



SHANDONG TIANLI PHARMACEUTICAL CO., LTD.

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03/03/2023

CERTIFICATE OF ANALYSIS

METAPHARMACEUTICA

Product Name: Ascorbic Acid

Quantity: 18MT

Batch No.: 012207081

Date of Certificate: Jul.27, 2022

Date of Manufacture: Jul.24, 2022

Date of Expiry: Jul.23, 2025

N DE LOTE:

0030323

Items	Standard	Results
Appearance	White crystalline powder	White crystalline powder
Identification	Positive	Positive
Clarity of solution	Clear	Clear
Color of solution	$\leq \text{BY}_7$	$< \text{BY}_7$
Assay	99.0~100.5%	99.4%
Loss on Drying	$\leq 0.4\%$	0.05%
*Residue on ignition	$\leq 0.1\%$	0.04%
Specific rotation	$+20.5^\circ \sim +21.5^\circ$	$+20.89^\circ$
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°C	191°C
Heavy metals	$\leq 3\text{ppm}$	$< 3\text{ppm}$
*Iron	$\leq 2\text{ppm}$	$< 2\text{ppm}$
*Copper	$\leq 2\text{ppm}$	$< 2\text{ppm}$
*Impurity E	$\leq 0.2\%$	$< 0.2\%$
*Arsenic	$\leq 1\text{ppm}$	$< 1\text{ppm}$
*Lead	$\leq 1\text{ppm}$	$< 1\text{ppm}$
*Cadmium	$\leq 1\text{ppm}$	$< 1\text{ppm}$
*Mercury	$\leq 0.1\text{ppm}$	$< 0.1\text{ppm}$
*Organic volatile impurities	Methanol $\leq 3000\text{ppm}$	$< 3000\text{ppm}$
*Related Substances	Impurity C $\leq 0.15\%$ Impurity D $\leq 0.15\%$ Any other unspecified impurities $\leq 0.10\%$ Total impurity $\leq 0.2\%$	Complies QA PASS
*Total Plate Count	$\leq 1,000\text{cfu/g}$	$< 1,000\text{cfu/g}$

According to BP2021/USP43/FCC12/EP10/E300

Tester Li Jianting

Checked by Mu Yonghua

Approved by Zheng Yanfei

*These items are periodic analyses.