Characterization of a new albumin binding adsorbent

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Introduction

A new affinity chromatography prototype resin for purification or removal of HSA was investigated. The prototype resin, Capto™ Blue, is made by immobilizing Cibacon™ Blue to a new High Flow Agarose matrix with superior robustness and flow properties compared to existing agarose matrices. A new immobilization chemistry has greatly improved chemical stability and reduced leakage. The combination of high throughput and CIP stability makes this an excellent resin for large scale chromatography.

Stability study

The stability of the resin has been tested for storage in three different concentrations of sodium hydroxide at ambient temperature. Samples have been withdrawn at several occasions and the ligand concentration and HSA capacity have been determined according to standard quality control methods. As can be seen in figure 1 and 2 the HSA capacity is retained after 30 days of storage even though the ligand concentration has decreased 3 to 13 %. It can be noted that no change at all is observed after the contact time of 96 h.

Capto Blue has been challenged in a repetitive way by exposing it to a number of cycles of binding buffer, human serum, wash, elution of HSA and cleaning with 0,5 M NaOH. After every tenth cycle the column was tested for HSA capacity according to standard quality control method. A small decrease in capacity can be observed after 50 cycles. Figure 3.

Application

The selectivity of this new adsorber was investigated by a one step purification of HSA from human serum figure 4. Total load of HSA corresponds to 50 % of the maximum capacity. Load, wash and elute were analyzed with electrophoresis, figure 5. The selectivity is as expected with purity comparable to the reference sample used.

Conclusion

The binding capacity is in the range 30 mg HSA/ml gel. The stability studies show that the resin has a good stability to alkaline conditions which extends functional lifetime and reduces overall production costs. As expected the selectivity for HSA is good. The electrophoreses profiles show that the purity of the eluate is comparable to the commercial reference.

Custom Design Media (CDM)

Custom Design Media (CDM) has over 20 years experience in the preparation of chromatography media.

New chromatography media will be prepared in close collaboration with the customer to fulfill the requirements of their designated process.

Development is fast and CDM can manufacture in process scale within four months under normal circumstances.

Several CDM chromatography media have become standard products and are fully supported with regulatory documentation. All projects run according to ISO 9001.

1 Media definition

- Decide type of matrix, ligand and coupling chemistry
- Define desired product function

2 Media assurance

- Synthesis robustness
- Analytical methods
- Preliminary specifications
- Customer evaluation of sample
- Pilot scale delivery

3 Full scale production and validation

- Scale up to meet the future delivery plan
- Validation of test methods and production
- Validation of production process
- Stability studies, Regulatory Support
- Full scale delivery

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