

FINISHED PRODUCT (BULK DRUG)

CERTIFICATE OF ANALYSIS

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

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

Batch No. : CB-240640

Date of Sampling : 28/07/24

Batch Size : 800 Kg

Qty. Sampled : 150 gm

A.R. No : APL3/FP/241921

Date of Release : 31/07/24

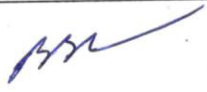


Mfg. Date : Jul'2024

Exp. Date : Jun'2029

Testing specification No: QCD/SP/FP/CF/01

S.R. No	TESTS	SPECIFICATIONS	RESULTS
1.	Description	Silky, white crystals, white glistening needles or a white Crystalline powder, Odourless; sublimes readily.	White Crystalline powder, Odourless.
2.	Solubility	Freely soluble in chloroform and in boiling water; sparingly soluble in water and in ethanol (95%); slightly soluble in ether.	Complies
3.	Identification Tests A is carried out.	A: Determine by infrared absorption spectrophotometer (2.4.6), after drying the substance under examination, at 100° for 1 hour. Compare the spectrum with that obtained with caffeine RS or with the reference spectrum of caffeine.	Complies
4.	Appearance Of Solution	1.0 % w/v solution is clear and colourless.	Solution is clear and colourless.
5.	Acidity Or Alkalinity	NMT 0.1 ml of 0.02M sodium hydroxide is required to change to blue colour.	0.03 ml of 0.02M sodium hydroxide is required to change to blue colour.
6.	Related Substance (By HPLC)	Individual Impurity NMT 0.1 %	0.015 %
		Total impurities NMT 0.1 %	0.027 %
7.	Arsenic	Not more than 3 ppm	Less than 3 ppm
8.	Heavy Metals	Not more than 20 ppm	Less than 20 ppm
9.	Sulphated Ash	Not more than 0.1%	0.05 %
10.	Loss on Drying	Not more than 0.5%	0.25 %
11.	Assay (By HPLC)	Caffeine contents, Not less than 98.5 % and Not more than 101.5 % of C ₈ H ₁₀ N ₄ O ₂ , Calculated on the dried basis.	99.6 %

REMARK: The sample complies /Does not comply with IP standard specifications.

Prepared By : Bhushan Chaudhari	Approved By : Mandar Mhatre	Authorized By: Zunjar S. Bagal
Designation: QC Executive/Designee	Designation: QC Manager/Designee	Designation : QA Manager/Designee
Sign 	Sign 	Sign 
Date: 31/07/24	Date: 31/07/24	Date: 31/07/24

FORMAT NO: QCD/GE/F/21/09/01

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