



CSPC INNOVATION PHARMACEUTICAL CO., LTD.

CERTIFICATE OF PRODUCT ANALYSIS

No.: REC-ZL-G6102(08)

Product: Caffeine (Anhydrous) Batch No.: 1031908452 Quantity: 1000 kg
 Analysis Standard: BP2018, EP9.0, USP41, FCC11 Analysis Date: 2019.08.07 Report Date: 2019.08.12
 Manu. Date: 2019.08 Retest Date: 2023.07

Analysis Contents	Analysis Standards	Analysis Results
【Characters】		
Appearance	White crystalline powder or silky, white crystals	White crystalline powder
【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
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
Organic impurities (USP)		
-Individual impurities	≤0.1%	<0.1%
-Total impurities	≤0.1%	<0.1%
Lead (FCC)	≤1mg/kg	<1mg/kg
Other Alkaloids (FCC)	No precipitate is formed	Pass
Melting Range (FCC)	235~237.5 °C	236.0~236.8°C
Readily Carbonizable Substances (FCC)	Passes Test	Pass
Loss on drying (BP/EP)	≤0.5%	0.11%
Residue on ignition (BP/EP)	≤0.1%	0.04%
【Assay】 (USP)	98.5%~101.0%	99.8%

Conclusion: The above product conforms to BP2018, EP9.0, USP41, FCC11 requirement on Caffeine

Chief of Quality Analysis Dept:

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