QUALITY PURIFIES.



Lewatit® PH 1074 HEP – Reliable purification of high molecular weight biologics from bioprocessing broths and decolorization of sugar syrups

Lewatit® PH 1074 HEP is a new macroporous, strongly basic (type 1) anion exchange resin that is highly efficient at supporting downstream processes for capture, separation, purification, and polishing of selected biological compounds, e.g., deriving from bioprocessing broths or plant- and animal-based extractions. Additionally, it is suitable for decolorization of highly colored liquid sugar syrups. Exhibiting all advantages of an acrylic-based resin, its specially designed matrix provides best adsorption and desorption properties.

Applications and properties

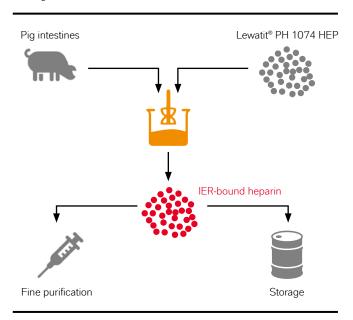
Lewatit® PH 1074 HEP is optimized for biopharmaceutical processing applications to reliably support the capture and purification of high molecular weight compounds. Their significantly larger and complex structures require a special resin matrix design to achieve optimum adsorption capacity and elution efficiency. Due to its strongly basic functional groups, able to interact with, for example, highly sulfated sugar polymers from heparin and derived glycosaminoglycans (GAGs), Lewatit® PH 1074 HEP supports adsorption and ion exchange in the best way. Applications for Lewatit® PH 1074 HEP include:

- Decolorization of syrups from cane sugar production
- Heparin extraction and purification, including heparin storage on resin
- Chondroitin sulfate extraction and purification
- Nadroparin calcium extraction and purification
- Dermatan sulfate extraction and purification
- Decolorization of bioprocessing solutions

Application example – heparin

As one of the well-known biopharmaceuticals, heparin is applied in the prevention of venous thrombosis and as an anticoagulant, e.g., during heart surgery and dialysis. At the present time, heparin is derived mainly from mucosal tissues of slaughtered meat animals, such as porcine intestines. Similar to all GAGs it is characterized by its highly sulfated sugar matrix. For extraction of heparin from crude enzymatically digested intestinal slurries, Lewatit® PH 1074 HEP is added to the mixture. Afterwards it can easily be separated from the solution. For fine purification this procedure can be repeated after a successful elution of heparin from Lewatit® PH 1074 HEP using (alkaline) sodium chloride brine. The product additionally allows storage of resin-bound heparin, delivering corresponding advantages. Production of pharmaceutical-grade heparin is finished by completing alcohol precipitation, bleaching, washing, and oxidation steps.

Figure 1: Crude heparin is extracted from pig intestines by Lewatit® PH 1074 HEP. The resin allows storage of heparin and further purification processing.

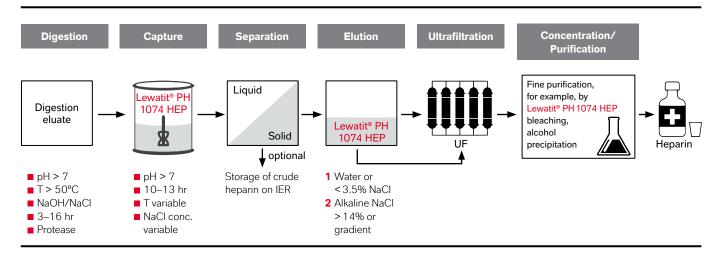


Certifications

The following certificates and statements are available for Lewatit® PH 1074 HEP:

- Non-GMO
- TSE/BSE
- Allergens
- Heavy metals
- Halal
- Kosher
- Council of Europe Resolution ResAP (2004)3 on ion exchange and adsorbent resins used in the processing of foodstuffs
- EU regulation No 1935/2004 of the European Parliament and the Council of the European Union on materials and articles intended to come into contact with food
- EU regulation No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

Figure 2: Schematic representation example of process steps including IER towards the production of pharmaceutical grade heparin.



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