

# BIONICHEPHARMA

## CERTIFICATE OF ANALYSIS

**PRODUCT:** Ascorbic Acid Injection USP 500mg/mL  
**PRODUCT CODE:** 0171AJ02  
**LOT NO:** 111002  
**DATE OF MANUFACTURE:** 03<sup>rd</sup> October 2011  
**EXP. DATE:** Sep 2014  
**PACK DESCRIPTION:** 1 x 50ml vial  
**CUSTOMER:** Bioniche Pharma USA  
**QUANTITY:** 18,450 vials

TEST	SPECIFICATION	RESULT
Appearance	A clear, slight yellow solution free from particulate matter.	COMPLIES
Identification	A. The deep blue colour becomes appreciably lighter or is completely discharged within 3 minutes. B. The RT assay peak and standard peak correspond. C. Responds to the flame test for sodium <191>.	COMPLIES
Assay of Ascorbic Acid	90.0 – 110.0% of label claim (L.C. = 500mg/ml of Ascorbic Acid)	105.7%
Limit of Oxalate	No turbidity is produced in 1 minute.	COMPLIES
pH	5.5 – 7.0	6.07
Particulate Matter	Essentially free from particles of foreign matter that can be observed on visual inspection.	COMPLIES
Particulate Matter (For Information Only)	Not more than 6,000 particles, per vial, greater than or equal to 10µm diameter. Not more than 600 particles, per vial, greater than or equal to 25µm diameter.	77 0
Volume of Injection	Minimum extracted volume is greater than the nominal volume.	COMPLIES
Residual Solvents	Materials used in the manufacturing of the batch meet the requirements of USP <467> in full.	COMPLIES
Bacterial Endotoxins	Contains not more than 1.2 USP Endotoxin Units per mg of Ascorbic Acid.	≤0.008 EU/mg
Sterility	Must be sterile.	Sterile

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 and with the specifications in the Regulatory Authorisation (where applicable). The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Qualified Person  
(Bioniche Teo)

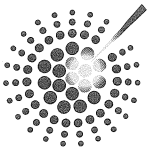
*John Folan*

Date:

*28/11/11*

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

Registered in Ireland. No. 313327 Directors: Matthew Erick (U.S.), John Hannon (Ire),  
Damien Kelly (Ire), John O'Brien (Ire)



**BIONICHEPHARMA**

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

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

Material Description: Ascorbic Acid 500mg/mL

**50ml Vial**

**Lot Number 111002**

**Distributor's NDC:**

**67457-118-50 (Bioniche USA)**

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

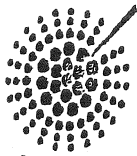
- (a) It is pharmaceutical material that is intended for human use only.
- (b) The material does not contain live livestock and poultry viral agents.
- (c) The material is prepared, packaged and physically labelled in the final dosage form ready for sale to the consumer.

John Foley

28/11/11

Qualified Person

Date



**BIONICHEPHARMA**

RELEASE FOR DISTRIBUTION AUTHORIZATION

PRODUCT NAME: ASCORBIC ACID INJECTION

PRODUCT NDC: 67457-118-50

PRODUCT LOT NUMBER(S): 111002

PRODUCT EXPIRATION DATE: SEP 2014

QUANTITY TO BE RELEASED FOR DISTRIBUTION: 18,450

RELEASED FOR DDN'S DISTRIBUTION BY: John Foley

TITLE: QP

DATE: 28-NOV-2011

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

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