



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

No. 37 Zhonggong Bei Street, Tiexi District, Shenyang, China. Post Code: 110026 FAX: 024-22724536 TEL: 024-22721818

CERTIFICATE OF ANALYSIS

BATCH NUMBER	DY0261610398	MANUFACTURE DATE	Mar.05.2016
BATCH SIZE	3500kg	TEST DATE OF APPLICATION	Mar.05.2016
QUANTITY	140 Cartons	RETEST DATE	Mar.04.2019

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)	2.4 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%	0.02%
16. Oxalic Acid	≤0.2%	< 0.2%
17. Related Substances	Impurity C : ≤0.15% Impurity D : ≤0.15% Unspecified Impurities: ≤0.10% Total Impurities other than C, D:≤0.2%	Not detected 0.01% Less than disregard limit Less than disregard limit
18. Residual Solvents	Methanol≤0.3%	0.0080%
19. Particle-Size	≤30% more than 40 mesh. ≥45% between 40 and 80 mesh.	More than 40 mesh:8% Between 40 and 80 mesh:72%
20. Loss on Drying	≤0.40%	0.02%
21. Total aerobic microbial count	≤10 ³ CFU/g	0"CFU/g" < 100"CFU/g"
22. Yeasts, Moulds	≤10 ³ CFU/g	0"CFU/g" < 100"CFU/g"
23. Coliforms	Not detected	Not detected
24. Staphylococcus aureus	Not detected	Not detected
25. Salmonella	Not detected	Not detected

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

Final Batch Disposition

Approved

[Handwritten signature]

By:

A01-04607