

EXAMPLE OF SPECIFICATION TABLE

Quality Attribute	Test Method	DS	DP
APPEARANCE			
Physical State	Visual Examination	X	X
Clarity & Color	Visual Examination	X	X
Particulate Matter	USP <788>		X
IDENTITY			
Identity	Peptide Mapping	X	
	Product ELISA	X	X
	SDS-PAGE	X	X
STRENGTH			
Potency	Product ELISA	X	X
Quantity	Protein by A280	X	X
PURITY/IMPURITIES			
Molecular Size	SEC-HPLC	X	X
Molecular Charge	IEX-HPLC or IEF	X	X
Residual impurities	RP-HPLC	X	X
Residual HCP	E. coli HCP	X	
Residual Host Cell DNA	qPCR	X	
SAFETY			
Bacterial Endotoxin	USP <85>	X	X
Bioburden	USP <61>	X	
Sterility	USP <71 >		X
GENERAL			
pH	pH Meter	X	X
Osmolality	USP <785>	X	X