AARTI PHARMALABS

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	**A.R. No**	:	APL3/FP/241921
Date of Sampling	:	28/07/24	**Date of Release**	:	31/07/24
Batch Size	:	800 Kg	**Mfg. Date**	:	Jul'2024
Qty. Sampled	:	150 gm	**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 $C_8H_{10}N_4O_2$, 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

AARTI PHARMALABS LIMITED

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