



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



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Certificate of Product Analysis

20051321

Product: Ascorbic Acid Batch No.: 1200451036 Quantity: 900 kg
Analysis standard: EP current edition Date of manufacture: Apr. 23, 2020 Analysis date: Apr. 24, 2020
Date of expiry: Apr. 22, 2023

Analysis contents	Analysis standard	Analysis results	Test method
Characters	White or almost white crystalline powder or colourless crystals	White crystalline powder	EP current edition
Identification B: IR	According to EP monograph	Positive	Ph.Eur. 2.2.24
Identification C: pH	According to EP monograph, 2.1-2.6	2.3	Ph.Eur. 2.2.3
Melting point	About 190°C	190°C	EP current edition
Appearance of solution	Clear solution, \leq BY ₇	Clear solution, $<$ BY ₇	Ph.Eur. 2.2.1, 2.2.2
Iron	\leq 2ppm	$<$ 2ppm	Ph.Eur. 2.2.23
Copper	\leq 5ppm	$<$ 5ppm	Ph.Eur. 2.2.23
Impurity E	\leq 0.2%	$<$ 0.2%	EP current edition
Sulphated ash	\leq 0.1%	0.02%	Ph.Eur. 2.4.14
Specific optical rotation	+20.5 °~+21.5 °	+21.0°	Ph.Eur. 2.2.7
Assay	99.0%~100.5%	99.8%	EP current edition
Residual solvents	Methanol \leq 3000ppm	59ppm	USP<467>
Related substances	Impurity C \leq 0.15%	$<$ 0.05%	Ph.Eur. 2.2.29
Related substances	Impurity D \leq 0.15%	$<$ 0.05%	Ph.Eur. 2.2.29
Related substances	Unspecified impurities: each impurity \leq 0.10%	$<$ 0.05%	Ph.Eur. 2.2.29
Related substances	Total of impurities other than C and D \leq 0.2%	$<$ 0.05%	Ph.Eur. 2.2.29

Conclusion: The product conforms to EP current edition

Additional tests	Retain on 40 mesh	4%	
	Between 40-80mesh	59%	
	Through 20 mesh	100%	In-house
	Through 100 mesh	26%	
	Through 200 mesh	11%	

This batch has been produced, (including packaging and quality control), at the production site mentioned herein, in full compliance with the current EU GMP requirements and with the specifications covered by the CEP No. R1-CEP 2004-019-Rov 05.

QC

Rechecker

Writer