# WATER TREATMENT PROCESS BY RO,DM,ULTRA FILTRATION WATER FOR INJECTION & LYOPHILIZATION

## INTRODUCTION :

In the pharmaceutical industry, water forms part of the product itself, production processes as well as cleaning. Altogether, this makes heavy demands on water quality. Utility water is insufficient because the water contains salts, organic matter, particles, and microorganisms that pollute or even destroy products and processes. ϖ Process water for the pharmaceutical industry must be of high quality and at the same time meet the regulatory requirements of the pharmacopoeia governing the water treatment equipment. ϖ Softened and demineralized water is used in many processes to ensure uniform water quality of the end product and to facilitate the final validation.

**SOURCE OF WATER:**

- Deep ground water
- Shallow ground water
- Upland lakes and reservoirs
- Rivers,canals and land reservoirs

**TYPES OF PHARMACEUTICAL WATER:**

- Drinking water.
- Purified water.
- Sterile purified water.
- Water for injection.
- Sterile water for injection.
- Bacteriostatic for injection.
- Sterile water for irrigation.
- Sterile water for inhalation.

**STORAGE** Water is generally stored in closed system with an air filter at a temperature of 800c to prevent microorganisms growth.

**PRE-TREATMENT:**

- Pumping and contaminant
- Screening
- Storage
- pre-conditioning
- pre-chlorination.

**METHODS OF WATER TREATMENT(REVERSE OSMOSIS):**

Osmosis is a special case of diffusion in which the molecules are water and the concentration gradient occurs across a semipermeable membrane. The semipermeable membrane allows the passage of water, but not ions (e.g., Na+, Ca2+, Cl-) or larger molecules (e.g: glucose, urea, bacteria).

Reverse osmosis: it is a membrane based process technology to purify water by separating the dissolved solids from feed stream resulting in permeate and rejects stream for a wide range of applications in domestic as well as industrial applications.

It uses semipermeable spiral wound membranes to separate and remove dissolved solids, organic pyrogens, submicron colloidal matter, bacteria from water. Feed water is delivered under pressure through semipermeable membrane, where water permeates through pores and is delivered as purified water called permeate water and impurities are rejected through reject stream.

**BASIC COMPONENTS OF A COMMON REVERSE OSMOSIS SYSTEM**

***Cold Water Line Valve:*** Valve that fits onto the cold water supply line. The valve has a tube that attaches to the inlet side of the RO pre filter. This is the water source for the RO system.

***Pre-Filter (s):*** Water from the cold water supply line enters the Reverse Osmosis Pre Filter first. There may be more than one pre-filter used in a Reverse Osmosis system. The most commonly used pre-filters are sediment filters. These are used to remove sand silt, dirt and other sediment. Additionally, carbon filters may be used to remove chlorine, which can have a negative effect on TFC (thin film composite) & TFM (thin film material) membranes. Carbon pre filters are not used if the RO system contains a CTA (cellulosetriacetate)membrane.

***Reverse Osmosis Membrane:*** The Reverse Osmosis Membrane is the heart of the system. The most commonly used is a spiral wound of which there are two options: the CTA (cellulose tri-acetate), which is chlorine tolerant, and the TFC/TFM (thin film composite/material), which is not chlorine tolerant. ϖ Post filter (s): After the water leaves the RO storage tank, but before going to the RO faucet, the product water goes through the post filter (s). The post filter (s) is generally carbon (either in granular or carbon block form). Any remaining tastes and odours are removed from the product water by post filtration.

***Automatic Shut Off Valve (SOV):*** To conserve water, the RO system has an automatic shutoff valve. When the storage tank is full (this may vary based upon the incoming water pressure) this valve stops any further water from entering the membrane, thereby stopping water production. By shutting off the flow this valve also stops water from flowing to the drain. Once water is drawn from the RO drinking water faucet, the pressure in the tank drops and the shut off valves opens, allowing water to flow to the membrane and waste-water (water containing contaminants) to flow down the drain.

***Check Valve:*** A check valve is located in the outlet end of the RO membrane housing. The check valve prevents the backward flow or product water from the RO storage tank. A backward flow could rupture the RO membrane.

***Flow Restrictor:*** Water flow through the RO membrane is regulated by a flow control. There are many different styles of flow controls. This device maintains the flow rate required to obtain the highest quality drinking water (based on the gallon capacity of the membrane). It also helps maintain pressure on the inlet side of the membrane. Without the flow control very little drinking water would be produced because all the incoming tap water would take the path of least resistance and simply flow down the drain line. The flow control is located in the RO drain line tubing.

