U.S. Food and Drug Administration

# Reverse Osmosis

**[DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB***

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**Related Program Areas:**
**Drugs, Medical Devices and Diagnostic Products**

**ITG SUBJECT: REVERSE OSMOSIS**

## Introduction

Reverse osmosis (RO) has been known for more than a century, but it did not become a commercial process until the early sixties when a special membrane was developed (1,2,3,4). Because RO operates at a comparatively low temperature and is relatively energy efficient, it is employed in various applications, e.g., desalination, treatment of waste water, reclamation of minerals, concentration of whey and other food products, and purification of water (5,6). In recent years, **RO has been used increasingly in making processed water for dialysis in hospitals and for certain cosmetics and drugs by pharmaceutical manufacturers** (7,8). In addition to these applications, **RO is capable of producing water of sufficient purity to be used as Water For Injection (WFI) and for the preparation of parenteral solutions** (9,10,11,12). This ITG will focus on the chemical and microbiological quality of water produced by reverse osmosis.

## Definition and Operating Principle

Reverse osmosis is a process which uses a membrane under pressure to separate relatively pure water (or other solvent) from a less pure solution. When two aqueous solutions of different concentrations are separated by a semi-permeable membrane, water passes through the membrane in the direction of the more concentrated solution as a result of osmotic pressure (Figure 1). If enough counter pressure is applied to the concentrated solution to overcome the osmotic pressure, the flow of water will be reversed (Figure 2).

FIG. 1

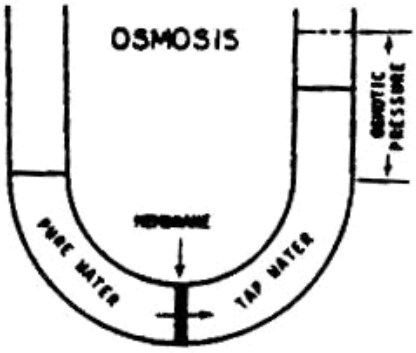
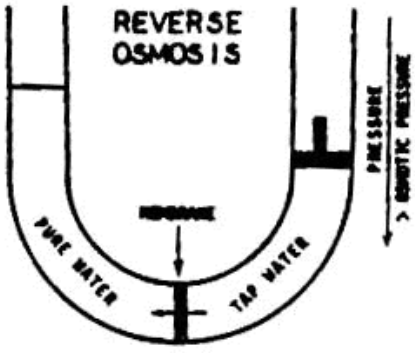



FIG. 2




Water molecules can form hydrogen bonds in the RO membrane and fit into the membrane matrix. The water molecules that enter the membrane by hydrogen bonding can be pushed through under pressure. Most organic substances with a molecular weight over 100 are sieved out, i.e., oils, pyrogens and particulates including bacteria and viruses (13).