

BIONICHEPHARMA

CERTIFICATE OF ANALYSIS

PRODUCT: Cryoserv
PRODUCT CODE: 0178AF02
LOT NO: 100709
PACK SIZE: 12 X 10mL
EXPIRY: Jun 2013
DATE OF MANUFACTURE: 10th Jul 2010
CUSTOMER: Bioniche USA
QUANTITY: 11,868 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
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	1.0ml
Water Content	Not more that 0.5 %	0.04%
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} : 0.10 A_{285}/A_{275} : 0.41 A_{295}/A_{275} : 0.21
Particulate Matter	Not more than 6,000 particles greater than or equal to 10 μ m.	255
	Not more than 600 particles greater than or equal to 25 μ m diameter	14
Extractable Volume	The volume is not less than the labelled volume of 10ml	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.

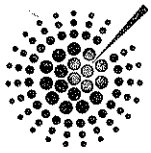
Qualified Person
(Bioniche Teo)

John Folan

Date: 24/09/10

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 Utts (U.S.)
Jack McGinley (U.S.), Edward Ogata (U.S.), Todd Warnock (U.S.), Steven Thornton (U.S.)



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**To USDA / FDA or
To Whom It May Concern**

Shipment Statement for Waiver of USDA, APHIS, VS Import Permit

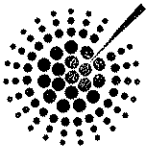
Material Description: **Cryoserv**
10 ml Vial Lot Number 100709

I can confirm the following for the material as listed:-

- (a) It is a cryopreservative solution.
- (b) The material does not contain live livestock and poultry viral agents.
- (c) The material is prepared, packaged and physically labelled in the final dosage form ready for sale to the consumer.
- (d) The material is chemically synthesised.

John Folan
Qualified Person

Date 24/09/10



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RELEASE FOR DISTRIBUTION AUTHORIZATION

PRODUCT NAME: CRYOSERV 10mL

PRODUCT NDC: N/A

PRODUCT LOT NUMBER(S): 100709

PRODUCT EXPIRATION DATE: JUN 2013

QUANTITY TO BE RELEASED FOR DISTRIBUTION: 989 X 12 PACKS

RELEASED FOR DDN's DISTRIBUTION BY: John Folan

TITLE: QA MANAGER / QP

DATE: 24-SEP-2010

Fax to 901-795-0229 (fax to email) or email QARelease@ddnnet.com