters

The USP states qualifications for sterility and packaging methods that delineate between the various specific types of Water[17]. However, there are two basic types of water preparation, Water for Injection and Purified Water. Considering the required treatment objectives of USP water preparation systems, several categories of treatment warrant examination: dechlorination, ion reduction, bacterial control, and removal of specific impurities[18, 19].

Treatment of water

The treatment of water consists of colleting of water, disinfecting, coagulating, flocculating, setting, fluoridating neutralizer, filtering adsorbing, aerating, fluoridation neutralizing, distributing and finally collection of water for use[20].

Market preparations of water

Aqueous solutions are the most prevalent of the oral solutions. Drugs are dissolved in water along with any necessary flavorings, preservatives, or buffering salts [(21)]. Distilled or purified water should always be used when preparing pharmaceutical solutions, like syrups, aromatic waters, mucilages.

Water as a medicine

Consuming ordinary drinking water by the right method purifies human body. It renders the colon more effective by forming new fresh blood, known in medical terms as Haematopaises. That the mucosal folds of the colon and intestines are activated by this method, is an undisputed fact, just as the theory that new fresh blood is produced by the mucosal fold.[22] The water is used as a medicine in the treatment of constipation, acidity, diabetes, BP & hypertension, cancer, pulmonary tuberculosis, asthma, arthritis, dysentery, kidney stone, lower back pain, burns, common cold etc.

CONCLUSION

Water acts as a solvent for an unusual range of substances. Because of its strong permanent dipole, water often acts as a ligand in complex substances. Water used to formulate a product should contain no organisms capable of growing in the product. Considering the required treatment objectives of USP water preparation systems, several categories of treatment warrant examination: dechlorination, ion reduction, bacterial control, and removal of specific impurities.

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