



石药集团 维生药业(石家庄)有限公司
CSPC WEISHENG PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.



Certificate of Analysis

COA NO.: 19121716

Product: Ascorbic Acid
Batch Number: 1191050005
Manufacture Date: Oct. 1, 2019

Analysis Standard: BP2019/USP42/FCC11/EP9/E300
Quantity: 2700kg
Expiry Date: Sep. 30, 2022

Analysis contents	Analysis standard	Results
Characteristics	White or almost white crystalline powder or colourless crystals	Pass
*Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in chloroform	Pass
Identification A	Positive reaction	Pass
Identification B	IR	Pass
Melting point	About 190°C	190°C
Specific rotation	+20.5°~+21.5°	+21.1°
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%	99.8%
Clarity of solution	Clear	Pass
Color of solution	≤BY ₇	<BY ₇
*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)	≤1ppm	<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	Absence in 1g	Pass
*Salmonella	Absence in 25g	Pass
*Staphylococcus Aureus	Absence in 25g	Pass
*Residual solvents	Meets requirement	Pass

Conclusion: The above product conforms with BP2019/USP42/FCC11/EP9/E300 standard.

QC

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.