



# BIOLOGICS CMC METHODS

METHODOLOGY	PLATFORM METHOD AVAILABLE AT ELEMENT	APPROXIMATE LOQ Limit of Quantitation	APPROXIMATE LOD Limit of Detection
<b>IDENTITY</b>			
Dot Blot	Yes	N/A	N/A
CE-SDS (ProteinSimple Maurice)	Yes	N/A	N/A
Peptide Map by LC-MS	Yes	N/A	N/A
<b>PURITY</b>			
Protein Composition by CE-SDS (ProteinSimple Maurice)	Yes	Varies	~e13 vg/mL
Charge Heterogeneity by cIEF (ProteinSimple Maurice)	Yes	< e12 vg/mL	< e12 vg/mL
Purity by HPLC-DAD	Yes	Varies	Varies
Empty vs Full by BIASeparation	Yes	Varies	Varies
<b>PROCESS IMPURITIES CLEARANCE</b>			
Kanamycin Resistance Cassette by ddPCR	Yes	0.001 pg/μl	0.001 pg/μl
Kanamycin by LC-MS	Yes	5 ppb	<5 ppb
IPTG by LC-MS	Yes	100 ppb	<100 ppb
Penicillin by LC-MS	Yes	10 ppb	1 ppb
Streptomycin by LC-MS	Yes	100 ppb	100 ppb
FBS by ELISA	Yes	300 ppb (0.00003%)	300 ppb (0.00003%)
Triton-X by HPLC-DAD	Yes	50 ppm	20 ppm
Gentamicin by LC-MS	Yes	10 ppb	3 ppb
Clindamycin by LC-MS	Yes	1 ppb	0.1 ppb
Poloxamer 188 by HPLC-RI	Yes	0.002% (2 ppm)	0.001% (1 ppm)
Iodixanol by HPLC-DAD	Yes	200 ppb	50 ppb

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## BIOLOGICS CMC METHODS (CONTINUED)

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<b>PROCESS IMPURITIES CLEARANCE (CONTINUED)</b>			
Host Cell DNA by ddPCR (CHO, HEK293)	Yes	0.02 pg/μl	0.02 pg/μl
Host Cell Protein by ELISA (SF9)	Yes	1 ng/mL	1 ng/mL
Benzonase by ELISA	Yes	0.31 ng/mL	0.06 ng/mL
Cesium Chloride by ICPMS	Yes	1.3 ppm	N/A
Antifoam 204 by HPLC-CAD	Yes	1 ppm	1 ppm
Deoxycholate by LC-MS	Yes	415 ppm	125 ppm
TrypLE by Activity Assay	Yes	5 nmol pNA	5 nmol pNA
Lysozyme by Activity Assay	Yes	Varies	Varies
<b>POTENCY</b>			
Total Protein by BCA	Yes	N/A	N/A
Physical Titer by ddPCR	Under Development	N/A	N/A
Infectious Titer by Cell Culture	Yes	N/A	N/A
Transgene Expression by Cell Culture and Bioactivity	No, case-by-case basis	N/A	N/A
<b>COMPENDIAL</b>			
Osmolality	Yes	N/A	N/A
pH	Yes	N/A	N/A
Appearance	Yes	N/A	N/A
Dynamic Light Scatter by Brookhaven	Yes	N/A	N/A
<b>SAFETY</b>			
Adventitious Agents by Cell Culture	Yes	N/A	N/A
Elemental Analysis by ICPMS	Yes	N/A	N/A
Sterility	Yes	N/A	N/A
Bioburden	Yes	N/A	N/A
Endotoxin	Yes	N/A	N/A
Mycoplasma	Yes	N/A	N/A

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