



CSPC INNOVATION PHARMACEUTICAL CO., LTD.

CERTIFICATE OF PRODUCT ANALYSIS

No. : REC-ZL-G6114(01)

Product: Caffeine (Anhydrous) Batch No. : 1032308512 Trace:16 Quantity: 1000 kg
Analysis Standard: BP2023、EP11.0、USP2021、FCC12 Analysis Date: 2023.08.17 Report Date: 2023.08.22
Manu. Date: 2023.08 Retest Date: 2028.07

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 (96 percent). 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%	0.04%
Loss on drying (BP/EP)	≤0.5%	0.05%
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 °C	Pass
*Readily Carbonizable Substances (FCC)	Passes Test	Pass
【Assay】 (USP)	98.5%~101.0%	99.8%

Conclusion: The above product conforms to BP2023、EP11.0、USP2021、FCC12 requirement on Caffeine
Remark: "*" means this item is spot test.

Chief of Quality Analysis Dept:

梁彭欣

Rechecker:

孙佳佳

Reporter:

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No.: REC-ZL-G6114(01)

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*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%	0.04%
Loss on drying (BP/EP)	≤0.5%	0.03%
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 °C	Pass
*Readily Carbonizable Substances (FCC)	Passes Test	Pass
【Assay】(USP)	98.5%~101.0%	99.7%
Conclusion: The above product conforms to BP2023、EP11.0、USP2021、FCC12 requirement on Caffeine		
Remark: "*" means this item is spot test.		

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CERTIFICATE OF PRODUCT ANALYSIS

No.: REC-ZL-G6114(01)

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Manu. Date: 2023.08 Retest Date: 2028.07

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【Characters】		
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【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%	0.07%
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 °C	Pass
*Readily Carbonizable Substances (FCC)	Passes Test	Pass
【Assay】 (USP)	98.5%~101.0%	99.6%
Conclusion: The above product conforms to BP2023, EP11.0, USP2021, FCC12 requirement on Caffeine		
Remark: "*" means this item is spot test.		

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