



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



COA NO.: 13081070

Certificate of Analysis

Product: Ascorbic Acid

Analysis Standard: BP2012/USP35/FCC8/ EU No 231/2012

Batch Number: 1130270038

Quantity: 3000kg

Manufacture Date: Feb. 8, 2013

Expiry Date: Feb. 7, 2016

Analysis contents	Analysis standard	Analysis results	Test method
Appearance	White or almost white crystalline powder or colourless crystals	Pass	BP2012
Identification	Positive reaction	Pass	BP2012
Melting point	190°C, approx	190°C	USP35
Specific rotation	+20.5°~+21.5° at 25°C	+21.0°	USP35
pH	2.1~2.6 (in 5% solution)	2.4	BP2012
	2.4~2.8 (in 2% solution)	Pass	E300
Residue on ignition	≤0.1%	0.05%	USP35
Assay	99.0%~100.5%	99.8%	BP2012
Loss on drying	≤0.15%	0.07%	USP35
Heavy metals	≤10ppm	<10ppm	BP2012
Lead	≤2ppm	<2ppm	BP2012
Mercury	≤1ppm	<1ppm	BP2012
Clarity of solution	Clear	Pass	BP2012
Color of solution	≤BY ₇	<BY ₇	BP2012
Impurity E	≤0.2%	<0.2%	BP2012
Copper	≤5ppm	<5ppm	BP2012
Iron	≤2ppm	<2ppm	BP2012
Arsenic	≤3ppm	<3ppm	USP35
Residual solvents	Meets requirement	Pass	USP35
Related substances	Impurity C ≤0.15%	Pass	BP2012
	Impurity D ≤0.15%	Pass	BP2012
	Unspecified impurities: each impurity ≤0.10%	Pass	BP2012
	Total of impurities other than C and D ≤0.2%	Pass	BP2012

Conclusion: The product conforms with the above analysis standard.

QC

Rechecker

Writer

Manufacturer: CSFC Weisheng Pharmaceutical (Shijiazhuang) Co., Ltd.
ADD: NO.236 Huanghe Street High-Tech Industrial Development Zone, Shijiazhuang City,
Hebei Provinces, China
P.O.NO.: 27607