most cities and towns where water is purified for drinking usually contains less than 0.1% of total solids, determined by evaporating a 100-mL sample to dryness and weighing the residue (which weighs <100 mg). Drinking water must meet the U.S. Public Health Service regulations with respect to bacteriologic purity. Acceptable drinking water should be clear, colorless, odorless, and neutral or only slightly acidic or alkaline, the deviation from neutral being due to the nature of the dissolved solids and gases (carbon dioxide contributing to the acidity and ammonia to the alkalinity of water).

Ordinary drinking water from the tap is not acceptable for the manufacture of most aqueous pharmaceutical preparations or for the extemporaneous compounding of prescriptions because of the possible chemical incompatibilities between dissolved solids and the medicinal agents being added. Signs of such incompatibilities are precipitation, discoloration, and occasionally effervescence. Its use is permitted in washing, in extraction of crude vegetable drugs, in preparation of certain products for external use, and when the difference between tap water and purified water is of no consequence. Naturally, when large volumes of water are required to clean pharmaceutical machinery and equipment, tap water may be economically employed so long as a residue of solids is prevented by using purified water as the final rinse or by wiping the water dry with a meticulously clean cloth.

Purified Water, USP, is obtained by distillation, ion exchange treatment, reverse osmosis, or other suitable process. It is prepared from water complying with the federal Environmental Protection Agency with respect to drinking water. Purified Water, USP, has fewer solid impurities than ordinary drinking water. When evaporated to dryness, it must not yield more than 0.001% of residue (1 mg of solids per 100 mL of water). Thus, purified water has only 1% as much dissolved solids as tap water. Purified Water, USP, is intended for use in the preparation of aqueous dosage forms except those intended for parenteral administration (injections). Water for Injection, USP; Bacteriostatic Water for Injection, USP; or Sterile Water for Injection, USP, is used for injections. These are discussed in Chapter 15.

The main methods used in the preparation of purified water are distillation, ion exchange, and reverse osmosis; these methods are described briefly next.

Distillation Method

Many stills in various sizes and styles with capacities ranging from about 0.5 to 100 gallons of distillate per hour are available to prepare purified water. Generally, the first portion of aqueous distillate (about the first 10% to 20%) must be discarded because it contains many foreign volatile substances usually found in urban drinking water, the usual starting material. Also, the last portion of water (about 10% of the original volume of water) remaining in the distillation apparatus must be discarded and not subjected to further distillation because distillation to dryness would undoubtedly result in decomposition of the remaining solid impurities to volatile substances that would distill and contaminate the previously collected portion of distillate.

Ion Exchange Method

On a large or small scale, ion exchange for the preparation of purified water offers a number of advantages over distillation. For one thing, the requirement of heat is eliminated and with it, the costly and troublesome maintenance frequently encountered in the operation of the more complex distillation apparatus. Because of the simpler equipment and the nature of the method, ion exchange permits ease of operation, minimal maintenance, and a more mobile facility. Many pharmacies and small laboratories that purchase large volumes of distilled water from commercial suppliers for use in their work would no doubt benefit financially and in convenience through the installation of an ion exchange demineralizer in the work area.

The ion exchange equipment in use today generally passes water through a column of cation and anion exchangers consisting of water-insoluble synthetic polymerized phenolic, carboxylic, amino, or sulfonated resins of high molecular weight. These resins