

## CSPC INNOVATION PHARMACEUTICAL CO., LTD.

## CERTIFICATE OF PRODUCT ANALYSIS

No.: REC-ZL-G6102(08)

Product:   Caffeine   (Anhydrous)			
Manu. Date:         2019.09         Retest Date:         2023.08           Analysis Contents         Analysis Standards         Analysis Results           [Characters]         White crystalline powder or silky, white crystals         White crystalline powder or silky, white crystals           [Identification] (USP/FCC)         A. Infrared Absorption Conforms to the USP Caffeine RS         Pass           B. The retention time of caffeine peak preparation obtained in the Assay         Pass           [Tests]         Appearance of solution (BP/EP)         Clear colourless         Pass           Sulphates (BP/EP)         ≤500ppm         <500ppm         <500ppm           Related substances (BP/EP)         ≤500ppm         <0.10%         <0.10%           -Unspecified impurities         <0.10%         <0.10%         <0.10%           -Unspecified impurities         <0.10%         <0.10%         <0.10%           -Total impurities         <0.10%         <0.10%         <0.10%           -Total impurities         <0.1%         <0.1%         <0.1%           -Tot	Product: <u>Caffeine (Anhydrous</u>	Batch No.: 1031909716 Trace: 02	
Analysis Contents  [Characters]  Appearance  White crystalline powder or silky, white crystals  [Identification] (USP/FCC)  A. Infrared Absorption B. The retention time of caffeine peak preparation obtained in the Assay  [Tests]  Appearance of solution (BP/EP) Clear colourless Sulphates (BP/EP) Sulp	Analysis Standard: BP2018, EP9.0	<u>O. USP41, FCC11</u> Analysis Date: <u>2019.09.08</u>	Report Date: <u>2019.09.12</u>
Characters   Appearance   White crystalline powder or silky, white crystals	Manu. Date: 2019.09	Retest Date: <u>2023.08</u>	
Appearance White crystalline powder or silky, white crystals  [Identification] (USP/FCC)  A. Infrared Absorption Conforms to the USP Caffeine RS Pass B. The retention time Corresponds to the Standard Pass  [Itests]  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%	Analysis Contents	Analysis Standards	Analysis Results
Composition   Conforms to the USP Caffeine RS   Pass	[Characters]		
A. Infrared Absorption   Conforms to the USP Caffeine RS   Pass	Appearance	White crystalline powder	White crystalline powder
A. Infrared Absorption		or silky, white crystals	
B. The retention time Corresponds to the Standard Pass of caffeine peak preparation obtained in the Assay  [Tests]  Appearance of solution (BP/EP) Clear colourless Pass Sulphates (BP/EP) \$\leq 500ppm\$  Related substances (BP/EP)  -Each impurity A, B, C, D, E, F \$\leq 0.10\% \$\l	【Identification】(USP/FCC)		
of caffeine peak preparation obtained in the Assay  [Tests]  Appearance of solution (BP/EP) Clear colourless Pass Sulphates (BP/EP) \$500ppm \$  Related substances (BP/EP)  -Each impurity A, B, C, D, E, F \$0.10% \$0	A, Infrared Absorption	Conforms to the USP Caffeine RS	Pass
Tests   Appearance of solution (BP/EP)   Clear \ colourless   Pass	B. The retention time	Corresponds to the Standard	Pass
Appearance of solution (BP/EP)  Sulphates (BP/EP)  Related substances (BP/EP)  -Each impurity A, B, C, D, E, F  -Unspecified impurities  Solution (BP/EP)  Not more than 0.2ml of 0.01M sodium hydroxide  Organic impurities (USP)  -Individual impurities  Solution  Organic impurities  Solution  Organic impurities  Solution  Organic impurities  Solution  Organic impurities  Solution  Solu	of caffeine peak	preparation obtained in the Assay	
Sulphates (BP/EP)       ≤500ppm       <500ppm	[Tests]		
Sulphates (BP/EP)       ≤500ppm       <500ppm	Appearance of solution (BP/E	P) Clear 、colourless	Pass
Related substances (BP/EP)			<500ppm
-Bach Impurity A, B, C, B, E, F  -Unspecified impurities			
-Unspectified impurities	-Each impurity A, B, C, D, E	、F ≤0.10%	<0.10%
-Total impurities	-Unspecified impurities	≤0.10%	<0.10%
Organic impurities (USP)  -Individual impurities  -Total impurities  Lead (FCC)  Other Alkaloids (FCC)  Melting Range (FCC)  Readily Carbonizable Substances (FCC)  Residue on ignition (BP/EP)  (Assay) (USP)  Not more than 6.2mT of clean		≤0.10%	<0.10%
-Individual impurities	Acidity (BP/EP)	Not more than 0.2ml of 0.01M sodium hydrox	ide <0.2ml
-Individual impurities  -Total impurities  40.1%  Lead (FCC)  Other Alkaloids (FCC)  Melting Range (FCC)  Readily Carbonizable Substances (FCC)  Loss on drying (BP/EP)  Residue on ignition (BP/EP)  【Assay】 (USP)  -Total impurities  40.1%  -Img/kg  Pass  236.0~236.7°C  Passes Test  Pass  40.5%  0.11%  0.04%  99.7%	Organic impurities (USP)	<b>发生的复数形</b>	
-Total impurities	-Individual impurities	≤0.1%	<0.1%
Lead (FCC)       ≤1mg/kg       <1mg/kg		≤0.1%	<0.1%
Other Alkaloids (FCC)         No precipitate is formed IIII         Pass           Melting Range (FCC)         235~237.5 °C         236.0~236.7 °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%         99.7%		≤1mg/kg	<1mg/kg
Melting Range (FCC)       235~237.5 °C       236.0~236.7 °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%       99.7%		No precipitate is formed 权音专用	Pass
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%       99.7%	AMPENISTRATION OF THE PROPERTY	235~237.5 °C	236. 0∼236. 7°C
Loss on drying (BP/EP) ≤0.5% 0.11%  Residue on ignition (BP/EP) ≤0.1% 0.04%  【Assay】 (USP) 98.5%~101.0% 99.7%	Management of the control of the con	nces (FCC) Passes Test	Pass
Residue on ignition (BP/EP)       ≤0.1%       0.04%         【Assay】(USP)       98.5%~101.0%       99.7%	PO 00 00 00 00 00 00 00 00 00 00 00 00 00		0. 11%
[Assay] (USP) 98.5%~101.0% 99.7%		≤0.1%	0. 04%
DROOM FRO A MCD41 FCC11 requirement on Caffeine		98.5%~101.0%	99. 7%
		duct conforms to BP2018、EP9.0、USP41、FCC11	requirement on Caffeine

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