***Storage Tank:*** The standard RO storage tank holds up to 2.5 gallons of water. A bladder inside the tank keeps water pressurized in the tank when it is full.

Faucet: The RO unit uses its own faucet in areas where required by plumbing codes an air-gap faucet is generally used. ϖ Drain line: This line runs from the outlet end of the Reverse Osmosis membrane housing to the drain. This line is used to dispose of the impurities and contaminants found in the incoming water source (tap water). The flow control is also installed in this line.

**ADVANTAGES**

Reverse osmosis systems have plenty of advantages. They are friendly to the environment, as they do not produce or use any harmful chemicals during the process. These systems also require a minimal amount of power. Reverse osmosis systems work well in home filtration systems because they are typically small in size.

Taste of the purified water is another distinct advantage. Reverse osmosis removes dissolved minerals and other contaminants that cause water to smell unpleasant, taste poorly and take on unusual colours.

Removal of dissolved minerals, metals and other particles benefits plumbing systems. There is nothing in the water to corrode pipes or collect as sediment

**DISADVANTAGES**

Reverse osmosis treatments require an enormous amount of water. Such systems typically return as little as 5 to 15 percent of the water pushed through the system, which means it also takes a long time to properly treat the water. What's left then exits the system as waste water.

This amount of wastewater can burden home septic systems. Water entering the reverse osmosis system should also be free of bacteria. While reverse osmosis systems do remove nearly all microorganisms, the risk of contamination through tiny leaks or deteriorating parts prevents reverse osmosis systems from being used to remove bacteria.

**DEMINERALIZATION** is the process of removing mineral salts from water by using the ion exchange process. It is completely free of dissolved minerals as a result of one of the process.
Distillation
Deionization
Membrane filtration
Electro dialysis
Or other technologies.
Demineralized water also known as Deionized water.
Deionization is a physical process which uses specially-manufactured ion exchange resins which provides ion exchange site for the replacement of the mineral salts in water with water forming H+ and OH- ions. Because the majority of water impurities are dissolved salts, deionization produces a high purity water that is generally similar to distilled water, and this process is quick and without scale build-up.

**ION EXCHANGE RESINS**
***Cation exchange resins*** will release hydrogen ions (H+)or other positively charged ions in exchange for impurity cations present in water.
***Anion exchange resins*** will release hydroxyl (OH-)ions or other negatively charged ions in exchange for impurity anions present in water.
The application of ion-exchange to water treatment and purification. There are three ways in which ion-exchange technology can be used in water treatment and purification
Deionization types For many laboratory and industrial applications ,high purity water which is essentially free from ionic contaminants is required. Water of this quality can be produced by deionization. The two most common types of deionization are two bed deionization and mixed bed deionization
***The two-bed deionizer*** consists of two vessels  one containing a cation-exchange resin in the hydrogen ($H^+$) form and the other containing an anion resin in the hydroxyl ($OH^-$) form. Water flows through the cation column, whereupon all the cations are exchanged for hydrogen ions. To keep the water electrically balanced, for every monovalent cation,
e.g. $Na^+$, one hydrogen ion is exchanged and for every divalent cation, e.g. $Ca^{2+}$, or $Mg^{2+}$, two hydrogen ions are exchanged. The same principle applies when considering anion-exchange. The de-cationized water then flows through the anion column. This time, all the negatively charged ions are exchanged for hydroxide ions which then combine with the hydrogen ions to form water ($H_2O$).

In ***mixed-bed deionizers*** the cation-exchange and anion-exchange resins are intimately mixed and contained in a single pressure vessel. The thorough mixture of cation-exchangers and anion-

exchangers in a single column makes a mixed-bed deionizer equivalent to a lengthy series of two-bed plants.
Mini DM Plant Specifications : Model: eDM-5 Flow rate: 50 to 80 Lit/hr. Space requirement: very compact- 1 m x 1m Power: NIL, Min inlet pressure 0.5 kg/cm2 Output TDS: Less that 10 ppm Output DM Qty.: 500 Lit at 100 ppm TDS (Best suitable when feed water is corporation water TDS < 100 ppm)

Applications : Food Industry, Pharmaceutical industry, Automobile, laboratory

**Advantages and Limitations**
Like other ion exchange systems, demineralizers require filtered water in order to function efficiently. Resin foulants and degrading agents, such as iron and chlorine, should be avoided or removed prior to demineralization. Anion resins are very susceptible to fouling and attack from the organic materials present in many surface water supplies. Some forms of silica, known as colloidal, or non-reactive, are not removed by a demineralizer.
Variety of cost effective standard models.
Improved aesthetics and rugged design.
User friendly, low maintenance and easy to install.
Simpler distribution and collection systems.
Pre dispatch assembly check.
Less power consumption
Durable •
Economical
High shelf life

**ULTRA FILTRATION**
It is a variety of membrane filtration in which hydrostatic pressure forces a liquid against a semipermeable membrane.
Suspended solids and solutes of high molecular weight are retained while water and low molecular solutes pass through the membrane .

