



INTRODUCTION

An experiment was conducted to determine Host Cell Protein (HCP) concentration in drug substance X, according to Array Bridge CHO HCP ELISA protocol. Two batches of drug substance were analyzed and compared with Cygnus CHO ELISA results. Those samples were diluted to 4 mg/ml for analysis.

METHOD

The Array Bridge CHO HCP ELISA protocol was followed for HCP quantitation. HCP spike recovery at 10 ng/mg (40 ng of CHO HCP standards spiked in 4 mg/ml drug substance X) was evaluated.

RESULTS

Table 1. Assay Criteria

Parameter	Criterion	Result	Criterion Met Yes/No
HCP Standard Curve	Similar to that in the method	Pass	Yes
Standard Curve Correlation Coefficient	$R^2 \geq 0.990$	0.998	Yes
Spike Recovery (10 ng/mg spike) Drug Substance X, batch-1	70-130%	98%	Yes
Spike Recovery (10 ng/mg spike) Drug Substance X, batch-2	70-130%	105%	Yes

Table 2. Comparison between Array Bridge CHO HCP ELISA and Cygnus CHO HCP ELISA

Sample ID	Cygnus CHO HCP ELISA ppm (ng/mg)	Array Bridge CHO HCP ELISA ppm (ng/mg)
STL-xxxx1	<2	3
STL-xxxx2	<2	3

CONCLUSION

The analysis meets all system suitability and assay acceptance criteria for the method; the method is suitable for the analysis of HCP in drug substance X.