

<b>Test</b>	<b>Current Specification</b>	<b>Unit of Measure</b>	<b>Testing Methodologies</b>	<b>Preferred method</b>	<b>Expected results</b>
<b>Bacteria and Fungi/Sterility</b>	<b>Not Detected</b>	<b>N/A</b>	<b>USP &lt;71&gt;</b>	<b>compendial or regulatory</b>	<b>not detected</b>
			<b>EP</b>		
			<b>CP</b>		
			<b>JP</b>		
			<b>9CFR113.26</b>		
<b>Mycoplasma</b>	<b>Not Detected</b>	<b>N/A</b>	<b>Barille, MF and Kern, J (1971), P.S.E.M.B. 138,432</b>	<b>compendial or PCR</b>	<b>Not Detected</b>
			<b>21 CFR 620.3</b>		
			<b>EP</b>		
			<b>Realtime PCR</b>		
			<b>CHP &lt;3301&gt;</b>		
			<b>9CFR 113.26</b>		
			<b>MESF/01AA MEQC/SE.1</b>		
<b>Virus Testing - Cytopathic Agents</b>	<b>Not Detected</b>	<b>N/A</b>	<b>9 CFR Part 113.53 c [113.46,</b>	<b>compendial or regulatory</b>	<b>Not Detected</b>
			<b>EP</b>		
			<b>CHP &lt;3604&gt;</b>		
<b>Virus Testing - Hemadsorbing Agents</b>	<b>Not Detected</b>	<b>N/A</b>	<b>9 CFR Part 113.53 c [113.46,</b>	<b>compendial or regulatory</b>	<b>Not Detected</b>
			<b>EP</b>		
			<b>CHP &lt;3604&gt;</b>		
<b>Virus Testing - Bovine Virus Diarrhea</b>	<b>Tested</b>	<b>N/A</b>	<b>9 CFR Part 113.53 c [113.46,</b>	<b>compendial or regulatory</b>	<b>Tested</b>
			<b>EP</b>		

			CHP <3604>		
pH	6.5-8.5	N/A	USP<791>	compendial	7.0 to 8.0
			EP		
			CHP <0631>		
Osmolality	260-350	mOsm/kg	USP<785>	compendial	
			EP CHAPTER 2.2.35		
	<i>Recommended range: 270-330</i>		CP <0632>		
Total Protein	2.5-6 (or 25-60)	g/dl (or mg/ml)	Biuret Method for the Determination of Total Protein... Fund. Of Clin. Chem, pages 302 – 304	Biuret manual or automated	3.0 to 4.0
	3 - 4.5 -5.5		Biuret Method; Dumas et al (1975) Clin Chem 21. 1159		
			CHP < 0731 >		
Endotoxin	Test and Record	EU/ml	USP <85> / USP <151>	compendial or regulatory	10 EU/ml or less
	<30 EU/ml		EP		
	</+10 EU/ml		Guidance on validation of LAL test as an end-product endotoxin test... FDA, December 1987		

			CHP <1143>		
Hemoglobin	Test and Record	gm/dl (or mg/ml)	Fleming, AF and Woolf AJ (1965) Clin. Chem. 12, 67	compendial or Fleming and Woolf	30 or less
	</= 20 -25 mg/dl		CHP <3604>		
	<30EU/ml				
Electrophoretic Pattern	Normal	N/A	Cellulose Acetate	either method	
			Capillary electrophoresis		
Performance Testing	Tested and Acceptable	N/A	Company Specific Method	Company Specific Method	Tested and Acceptable
Radial immunodiffusion		N/A			
Immunoglobulin	<300	ug/ml or mg/dl	Enzyme linked Immunoabsorbent assay (ELISA)		
GGT	<10	IU/l	Automated vet panel		