

METAPHARMACEUTICAL

N DE LOTE:

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01/10/2021



SHANDONG TIANLI PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name: Ascorbic Acid

Quantity: 18MT

Batch No.: 012105145

Date of Certificate: May.31, 2021

Date of Manufacture: May.28, 2021

Date of Expiry: May.27, 2024

Items	Standard	Results
Appearance	White crystalline powder	White crystalline powder
Identification	Positive	Positive
Clarity of solution	Clear	Clear
Color of solution	≤BY ₁	<BY ₁
Assay	99.0~100.5%	99.6%
Loss on Drying	≤0.4%	0.05%
*Residue on ignition	≤0.1%	0.03%
Specific rotation	+20.5°~+21.5°	+20.91°
PH(with 2% water solution)	2.4~2.8	2.52
PH(with 5% water solution)	2.1~2.6	2.31
Melting range	About 190℃	191℃
Heavy metals	≤3ppm	<3ppm
*Iron	≤2ppm	<2ppm
*Copper	≤2ppm	<2ppm
*Impurity E	≤0.2%	<0.2%
*Arsenic	≤1ppm	<1ppm
*Lead	≤1ppm	<1ppm
*Cadmium	≤1ppm	<1ppm
*Mercury	≤0.1ppm	<0.1ppm
*Organic volatile impurities	Methanol ≤3000ppm	<3000ppm
*Related Substances	Impurity C≤0.15% Impurity D≤0.15% Any Other Unspecific Impurities Impurity≤0.10% Total Impurity≤0.2%	SHANDONG TIANLI PHARMACEUTICAL CO., LTD Complies QA
*Total Plate Count	≤1,000cfu/g	≤1,000cfu/g

According to BP2021/USP45/FCC12/EP10/E300

Tester Li Jianting

Checked by Mu Yonghua

Approved by Luan Shaohua

*These items are periodic analyses.

