

Bioniche Teo,
 Inverin, Co. Galway, Republic of Ireland.
 Telephone: 091/593202.
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Bioniche

CERTIFICATE OF ANALYSIS

PRODUCT: Cryoserv
PRODUCT CODE: 0178AJ02
LOT NO: 070519
EXPIRY: April 2010
DATE OF MANUFACTURE: 21st May 2007
QUANTITY: 10,416 Vials

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

TEST	SPECIFICATION	RESULT		
		B	M	E
Appearance	A clear colourless solution, essentially free from visible signs of contaminants	Complies		
Assay of Dimethylsulfoxide	Not Less than 99.0 % area	100.0%	100.0%	100.0%
Limit of Dimethyl Sulfone	NMT 0.03 %	ND	ND	ND
Total Impurities	NMT 0.1 %	ND	ND	ND
Identification	GC Chromatogram conforms to standard	Complies		
Colour	20 APHA units or less	Complies		
Specific Gravity	1.095 – 1.101	1.100	1.100	1.100
Congealing Temperature	18.0 – 20.0°C	18.5°C	18.7°C	18.4°C
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	Complies		
Water Content	Not more that 0.5 %	0.21%	0.02%	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	Complies		
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	1997	2564	2650
		0	10	37
Extractable Volume	The volume is not less than the labelled volume of 50ml	Complies		
Sterility	Must be sterile	Sterile	Sterile	Sterile
Bacterial Endotoxins	Not more than 0.5 USP Endotoxin units per ml of Dimethyl Sulfoxide	<0.2 EU/ml	<0.2 EU/ml	<0.2 EU/ml

N/D=None Detected B=Beginning M=Middle E=End *≤ 0.5 USP EU/mL

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 current EU / US GMP requirements and with the specifications in the Regulatory Authorisation (Where Applicable). The batch processing and analysis records were reviewed and found to be in compliance with GMP.

Qualified Person  Date: 5th November 2007
 (Bioniche Teo)

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CERTIFICATE OF ANALYSIS

PRODUCT: Cryoserv
PRODUCT CODE: 0178AJ02
LOT NO: 070519
EXPIRY: April 2010
DATE OF MANUFACTURE: 21st May 2007
QUANTITY: 2,190 Vials

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

TEST	SPECIFICATION	RESULT		
		B	M	E
Appearance	A clear colourless solution, essentially free from visible signs of contaminants	Complies		
Assay of Dimethylsulfoxide	Not Less than 99.0 % area	100.0%	100.0%	100.0%
Limit of Dimethyl Sulfone	NMT 0.03 %	ND	ND	ND
Total Impurities	NMT 0.1 %	ND	ND	ND
Identification	GC Chromatogram conforms to standard	Complies		
Colour	20 APHA units or less	Complies		
Specific Gravity	1.095 – 1.101	1.100	1.100	1.100
Congeaing Temperature	18.0 – 20.0°C	18.5°C	18.7°C	18.4°C
Acidity	Not more than 5.0 ml of 0.01N Sodium Hydroxide is consumed	Complies		
Water Content	Not more that 0.5 %	0.21%	0.02%	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	Complies		
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	1997	2564	2650
		0	10	37
Extractable Volume	The volume is not less than the labelled volume of 50ml	Complies		
Sterility	Must be sterile	Sterile	Sterile	Sterile
Bacterial Endotoxins	Not more than 0.5 USP Endotoxin units per ml of Dimethyl Sulfoxide	<0.2 EU/ml	<0.2 EU/ml	<0.2 EU/ml

N/D=None Detected B=Beginning M=Middle E=End *≤ 0.5 USP EU/mL

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 current EU / US GMP requirements and with the specifications in the Regulatory Authorisation (Where Applicable). The batch processing and analysis records were reviewed and found to be in compliance with GMP.

Qualified Person
 (Bioniche Teo)



Date: 21 NOV 2007