



# BIONICHE PHARMA

## CERTIFICATE OF ANALYSIS

**PRODUCT:** Cryoserv  
**PRODUCT CODE:** 0178AJ02  
**LOT NO:** 100920  
**PACK SIZE:** 6 X 50mL  
**EXPIRY:** Aug 2013  
**DATE OF MANUFACTURE:** 21<sup>st</sup> September 2010  
**CUSTOMER:** Bioniche USA  
**QUANTITY:** 11,040 Vials

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

TEST	SPECIFICATION	RESULT
Appearance	A clear colourless solution, essentially free from visible signs of contaminants	Complies
Assay of Dimethylsulphoxide	Not Less than 99.0 % area	100.0%
Limit of Dimethyl Sulfone	NMT 0.03 %	ND
Total Impurities	NMT 0.1 %	ND
Identification	GC Chromatogram conforms to standard	Complies
Colour	20 APHA units or less	Complies
Specific Gravity	1.095 – 1.101	1.099 g/cm <sup>3</sup>
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	0.5ml
Water Content	Not more that 0.5 %	0.02%
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	$A_{275}$ : 0.07 $A_{285} / A_{275}$ : 0.29 $A_{295} / A_{275}$ : 0.16
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	234 37
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	<0.4 EU/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 John Folan Date: 12/11/10  
 (Bioniche Teo)

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