

# Aggregate Analysis of Recombinant Human Growth Hormone

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## Overview

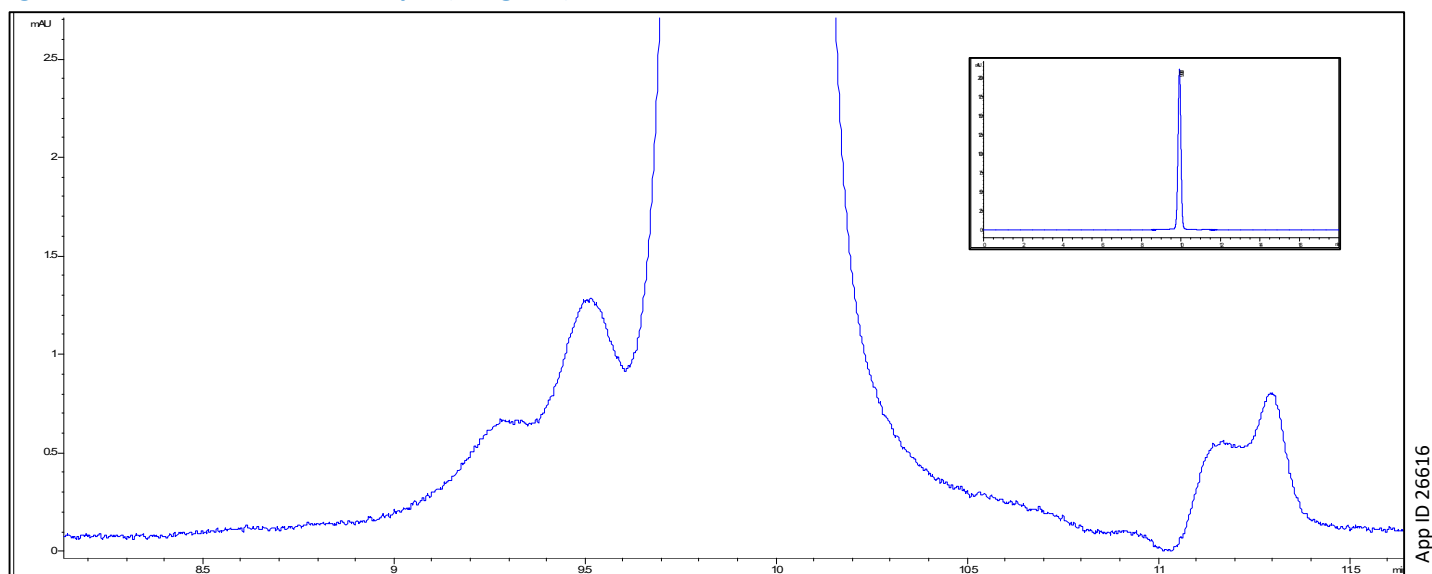
Aggregate analysis by size exclusion chromatography (SEC) of small, recombinant proteins can be challenging as they are more sensitive to non-specific interactions. That is, hydrophobic and/or ionic interactions may lead to poor chromatographic performance including peak tailing or analyte adsorption. Consequently, purity of monomer, as defined as a percentage by integrated peak areas, may be misreported.

In this application note, we demonstrate the SEC separation of recombinant human growth hormone (rhGH), somatotropin. Somatotropin is a recombinant polypeptide with a molecular weight of 22.1 kD. Using a mobile phase composition of moderate phosphate and sodium chloride concentrations, percent purity by peak area was determined to be 99.1%. Good peak shape and separation of high molecular weight aggregate was observed. Further optimization might include addition of organic or other additives to the mobile phase to modulate retention, if separation of excipients such as surfactant was necessary.

## LC Conditions

**Column:** Biozen™ 3  $\mu\text{m}$  dSEC-2, 200 Å  
**Dimension:** 300 x 7.8 mm  
**Part No.:** [00H-4788-K0](#)  
**Mobile Phase:** 50 mM Sodium Phosphate + 300 mM NaCl, pH 6.8  
**Flow Rate:** 1 mL/min  
**Injection Volume:** 10  $\mu\text{L}$   
**Temperature:** 30 °C  
**Detection:** UV @ 280 nm  
**Sample:** Somatotropin, USP Standard 1615708 (5 mg/mL)

**Figure 1. SEC Profile for Somatotropin (5 mg/mL)**



App ID 26616



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