

### ***Demineralisation of Water***

Many pharmaceutical processes require softened, or demineralized, water in their manufacturing process. Purolite produces the whole range of cation and anion exchange resins required to soften, or totally demineralize, water. These resins are produced to meet FDA and EU regulatory requirements, which specify permitted chemicals used in their manufacture, maximum release of TOC and other chemicals to the product water, together with analytical methods for their detection and the conditions of use of the resin products.

Disinfection of water produced by the ion exchange process for pharmaceutical manufacture is often treated by UV radiation, immediately following ion exchange or at the point of use.

### ***Drug Purification***

Ion exchange resins and adsorbents can be used in many different drug-processing applications, from extraction, isolation and purification to immobilization and stabilisation. Purification alone, for example, may consist of different stages and processes: chromatographic separation; decolorization; deashing; metals removal; and conversion. The process may also take advantage of heterogeneous catalytic reactions in the presence of specific ion exchange catalysts.

The use of ion exchange resins and selective adsorbents results in the advantage of higher purity of the final product, together with minimization of losses, due to the high capacity and selectivity of the resins.

The most suitable ion exchange resins and adsorbents for a given application are selected on consideration of functional groups (weak or strong, acid or base, neutral), porosity, pore diameter, hydrophilic / hydrophobic nature, and ability to resist fouling. Often, the final resin selection is a compromise between the capacity, selectivity and elution profile. Industrial antibiotics production from fermentation broths is a significant area of both ion exchange and synthetic adsorbent use.

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### **Cephalosporin-C**

The manufacture of Cephalosporin-C typically takes place in a number of sequential steps.

A fermentation broth is produced containing 5 to 15 g/l cephalosporin, together with impurities, which is then passed through a weak base anion exchanger to remove residual ions and to decolorize. Decolorization is completed using an adsorbent resin, prior to completely adsorbing Cephalosporin-C onto a second adsorbent resin. The Cephalosporin-C is eluted from the adsorbent resin using isopropyl alcohol, and converted to the sodium form using a strong acid cation resin. Purolite manufactures all resins and adsorbents for these processes

### **Streptomycin Sulphate Production**

The manufacture of Streptomycin is typically carried out in the following sequential steps. A fermentation broth is produced containing Streptomycin in the presence of impurities. The fermentation broth is filtered, and the clear extract passed through a weak acid cation bed to extract the Streptomycin. The Streptomycin is eluted using hydrochloric acid, decolorized and converted to the sulphate form using a strong base anion resin. Freezing and drying achieve purification .

### **Other Processes and Applications**

The extraction of opium alkaloids, enzymes (such as, lysozyme from albumen), heparin, together with the extraction and purification of amino acids, and the decolorization and stabilization of vitamins, are further examples of the application of ion exchange and adsorbent technology in pharmaceutical production.

Sodium form strong acid cation exchangers are used to remove calcium ions from collected blood to inhibit coagulation without the use of additional chemicals.

Carboxylic resins are used to remove zinc ions from blood plasma.

Strong acid cation exchangers are also used in the analytical determination of sodium levels in blood, and in the analysis of urine.

**Purolite** offers hydrophobic adsorbent products for adsorption and reverse phase chromatography to separate proteins, insulin, peptides, nucleonic acids, targeted antibiotics and many more specific pharmaceutical compounds and solutions.

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