



BIONICHE PHARMA

CERTIFICATE OF ANALYSIS

PRODUCT: Cryoserv
PRODUCT CODE: 0178AF02
LOT NO: 090810
PACK SIZE: 12 X 10mL
EXPIRY: Jul 2012
DATE OF MANUFACTURE: 20th August 2009
CUSTOMER: Bioniche USA
QUANTITY: 12,084 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	1.100	
Specific Gravity	1.095 – 1.101	0.6ml	
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	0.05%	
Water Content	Not more than 0.5 %	A ₂₇₅ : 0.088 A ₂₈₅ /A ₂₇₅ : 0.399 A ₂₉₅ /A ₂₇₅ : 0.218	
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	588 5	
Particulate Matter	Not more than 6,000 particles greater than or equal to 10µm. Not more than 600 particles greater than or equal to 2.5µm diameter	Complies	
Extractable Volume	The volume is not less than the labelled volume of 50ml	Sterile	
Sterility	Must be sterile	<0.2 EU/ml	
Bacterial Endotoxins	Not more than 0.5 USP Endotoxin units per ml of Dimethyl Sulfoxide		

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
(Bioniche Teo)

Geraldine Gallagher

Date: *Oct 7, 2009*

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