



BIONICHEPHARMA

CERTIFICATE OF ANALYSIS

PRODUCT: Cryoserv
PRODUCT CODE: 0178AJ02
LOT NO: 091125
PACK SIZE: 6 X 50mL
EXPIRY: Oct 2012
DATE OF MANUFACTURE: 29th November 2009
CUSTOMER: Bioniche USA
QUANTITY: 8400 Vials

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

TEST	SPECIFICATION	RESULT	
		Beginning	End
Appearance	A clear colourless solution, essentially free from visible signs of contaminants	Complies	
Assay of Dimethylsulphoxide	Not Less than 99.0 % area	100.0%	100.0%
Limit of Dimethyl Sulfone	NMT 0.03 %	ND	ND
Total Impurities	NMT 0.1 %	ND	ND
Identification	GC Chromatogram conforms to standard	Complies	
Colour	20 APHA units or less	Complies	
Specific Gravity	1.095 – 1.101	1.099	
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	1.0ml	
Water Content	Not more that 0.5 %	0.09%	
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	A_{285} : 0.071 A_{285} / A_{275} : 0.278 A_{295} / A_{275} : 0.125	
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	587 14	
Extractable Volume	The volume is not less than the labelled volume of 50ml	Complies	
Sterility	Must be sterile	Sterile	
Bacterial Endotoxins	Not more than 0.5 USP Endotoxin units per ml of Dimethyl Sulfoxide	<0.2EU/ml	

ND=None Detected

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. The batch processing and analysis records were reviewed and found to be in compliance with GMP.

Qualified Person *Janet Teo* Date: 13/01/10
 (Bioniche Teo)

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