

FINISHED PRODUCT (BULK DRUG)

CERTIFICATE OF ANALYSIS

(Under the Drugs & Cosmetics Act 1940 and Drugs & Cosmetics Rules 1945 thereunder)

Name of the Product: **CAFFEINE BP (ANHYDROUS)**

Batch No. : CB-221804

Date of Sampling : 14/12/22

Batch Size : 800 Kg

Qty. Sampled : 100 gm

A.R. No : APL3/FP/223224

Date of Release : 17/12/22

Mfg. Date : Dec'2022

Exp. Date : Nov'2027

Testing specification No: **QCD/SP/FP/CF/02**

Sr.No.	TESTS	SPECIFICATIONS	RESULTS
1	Description	White or almost white, crystalline powder or silky, white or almost white, crystals.	White crystalline powder.
2	Solubility	Sparingly soluble in water, Freely soluble in boiling water; slightly soluble in ethanol (96%). It dissolves in concentrated solution of alkali benzoates or salicylates.	Complies
3	Identification First Identification; A, B, E	A: Melting point: 234°C to 239°C B: Infrared spectrum obtained with sample preparation should be concordant that obtained with standard preparation E: It complies the test for loss on drying.	236.4°C Infrared spectrum obtained with sample preparation is concordant that obtained with standard preparation Complies
4	Appearance Of Solution	Solution S is clear and colourless.	Complies
5	Acidity	Not more than 0.2 ml of 0.01 M Sodium hydroxide is required to change the color of indicator to blue	0.06 ml of 0.01M Sodium hydroxide is required.
6	Related Substances (By HPLC)	Liquid chromatography.(Unspecified impurity) Impurity A NMT 0.10 % Impurity C NMT 0.10 % Impurity D NMT 0.10 % Impurity F NMT 0.10 % Other impurity: (NMT 0.10 %) Total Impurity: (NMT 0.10 %)	BDL BDL ND BDL ND BDL
7	Sulphate	Not more than 500 ppm	Less than 500 ppm
8	Heavy Metals	Not more than 20 ppm	Less than 20 ppm
9	Loss On Drying	Not more than 0.5 %	0.22 %
10	Sulphated Ash	Not more than 0.1%	0.04 %
11	Assay	Caffeine contains Not less than 98.5% and Not more than the equivalent of 101.5% of 1,3,7-Trimethyl -3,7-dihydro-1H-purine-2, 6-dione, Calculated with reference to the dried substances.	99.8 %
12	Additional test		
	Particle size	100 % passes through 20 mesh	Complies

REMARK: The sample complies / ~~Does not comply~~ with B.P. standard specifications

BDL = Below Detection Limit, ND = Not Detected

Analysed By : Nitin Raut	Approved By : Bijay Kumar Jha	Authorized By: Zunjar S. Bagal
Designation: QC Chemist	Designation: QC Manager	Designation: Manager Q.A.
Sign & Date:  17/12/22	Sign & Date:  17/12/22	Sign & Date:  17/12/22

FORMAT NO: QCD/GE/F/21/09/00

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