

# EXAMPLE OF ANALYTICAL TABLE FOR PHASE I DRUG SUBSTANCE PROCESS DEVELOPMENT AND MFG

Assay/Stage	In-process & DS Release						Reference material Characterization	DS stability
	Fermentation	Step 1	Step 2	Step 3	Step 4	Step 5		
Appearance			AD	AD	AD	AD	QC	QC
OD600	AD	AD						
BCA (Total protein)		AD						
A280			AD	AD	AD	AD	QC	QC
ELISA	AD	AD	AD				QC	AD
SDS-PAGE			AD	AD	AD	AD	QC	AD
AEX-HPLC				AD	AD	AD	QC	AD
RP HPLC								
SEC-HPLC			AD	AD	AD	AD	QC	AD
pH			AD	AD	AD	AD	QC	AD
Osmolality						AD	QC	AD
Conductivity							QC	
Residual DNA						AD	QC	AD
Mass Spectrometry				AD			QC	AD
Peptide Mapping test				AD			QC	AD
Residual Host Cell Protein ELISA			AD	AD	AD	AD	QC	AD
Bioburden						AD	QC	AD
Endotoxin			AD	AD	AD	AD	QC	AD

AD	Analytical Development
QC	Quality Control
A-280	Internal Analysis
MS	Outsourced Analysis

Indicate in-line, at-line and retrospective sampling

at-line - where the samples are removed and analyzed close to the process stream