



东北制药集团股份有限公司

NORTHEAST PHARMACEUTICAL GROUP CO., LTD.

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Specification Category: 203

CERTIFICATE OF ANALYSIS

Ascorbic Acid ($C_6H_8O_6$) EP/E300/USP/FCC

Food Additive

BATCH NUMBER	DY 0261421041	MANUFACTURE DATE	Dec.8.2014
BATCH SIZE	3500 kg	TEST DATE OF APPLICATION	Dec.9.2014
QUANTITY	140 Cartons	RETEST DATE	Dec.7.2017

Analysis Items		Specifications	Analysis Results
1.	Characteristics	White or almost white, crystalline powder or colorless crystals	White crystalline powder
2.	Identification	IR: Complies CA: Positive	Complies Positive
3.	Clarity of Solution	Clear	Clear
4.	Colour of Solution	$\leq BY_7$	$< BY_7$
5.	Melting Point	About 190°C	190°C
6.	Assay	99.0% ~ 100.5%	99.7%
7.	Acidity (pH)	2.1 ~ 2.6 (5% aqueous solution)	2.38
8.	Sulphated Ash	$\leq 0.1\%$	0.01%
9.	Specific Rotation	$+20.5^\circ \sim +21.5^\circ$	$+21.05^\circ$
10.	Heavy Metals	$\leq 10\text{ppm}$	$< 3\text{ppm}$
11.	Oxalic Acid	$\leq 0.2\%$	$< 0.2\%$
12.	Copper	$\leq 5\text{ppm}$	$< 5\text{ppm}$
13.	Iron	$\leq 2\text{ppm}$	$< 2\text{ppm}$
14.	Related Substances	Impurity C: $\leq 0.15\%$ Impurity D: $\leq 0.15\%$ Unspecified Impurities: $\leq 0.10\%$ Total Impurities other than C, D: $\leq 0.2\%$	Not detected 0.02% Less than disregard limit Less than disregard limit
15.	Residual Solvents	Methanol $\leq 0.3\%$	0.0118%
16.	Particle-Size	$\leq 30\%$ more than 40 mesh. $\geq 45\%$ between 40 and 80 mesh.	More than 40 mesh: 13% Between 40 and 80 mesh: 73%
17.	Arsenic	$\leq 3\text{ppm}$	$< 3\text{ppm}$
18.	Lead	$\leq 2\text{ppm}$	$< 2\text{ppm}$
19.	Mercury	$\leq 1\text{ppm}$	$< 1\text{ppm}$
20.	Acidity(pH)	2.4~2.8 (2% aqueous solution)	2.52
21.	Loss on Drying	$\leq 0.40\%$	0.05%

We, Northeast Pharmaceutical Group Co., Ltd., certify that this batch of Ascorbic Acid meets the requirements of European Pharmacopoeia 8th, E300, United States Pharmacopoeia 37 and FCCIX., GMO free.

Supervisor 

Final Batch Disposition

Approved

By: 