



CSPC INNOVATION PHARMACEUTICAL CO., LTD.

CERTIFICATE OF PRODUCT ANALYSIS

No.: REC-ZL-G6114(01)

Product: Caffeine (Anhydrous) Batch No.: 1032106710 Trace: 01 Quantity: 2000 kg
Analysis Standard: BP2020, EP10.0, USP42, FCC11 Analysis Date: 2021.06.13 Report Date: 2021.06.16
Manu. Date: 2021.06 Retest Date: 2025.05

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%

0.07%

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%

99.9%

Conclusion: The above product conforms to BP2020, EP10.0, USP42, FCC11 requirement on Caffeine

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

Chief of Quality Analysis Dept:

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