杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

L-Ornithine-L-Asparate(injection)

Batch No.: A140815	**Quantity:** 500G
Manufacture Date: 2014.08.10	**Expiry Date:** 2017.06

TESTS:

Items	Specification	Results
Appearance	White or off white crystalline or powder	White or off white crystalline or powder
Specific Rotation	+27° ~+ 29°	+27.8°
Identification	Blue Purple	Conforms
	The infrared absorption spectrum concordant with the spectrum of Ornithine Asparate reference standard	Conforms
pH	6.0~7.0	6.2
Solution Transmittance	≥ 98%	99.8%
Related Compounds	Impurity A≤ 0.1%	0.03%
	Impurity B ≤ 0.3%	0.09%
	Impurity C ≤ 0.1%	0.02%
	Impurity D≤0.1%	0.01%
	Impurity E≤0.15%	0.07%
	Any unspecified impurity≤ 0.1%	0.03%
	Total impurities≤ 1.0%	0.27%
Amino acid peak area ratio	Peak area ratio between Aspartate and Ornithine should be 2.61~3.01	2.73
Protein	Not be turbid	Conforms
Chloride	≤ 0.03%	Conforms

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Sulfate	≤ 0.02%	Conforms
Ammonium Salt	≤ 0.04%	Conforms
Barium Salt	Both sample tube and reference tube are clear.	Conforms
Loss on drying	≤ 7.0%	2.8%
Residue on ignition	≤ 0.1%	0.07%
Iron Salt	≤ 0.003%	Conforms
Heavy Metal	≤ 10ppm	Conforms
Arsenic Salt	≤ 0.0002%	Conforms
Microbial Limit	Bacteria ≤ 1000cfu/g;	Conforms
	Mold&Yeast ≤ 100cfu/g;	Conforms
	E. coli : Negative	Negative
Endotoxin	<0.06EU/g	Conforms
Assay	NMT 98.0%, calculated on dried basis	99.1%
Conclusion: The results conform with the standard.		

Analyst: Joe Yu **Checker: Agnes Zhong** **QA.Manager: Sun Wenhu**

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