



Todo Droga
Quimica Mayorista

Specification Category: 203



东北制药集团股份有限公司
NORTHEAST PHARMACEUTICAL GROUP CO., LTD

CERTIFICATE OF ANALYSIS
Ascorbic Acid ($C_6H_8O_6$) EP/E300/USP/FCC
Food Additive

BATCH NUMBER	DY0261521278	MANUFACTURE DATE	Nov.15.2015
BATCH SIZE	3500kg	TEST DATE OF APPLICATION	Nov.16.2015
QUANTITY	140 Cartons	RETEST DATE	Nov.14.2018

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. Assay	99.0% ~ 100.5%	99.6%
4. Acidity(pH)	2.1 ~ 2.6(5% aqueous solution) 2.4 ~ 2.8(2% aqueous solution)	2.3 2.5
5. Clarity of Solution	Clear	Clear
6. Colour of Solution	≤BY ₁	< BY ₁
7. Heavy Metals	≤10ppm	< 3ppm
8. Copper	≤5ppm	< 5ppm
9. Iron	≤2ppm	< 2ppm
10. Lead	≤2ppm	< 2ppm
11. Arsenic	≤3ppm	< 3ppm
12. Mercury	≤1ppm	< 1ppm
13. Specific Rotation	+20.5° ~ +21.5°	+21.0°
14. Melting Point	About 190°C	190°C
15. Sulphated Ash	≤0.1%	0.03%
16. Oxalic Acid	≤0.2%	< 0.2%
17. Related Substances	Impurity C : ≤0.15%	Not detected
	Impurity D : ≤0.15%	0.02%
	Unspecified Impurities: ≤0.10%	Less than disregard limit
	Total Impurities other than C, D: ≤0.2%	Less than disregard limit
18. Residual Solvents	Methanol ≤0.3%	0.0058%
19. Particle-Size	≤30% more than 40 mesh.	More than 40 mesh:24%
	≥45% between 40 and 80 mesh.	Between 40 and 80 mesh:62%
20. Loss on Drying	≤0.40%	0.02%

We, Northeast Pharmaceutical Group Co., Ltd., certify that this batch of Ascorbic Acid meets the requirements of European Pharmacopoeia 8th, E300, United States Pharmacopoeia 38 and FCCIX., GMO free.

Supervisor  2015.11.24

Final Batch Disposition

Approved

By:  2015.11.24



A01-02886