Case study

Addressing customer issue in mAb purification

INTRODUCTION

A leading CDMO company specializing in life sciences research and early-phase drug discovery services experienced a recovery issue for mAb due to incomplete elution.

CHALLENGE

The customer in question identified a decrease in elution recovery to roughly 63% and a sharp "strip peak." Two possible explanations for the phenomenon were proposed. First, elution could have been incomplete. Second, the aggregates from the feedstream could have bound strongly to the resin, separating from monomers.

When the strip fraction was analyzed by SEC-HPLC, over 50% of high molecular weight (HMW) species indicated the presence of a higher quantity of aggregates in the feedstream or, alternatively, the formation of aggregates in strip buffer condition (1M acetic acid).

Avantor Bridgewater Innovation Center

AVANTOR SOLUTION

Upon reviewing the customer's data, an Avantor team performed a quick internal investigational study using two different mAbs, mimicking the customer's process conditions. Study data summary was presented to the customer to resolve the issue.

RESULT – VALUE TO CUSTOMER

No strip peak was detected for the first mAb, but a small strip peak – which was resolved by the addition of a 0.05M NaCl to the elution buffer – was observed for the second mAb. These results, indicating the presence of HMW species in the feedstream, were summarized for the customer.

CUSTOMER BENEFIT

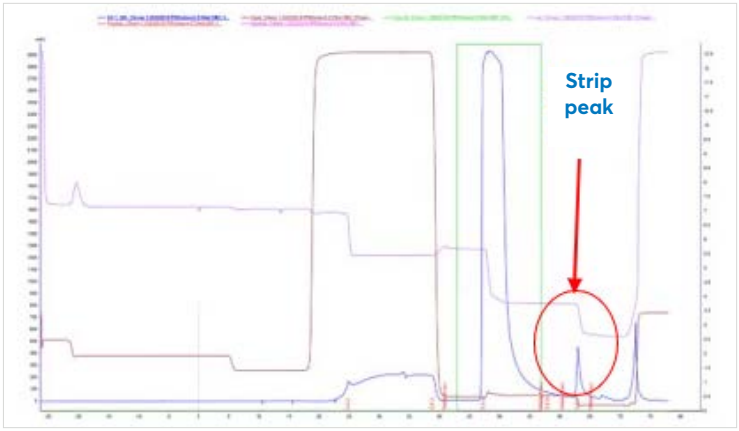
Based on the data collected by the Avantor team, the customer gained important insight that was used toward process optimization. The customer was satisfied with the Avantor team's support and engagement.

DETERMINE PROCHIEVA SEPARATION CAPABILITIES AND BENEFITS

Process parameters

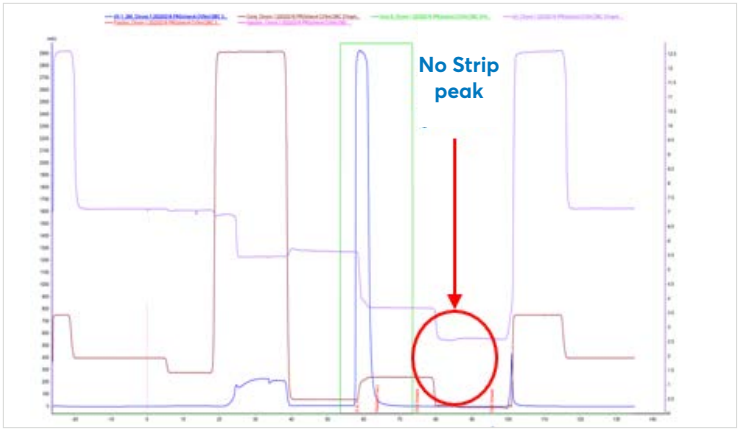
Process step	Buffer	pH	Cond (mS/cm)
Equilibration	50 mM Tris-HAc, 110 mM NaCl	7.2	13.7
Wash 2	50 mM Tris-HAc, 110 mM NaCl, 1 M NaCl	5.5	86.3
Wash 3	50 mM NaAc-HAc	5.5	3.3
Elution	50 mM NaAc-HAc	3.6	3.8
Strip	1 M HAc	-	-
Sanitization	0.1 N NaOH	-	-

Elution buffer



Recovery: ~89%

Elution buffer: 50 mM NaAc-HAc, pH



Recovery: ~92%

Elution buffer: 50 mM NaAc-HAc, 0.05M NaCl, pH 3.6

Outcome

With the addition of 0.05M NaCl to the pH 3.6 elution buffer, recovery improved from 89% to 92%. Additionally, the increased conductivity of ~5 mS/cm elution buffer did not produce an impact on product quality, as purity (SEC) remained above 99%. Affinity is a complex mode of interactions, however, and it is possible that a slight variation in recovery may occur for different molecules, process conditions and feedstream quality.

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