

Bioniche Teo,
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Bioniche

CERTIFICATE OF ANALYSIS

PRODUCT: Cryoserv
PRODUCT CODE: 0178AJ03
FILL VOLUME: 50mL
LOT NO: 071111
EXPIRY: Oct 2010
DATE OF MANUFACTURE: 18th November 2007
CUSTOMER: Bioniche Pharma
QUANTITY: 2,112 Vials

Cryoserv is a Sterile (According to Ph.Eur. / USP), Endotoxin Free* (According to Ph.Eur. / USP) Non-pyrogenic cryopreservative solution.

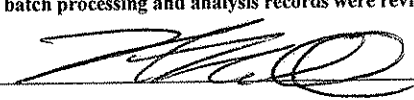
TEST	SPECIFICATION	RESULT		
		B	M	E
Appearance	A clear colourless solution, essentially free from visible signs of contaminants	Complies	Complies	Complies
Assay of Dimethylsulphoxide	Not Less than 99.0 % area	100.0%	100.0%	100.0%
Limit of Dimethyl Sulfone	NMT 0.03 %	ND	ND	ND
Total Impurities	NMT 0.1 %	ND	ND	ND
Identification	GC Chromatogram conforms to standard	Complies	Complies	Complies
Colour	20 APHA units or less	Complies	Complies	Complies
Specific Gravity	1.095 – 1.101	1.099	1.099	1.099
Congealing Temperature	Greater than or equal to 17.5°C	18.2°C	18.4°C	18.4°C
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	Complies	Complies	Complies
Water Content	Not more than 0.5 %	0.11%	0.02%	0.03%
Absorbance (UV)	The spectrum is smooth with no absorption maxima; the absorbance at 275 nm is not more than 0.20 AU, and the absorbance ratios A_{285}/A_{275} and A_{295}/A_{275} are not more than 0.65 and 0.45 respectively	Complies	Complies	Complies
Particulate Matter	Not more than 6,000 particles greater than or equal to 10µm. Not more than 600 particles greater than or equal to 25µm diameter	325	1550	2010
		90	13	40
Extractable Volume	The volume is not less than the labelled volume of 50ml	Complies	Complies	Complies
Sterility	Must be sterile	Sterile	Sterile	Sterile
Bacterial Endotoxins	Not more than 0.5 USP Endotoxin units per ml of Dimethyl Sulfoxide	<0.4 EU/ml	<0.4 EU/ml	<0.4 EU/ml

N/D=None Detected

B=Beginning M=Middle E=End *≤ 0.5 USP EU/mL

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated / manufactured at the above-mentioned site in full compliance with EU / US GMP requirements and with the specifications in the Regulatory Authorisation (Where Applicable). The batch processing and analysis records were reviewed and found to be in compliance with GMP.

Qualified Person
 (Bioniche Teo)



Date: 27 Feb 2008