Purolite Technical Description

Purolite have developed a range of chromatographic resins, under the "Praesto®" brand name, based on agarose for sale into the pharmaceutical industry where they are used in the production of biosimilars and antibody therapies. The resin is manufactured from agarose, a naturally occurring polysaccharide. Agarose is purified from agar, which is extracted from specific types of seaweed.

The manufacturing process involves taking the powdered polysaccharide and making an aqueous solution with a specific concentration, to give the final properties of the product. The solution is then mixed with an immiscible organic phase using a viscosity modifier to create an emulsion. The process is highly controlled to use the agitation speed in the emulsion to give highly specific particle size distributions. The emulsion is then cooled to create the solid resin bead. The organic phase and viscosity modifier is washed out using a solvent and then water.

The next stage of the process is to take the washed resin and crosslink the batch to increase the rigidity. This process uses a crosslinking agent which is accurately dosed into the process along with reagents to control the pH and added to prevent discolouration of the resin. Temperature control of this stage of the process is essential to achieve optimum crosslinking. The resin is then washed with water to remove excess reagents.

During the process of creating the resin beads, a wide normal distribution of particle sizes is formed. For optimum performance in customer processes, the range of particles is reduced to a specification for each product. Screening removes the fine and coarse resin from the batch. This is carried out using vibrating meshes and using water to wash the resin through. The portion that remains is final product (Praesto® Pure) that can be sold or functionalised into new products.

Praesto® Pure can be converted into an anion (Praesto® Q) or cation exchanger (Praesto® SP).

The process for Praesto® Q is to mix the resin in an aqueous a solution of the ligand. The ligand has dual functionality, one end of the molecule is attached to the resin matrix and the other end performs the anion exchanger role. The process is temperature controlled during the functionalisation process. Reagents are dosed into the process for pH control and added to prevent discolouration of the resin. The resin is then washed with water & solvent to remove excess reagents.

The process for Praesto® SP is two stages. The first stage begins with mixing the resin in water and adding a short length organic molecule to attach to the resin matrix. The process is temperature controlled during the functionalisation process. Reagents are dosed into the process for pH control and added to prevent discolouration of the resin. The resin is then washed with water & solvent to remove excess reagents. The second stage is further functionalisation of the resin with the organic molecule attached to the matrix. This is carried out by mixing the resin in water and adding a salt to functionalise the end of the organic molecule into the cation form. The process is temperature controlled during the functionalisation process. Reagents are dosed into the process for pH control. The resin is then washed with water to remove excess reagents.

The crosslinked "base bead" can be further processed prior to coupling with a protein ligand. This process is the [redacted] & condensation crosslink, which is designed to give an open pore structure for improved mass transfer. The [redacted] step reacts the agarose base bead with [redacted] water, which is immediately followed by the condensation crosslink to link together the [redacted] moieties.

This product is then washed and further processed on smaller scales or sent to customers for their own ligand to be coupled.