

石药集团维生药业(石家庄)在CSPC WEISHENG PHARMACEUTICAL (SHIJIAZHUA

Certificate of Analysis

COA NO.: 21071309

Product: Ascorbic Acid

Analysis Standard: BP/USP/FCC/EP/E300

Batch Number: 1210720026

Quantity: 2000kg

Manufacture Date: Jul. 6, 2021

Expiry Date: Jul. 5, 2024

Analysis contents	Analysis standard	Results
Characteristics	White or almost white crystalline	Pass
	powder or colourless crystals	
*Solubility	Freely soluble in water, slightly	Pass
	soluble in ethanol, insoluble inchloroform	
Identification A	Positive reaction	Pass
*Identification B	IR	Pass
Melting point	About 190°C	190°C
Specific rotation	+20.5°~+21.5°	+21.0°
pH (5%, W/V)	2.1-2.6	2.3
*pH (2%, W/V)	2.4~2.8	Pass
*Loss on drying	≤0.1%	Pass
Residue on ignition	≤0.1%	<0.1%
Assay	99.0%~100.5%	99.7%
Clarity of solution	Clear	Pass
Color of solution	≤BY ₇	<by<sub>7</by<sub>
*Impurity E	≤0.2%	< 0.2%
*Impurity C	≤0.15%	<0.15%
*Impurity D	≤0.15%	<0.15%
*Unspecified impurities	≤0.10%	<0.10%
*Total of impurities other than C and D	≤0.2%	<0.2%
*Heavy metal	≤10ppm	<10ppm
*Copper	≤5ppm	<5ppm
*Iron	≤2ppm	<2ppm
*Cadmium(ICP-MS)	≤1ppm	<1ppm
*Mercury(ICP-MS)	≪Ippm	<1ppm
*Lead(ICP-MS)	≤1ppm	<1ppm
*Arsenic(ICP-MS)	≤1ppm	<1ppm
*Total Plate Count	≤1000cfu/g	<1000cfu/g
*Yeast and Molds	≤100cfu/g	<100cfu/g
*Escherichia coli	Negative	Pass
*Salmonella	Negative	Pass
*Staphylococcus Aureus	Negative	Pass
*Residual solvents	Meets requirement	Pass

Conclusion: The above product conforms with BP/USP/FCC/EP/E300 standard.

Rechecker

Writer

Manufacturer: CSPC Weisheng Pharmaceutical (Shijiazhuang) Co., Ltd.

ADD: NO.236 Huanghe Street High-Tech Industrial Development Zone, Shijiazhuang City, Hebei Province, China

* These items as below are sample test.

Address: No. 236 Huanghe Road, Shijiazhuang, Hebei, 050035 China

STATEMENT

July.16th, 2021

To whom it may concern,

We, CSPC WEISHENG PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD, hereby to certify that, the name and batch numbers of the goods we supplied are as follows:

Ascorbic Acid is NLT50% pass through 40mesh and remain on 80mesh: 1210720018、1210720019、1210720020、1210720021、1210720022、1210720023、1210720024、1210720025、1210720026、1210720027、1210720028

The COA version we are currently implementing is BP2021/USP 43/FCC11/EP10 /E300: 1210720018、1210720019、1210720020、1210720021、1210720022、1210720023、1210720024、1210720025、1210720026、1210720027、1210720028

CSPC WEISHENG PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD

July.16th, 2021