**PROCESS**
It tries to eliminate the need for clarifiers and multimedia filters for waste streams to meet critical discharge criteria or to be further processed by waste water recovery systems for water recovery. Efficient ultrafiltration systems utilize membranes which can be sub-merged, back flushable, air sourced, spiral wound UF/MF membrane that offers superior performance for the clarification of waste water and process water.

**WATER FOR INJECTION(WFI)**

water for injection or WFI is sterile, distilled, non-pyrogenic water available in a single dose container for intravenous administration .WFI is also available as a dispensing container for diluent use. WFI is purified by distillation or by reverse osmosis and contains no added substances.

**FACTORS AFFECTING WFI**

1. Quality of feed water. e.g. Chlorine in water
2. Size of the evaporator.
3. Re-dissolving volatile impurities.
4. Contamination of the vapour and distillate from metal part of the still.

**Pharmaceutical Water Compendial Types**

***1.Bulk forms*** which are typically produced on site where they are used.

A-Purified Water (PW)

B-Water for Injection (WFI)

2***.Packaged Forms*** which are produced, packaged, and sterilized to preserve microbial quality throughout their packaged shelf life.

A-Bacteriostatic WFI

B-Sterile Water for Inhalation

C-Sterile Water for Injection

D-Sterile Water for Irrigation

E-Sterile purified water

**Bulk forms**

***A-Purified water:*** (USP), is used in the preparation of some bulk pharmaceutical chemicals, do not use purified water in preparations intended for parenteral administration. Must be protected from microbial proliferation.

***B-Water for injection, USP:*** conforms with the standards of purified water, USP but is also pyrogen-free. Intended to be used in the manufacture of injectable products which are to be sterilized after their preparation. Intended to be used for 24-hours after its collection. It must be protected from microbial contamination.

**Packaged Forms**

***Bacteriostatic Water for Injection*** is sterile water containing 0.9% benzyl alcohol that is used to dilute or dissolve medications; the container can be reentered multiple times (usually by a sterile needle) and the benzyl alcohol suppresses or stops the growth of most potentially contaminating bacteria. The Bacteriostatic Water can be used in diluting drugs that can subsequently be administered by intravenous, intramuscular, or subcutaneous injection. Bacteriostatic Water for Injection is supplied in a multiple-dose 30 mL plastic containers and not pressurized. It is not used for neonatal medications because of possible blood pressure changes and toxicity of benzyl alcohol. If Bacteriostatic Water is injected intravenously without any diluted compound, it may cause some red blood cell lysis because it is not isotonic. Bacteriostatic Water for Injection, USP must be made approximately isotonic prior to use.. Some side effects that may occur after drugs are added to Bacteriostatic Water include fever, abscess formation, venous thrombosis or phlebitis, tissue necrosis, and infections.

***Sterile Water for Inhalation*** is Water for Injection that is packaged and rendered sterile and is intended for use in inhalators and in the preparation of inhalation solutions. It carries a less stringent specification for bacterial endotoxins than Sterile Water for Injection, and therefore, is not suitable for parenteral applications

***Sterile Water for Injection, USP*** is a sterile, non-pyrogenic preparation of water for injection which contains no bacteriostatic, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. For I.V. injection, add sufficient solute to make an approximately isotonic solution.PH 5.0 to 7.0 Precautions: Do not use unless water is clear, seal is intact and container is undamaged.

***Sterile Water for Irrigation*** Sterile Water for Irrigation is a sterile, distilled, non-pyrogenic water for injection intended only for sterile irrigation, washing, rinsing and dilution purposes. pH 5.5 (5.0 to 7.0). Sterile Water for Irrigation contains no bacteriostat, antimicrobial agent or added buffer and is intended for use only as a single-dose or short procedure irrigation. When smaller volumes are required the unused portion should be discarded. Sterile Water for Irrigation may be classified as a sterile irrigant, wash, rinse, diluent and pharmaceutical vehicle. NOT FOR INJECTION BY USUAL PARENTERAL ROUTES Do not heat container over 66°C (150°F).
***Sterile purified water:*** Is purified water that is packaged and rendered sterile, contains no antimicrobial agent.

**DISTILLATION** is a process of converting water from liquid to gaseous form. TYPES OF DISTILLATION UNIT two types of WFI distillation unit Vapour compression still multiple still effect