CSPC INNOVATION PHARMACEUTICAL CO., LTD.

CERTIFICATE OF PRODUCT ANALYSIS

No.: REC-ZL-G6114(01)

Product: Caffeine (Anhydrous) Batch No.: 1032112051 Trace: 05 Quantity: 1000 kg

Analysis Standard: BP2020、EP10.0、USP2021、FCC12 Analysis Date: 2021.12.12 Report Date: 2021.12.17

Manu. Date: 2021.12 Retest Date: 2026.11

Analysis Contents	Analysis Standards	Analysis Results
【Characters】		
Appearance	White crystalline powder or silky, white crystals	White crystalline powder
Solubility	Sparingly soluble in water, freely soluble in boiling water, slightly soluble in ethanol (96percent). It dissolves in concentrated solutions of alkali benzoates or salicylates. It sublimes readily	Pass
【Identification】(USP/FCC)		
*A、Infrared Absorption	Conforms to the USP Caffeine RS	Pass
B、The retention time of caffeine peak	Corresponds to the Standard preparation obtained in the Assay	Pass
【Tests】		
Appearance of solution (BP/EP)	Clear 、colourless	Pass
Sulphates (BP/EP)	≤500ppm	<500ppm
Sulphated ash (BP/EP)	≤0.1%	0.03%
Loss on drying (BP/EP)	≤0.5%	0.06%
Organic impurities (USP)		
-Individual impurities	≤0.1%	<0.1%
-Total impurities	≤0.1%	<0.1%
*Related substances (BP/EP)		
-Each impurity A、B、C、D、E、F	≤0.10%	<0.10%
-Unspecified impurities	≤0.10%	<0.10%
-Total impurities	≤0.10%	<0.10%
*Acidity (BP/EP)	Not more than 0.2ml of 0.01M sodium hydroxide	<0.2ml
*Lead (FCC)	≤1mg/kg	<1mg/kg
*Other Alkaloids (FCC)	No precipitate is formed	Pass
*Melting Range (FCC)	235～237.5 ℃	Pass
*Readily Carbonizable Substances (FCC)	Passes Test	Pass
【Assay】(USP)	98.5%～101.0%	100.0%

分析报告专用

Conclusion: The above product conforms to BP2020、EP10.0、USP2021、FCC12 requirement on Caffeine

Remark: "*" means this item is spot test.

Chief of Quality Analysis Dept: 周云雪 Rechecker: 王丹娜 Reporter:

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No.: REC-ZL-G6114(01)

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B、The retention time of caffeine peak	Corresponds to the Standard preparation obtained in the Assay	Pass
【Tests】		
Appearance of solution (BP/EP)	Clear 、colourless	Pass
Sulphates (BP/EP)	≤500ppm	<500ppm
Sulphated ash (BP/EP)	≤0.1%	0.03%
Loss on drying (BP/EP)	≤0.5%	0.08%
Organic impurities (USP)		
-Individual impurities	≤0.1%	<0.1%
-Total impurities	≤0.1%	<0.1%
*Related substances (BP/EP)		
-Each impurity A、B、C、D、E、F	≤0.10%	<0.10%
-Unspecified impurities	≤0.10%	<0.10%
-Total impurities	≤0.10%	<0.10%
*Acidity (BP/EP)	Not more than 0.2ml of 0.01M sodium hydroxide	<0.2ml
*Lead (FCC)	≤1mg/kg	<1mg/kg
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