

BIONICHEPHARMA

CERTIFICATE OF ANALYSIS

PRODUCT: Cryoserv
PRODUCT CODE: 0178AJ02
LOT NO: 100413
PACK SIZE: 6 X 50mL
EXPIRY: Mar 2013
DATE OF MANUFACTURE: 13th April 2010
CUSTOMER: Bioniche USA
QUANTITY: 10,590 Vials

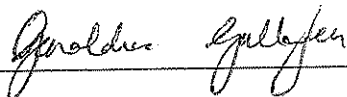
Cryoserv is a Sterile (According to Ph.Eur. / USP), Endotoxin Free* (According to Ph.Eur. / USP) Non-pyrogenic cryopreservative solution.

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	1.096 g/cm ³
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	0.52ml
Water Content	Not more that 0.5 %	0.11%
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} : 0.067 A_{285} / A_{275} : 0.213 A_{295} / A_{275} : 0.061
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	534 54
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
(Bioniche Teo)



Date:

09/06/10

Bioniche Teoranta Kilroe, Inverin, Co. Galway, Republic of Ireland • Ph 353 (0) 91 505600 • Fax 353 (0) 91 593228

Registered in Ireland. No. 130418 Directors: Pat McGrath (Ire), Joseph Damico (U.S.), David Koo (U.S.), James Uths (U.S.)
Jack McGinley (U.S.), Edward Ogata (U.S.), Todd Warnock (U.S.), Steven Thornton (U.S.)