Essentially Natural
Products with purpose.

The Essentially Natural Domain (Pty) Ltd | Reg. No. 2014/170069/07
Unit 14, Duville Business Park, 8 Arum Lily Street, Durbanville, Cape Town, South Africa 7550
www.essentiallynatural.co.za (T) 021 976 9116 (E) support@essentiallynatural.co.za

Name of the Product: CAFFEINE BP/USP (ANHYDROUS)

Batch No.	:	CB-211694	**A.R. No**	:	AIL3/FP/212976
Date of Sampling	:	24/12/21	**Date of Release**	:	30/12/21
Batch Size	:	800 Kg	**Mfg. Date**	:	Dec'2021
Qty. Sampled	:	100 gm	**Exp. Date**	:	Nov'2026

Testing specification No: QCD/SP/ FP/CF/27

S.R. No	TESTS	SPECIFICATIONS	RESULTS
1.	**Description**	White or almost white, crystalline powder or silky, white or almost white crystals	White crystalline powder
2.	**Solubility**		
a)	**(As per BP)**	Sparingly soluble in water, Freely soluble in boiling water, slightly soluble in ethanol (96%).It dissolve in concentrated solution of alkali benzoates or salicylates	Complies
b)	**(As per USP)**	Sparingly soluble in water and in alcohol, Freely soluble in chloroform, slightly soluble in ether.	Complies
3.	**Identification**		
i)	**(As per BP)**	**a:** Melting pointes: 234 °C to 239°C	236.8°C
		b: Infrared spectrum obtained with sample preparation should be concordant that obtained with standard preparation	Complies
		e: It complies the test of loss on drying	Complies
ii)	**(As per USP)**	**a:** Infrared spectrum obtained with sample preparation should be concordant that obtained with standard preparation	Infrared spectrum obtained with sample preparation is concordant that obtained with standard preparation
		b: The retention time of the caffeine peak in the chromatogram of the assay preparation correspond to that in the chromatogram of the standard preparation or obtained in the assay.	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	0.07 ml of 0.01 M Sodium hydroxide is required.

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S.R. No	TESTS	SPECIFICATIONS	RESULTS
6.	Related substances (As per BP)	Impurity A: NMT 0.10 %	BDL
		Impurity C: NMT 0.10 %	BDL
		Impurity D: NMT 0.10 %	ND
		Impurity F: NMT 0.10 %	BDL
		Other impurity: (NMT 0.10 %)	ND
		Total impurity: (NMT 0.10%)	BDL
7.	Chromatographic impurity (as per USP)	Individual Impurity NMT 0.1%	0.02 %
		Total Impurity NMT 0.1%	0.04 %
8.	Sulphate	Not more than 500 ppm	Complies
9.	Heavy metals (As per USP)	Not more than 0.001 %	Complies
10.	Loss on drying	Not more than 0.5 %	0.22 %
11.	Water	Not more than 0.5%	0.21 %
12.	Sulphated Ash	Not more than 0.1 %	0.04 %
13.	Residue on ignition	Not more than 0.1%	0.04 %
14. a)	Assay (As per BP) (On anhydrous basis)	Not less than 98.5% and Not more than 101.5% of $C_8H_{10}N_4O_2$, Calculated on the anhydrous basis	99.9 %
b)	Assay (As per USP) (On anhydrous basis)	Not less than 98.5% and Not more than 101.0% of $C_8H_{10}N_4O_2$, Calculated on the anhydrous basis	99.8 %
15.	Microbial Limit Test		
	Total fungal/yeast and mould count	Not more than 100 cfu/gm	Less than 10 cfu/gm
	Total Bacterial count	Not more than 1000 cfu/gm	Less than 10 cfu/gm
	Pathogens		
	E. Coli	absent/gm	Absent
	Salmonella	absent/gm	Absent
	s. aureus	absent/gm	Absent
	p. aeruginosa	absent/gm	Absent
	Candida Albicans	absent/gm	Absent
REMARKS: The material complies / ~~Does not comply~~ BP /USP Specification.			

BDL = Below Detection Limit, ND = Not Detected

Analysed By : Prafulla Girase	Approved By : Bijay Kumar Jha	Authorized By: Zunjar S. Bagal
Designation: QC Chemist	Designation: QC Manager	Designation: Manager Q.A.
Sign & Date: 30/12/20	Sign & Date: 30/12/20	Sign & Date: 30/12/20