LT BIOTECH UAB
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Lepta SuRe LX

1. Basic product information

Lepta SuRe LX is an affinity chromatography resin for antibody purification, which separates through the specific interaction between antigen and antibody. This chromatography resin is designed to handle high concentrations of monoclonal antibodies. Lepta SuRe LX has the characteristics of high capacity, high flow rate and alkali resistance:
(1) High flow rate, high dynamic binding capacity reduces processing time.
(2) The modified alkali-resistant rProtein A ligand can tolerate 0.5M NaOH for cleaning-in-place (CIP).

2. Chromatography resin parameters

Resin type	Affinity chromatography
Functional group	Alkali-resistant recombinant protein A
Matrix	Highly cross-linked agarose
Median particle size	85 µm
Dynamic binding capacity	>60 mg human IgG/ml *
Recommended flow rate	90~400 cm/h
Maximum flow rate	500 cm/h
Maximum working pressure	5 bar
Working temperature	2–40°C

** Measurement conditions of dynamic binding capacity: packing height, 10 cm; retention time, 6 minutes; test buffer, 0.02M NaH_2PO_4 solution, 0.15M NaCl, pH 7.4, when IgG breakthrough reaches 10% of starting concentration.*

3. Chemical resistance

pH stability*	3–12
Chemical stability	Common aqueous solution used in protein A chromatography

** The physical and chemical properties and functions of the chromatographic resin have no obvious change after being placed in an environment of 40°C and pH 3–12 for 7 days.*

4. Method of use

4.1 Chromatographic conditions

(1) Buffer selection: equilibration/binding/washing buffer: 20 mM sodium phosphate, 150 mM NaCl, pH 7.2. Elution buffer: 0.1M sodium citrate, pH 3.0–3.6.
(2) Flow rate: generally choose a linear flow rate of 90–400 cm/h according to the bed height of the column.
(3) Sample pretreatment: to prevent the sample from clogging the column, the sample needs to be filtered with a 0.45 µm microporous membrane before loading it. It is recommended that the pH and conductivity of the sample

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is adjusted to be consistent with the equilibration buffer (dilution, ultrafiltration can be used and desalting to adjust the pH and conductivity of the sample).

4.2 Chromatography steps

(1) Equilibration: use the equilibration buffer to fully equilibrate the chromatography column until the pH and conductivity are stable and basically consistent with the equilibration buffer. This step usually requires 3–5 column bed volumes (CV).
(2) Sample loading*: according to the binding capacity measured in the small test, determine the sample loading volume and loading amount of the sample on the Lepta SuRe LX.
(3) Washing: use equilibration buffer or other suitable buffer to wash the chromatography column until the UV stabilises and returns to the baseline.
(4) Elution: elute with lower pH.
(5) Re-equilibration: re-equilibrate the chromatography column with the equilibration buffer.

5. Cleaning and sterilisation

Contaminants (such as lipids, endotoxins and proteins) accumulate on the column as the number of uses of the chromatography resin increases. Determine the frequency of CIP according to the degree of contamination of the chromatography resin (if the contamination is considerable, CIP is recommended after each use to ensure repeatability of results and to prolong the working life of the chromatography resin). For different types of impurities and contaminants, the recommended cleaning conditions are as follows:
• Rinse the column with 3 CV of equilibration buffer.
• Flush the column with at least 2 CV of 0.5M NaOH for 10–15 minutes.
• Immediately flush the column with at least 5 CV of sterile equilibration buffer with pH 7–8.

To reduce the microbial load, it is recommended that 0.5~1M NaOH solution is used to treat the chromatographic resin. Treatment time is 15~30 minutes.

6. Storage

Keep the unopened chromatography resin in the original container and store at 4~30°C in a well-ventilated, dry and clean place. Do not freeze. Wash the used column with 2–3 CV of 20% ethanol solution and store at 2~8°C.

7. Destruction and recycling

Since chromatography resin is difficult to degrade in nature, it is recommended that the waste chromatography resin is incinerated to protect the environment. For chromatography resin that has been in contact with biologically active samples such as viruses and blood, follow the local biosafety requirements before destroying or disposing of it.

8. Packing method

Detailed information on resin packaging is available on request. Please contact your local distributor.

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9. Ordering information

Product name: Lepta SuRe LX

Product Cat. No	Package
651-00025	25 ml
651-00100	100 ml
651-00500	500 ml
651-01000	1 L
651-05000	5 L
651-10000	10 L
651-20000	20 L