AARTI INDUSTRIES LIMITED
Factory Address : Unit - V, L-28/29, MIDC Area, Tarapur, Tal. Palghar, Dist. Palghar - 401 506, Maharashtra.

CERTIFICATE OF ANALYSIS

Name of Product: Caffeine Anhydrous BP/Ph.Eur./USP

Batch No.	**CF/1630143 (M-01)**	**A.R.No.**	**AIL5/FP/160353**
Mfg. Date	**Aug.2016**	**Date of Sampling**	**17.08.16**
Exp. Date	**Jul. 2021**	**Date of Analysis**	**23.08.16**
Batch Qty.	**1075.00 Kg**	**Date of Release**	**23.08.16**

Sr.No.	Test	Specification	Results
7.	Assay by HPLC as per USP	Not less than 98.5% and not more than 101.0% on anhydrous basis.	99.81%
8.	Organic Impurities By HPLC as per USP	Individual Impurities : NMT 0.1%.	0.02%
		Total Impurities : NMT 0.1%	0.04%
9.	Sulfate as per BP/Ph.Eur.	Not more than 500 ppm	Complies
10.	Heavy Metals as per BP/Ph.Eur.	Not more than 20 ppm.	Complies
11.	Heavy Metals as per USP	Not more than 10 ppm.	Less than 10 ppm
		1) Arsenic (ICP-MS) < 1.0 ppm	Not Detected
		2) Cadmium (ICP-MS) < 1.0 ppm	Not Detected
		3) Lead (ICP-MS) < 2.0 ppm	Not Detected
		4) Mercury (ICP-MS) < 0.1 ppm	Not Detected
12.	Loss on drying as per BP/Ph.Eur.	Not more than 0.5%.w/w	0.33%
13.	Water Determination as per USP	Not more than 0.5%.	0.30%
14.	Sulfated ash as per BP/Ph.Eur.	Not more than 0.1% w/w	0.05%
15.	Residue on Ignition as per USP	Not more than 0.1% w/w	0.05%
16.	Assay by potentiometrically as per BP/Ph.Eur.	Not less than 98.5% and not more than 101.5% on dried basis.	99.14%
17.	A) Microbial Test	1) Total Aerobic Microbial Count: NMT 1000 cfu/ g	< 10 cfu/ g
		2)Total Combined Yeast and Mould Count : NMT 100 cfu/ g	< 10 cfu/ g
	B) Pathogens	1) Escherichia coli : Absent/g	Absent/g
		2)Salmonella: Absent/10g	Absent/10g
		3)Pseudomonas aeruginosa: Absent/g	Absent/g
		4)Staphylococcus aureus: Absent/g	Absent/g
		5) Candida Albicans: Absent/g	Absent/g

BDL- Below disregard limit

Remarks: The material complies as per BP/Ph.Eur./USP and above specification.

Prepared By	Checked By	Approved By
Sign.& Date: Gokhale 23.08.16	Sign.& Date: 23.08.16	Sign.& Date: 23.08.16
Name: Siddharth Gokhale	Name: Bhupendra Patil	Name: Abaso Shelake
Designation: Officer Q.C.	Designation: Executive Q.C.	Designation: Head Quality

Admn. Office : 71, Udyog Kshetra, 2nd Floor, L.B.S. Marg, Mulund Goregaon Link Road, Mulund (W), Mumbai - 400 080. Fax : 91-22-2590 4806
Regd. Office : Plot No. 801/23, G.I.D.C. Estate, Phase III Vapi - 396 195, Dist. Valsad, Gujarat INDIA.
E-mail : info@aartigroup.com • Website : www.aartigroup.com

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Sr.No.	Test	Specification	Results
1.	Description	A white or almost white, crystalline powder or granules or Silky, white or almost white crystals, white glistening needles,usually matted together, odourless, bitter in taste. sublimes readily. Its solution are neutral to litmus.	White crystalline powder, odourless, bitter in taste , sublimes readily. Its solution are neutral to litmus.
2.	A) Solubility as per BP/Ph.Eur.	Sparingly soluble in water, Freely soluble in boiling water,Slightly soluble in ethanol (96%). It dissolves in concentrated solutions of alkali benzoates or salicylates.	Complies
	B) Solubility as per USP	Sparingly soluble in water and in alcohol , Freely soluble in chloroform, Slightly soluble in ether.	Complies
3.	A) Identification as per BP/Ph.Eur.	A: Melting point: 234°C to 239°C	235.9°C
		B: The Infrared absorption spectrum of sample should be concordant with that of standard prepration of Caffeine WS.	Complies
		E: It complies with the test for loss on drying.	Complies
	B) Identification as per USP	A) The Infrared absorption spectrum of sample should be concordant with that of standard preparation of Caffeine WS	Complies
		B) The retention time of the Caffeine peak of the sample solution corresponds to that of the standard solution as obtained in the Assay test.	Complies
4.	Appearance of solution as per BP/Ph.Eur.	The solution S is clear and colourless	Complies
5.	Acidity or alkalinity as per BP/Ph.Eur.	Not more than 0.2 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to blue.	0.15 ml of 0.01 M sodium hydroxide is required.
6.	Related substances by HPLC as per BP/ Ph.Eur.	Impurity-A : NMT 0.10%.	BDL
		Impurity-C : NMT 0.10%.	Not Detected
		Impurity-D : NMT 0.10%.	BDL
		Impurity-F : NMT 0.10%.	BDL
		Unspecified Impurities : NMT 0.10%.	Not Detected
		Total Impurities : NMT 0.1%	BDL

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