



Amoli Organics Pvt. Ltd.

Factory : BLOCK NO. 422, ECP CANAL ROAD, VILLAGE LUNA, TA : PADRA, DIST : VADODARA, INDIA. PIN CODE 391440
Phone : (91) (02662) 611200
E-mail Address : baroda@amoliindia.com



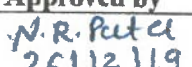
QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

PRODUCT:	Carbamazepine		
Standard For Release:	EP	Mfg Lic no.:	G/1518

Batch No.:	CAR/1911B/0216	A.R. No.:	FP/19/02369/08
Batch size:	357.15 kg	Date of sampling:	19/11/19
Mfg date:	NOV - 2019	Exp date:	OCT - 2024

Sr. No.	Test name	Test result	Acceptance criteria
1.0	Description	White crystalline powder.	A white or almost white crystalline powder.
2.0	Solubility	Very slightly soluble in water, freely soluble in methylene chloride, sparingly soluble in acetone and in ethanol (96%).	Very slightly soluble in water, freely soluble in methylene chloride, sparingly soluble in acetone and in ethanol (96%).
3.0	Identification		
	A. Melting point	192°C	Between 189°C and 193°C
	B. I.R.	IR spectrum of the test sample is concordant with that of standard.	IR spectrum of the test sample should be concordant with that of working standard carbamazepine.
4.0	Acidity or alkalinity	0.26 mL of 0.01M sodium hydroxide is required for each 1.0 g of Carbamazepine.	Not more than 0.5 mL of 0.01M sodium hydroxide is required for each 1.0 g of Carbamazepine.
		0.28 mL of 0.01M hydrochloric acid is required for each 1.0 g of Carbamazepine.	Not more than 1.0 mL of 0.01M hydrochloric acid is required for each 1.0 g of Carbamazepine.
5.0	Related substances (By HPLC) *		
	a) Imp-A	Below disregarded limit	a) Not more than 0.1%
	b) Imp-E	Not detected	b) Not more than 0.1%
	c) Max. unspecified impurity	Below disregarded limit	c) Not more than 0.10%
	d) Total Impurities	Below disregarded limit	d) Not more than 0.5%
6.0	Chlorides	Less than 140 ppm	Not more than 140 ppm
7.0	Heavy metals	Less than 20 ppm	Not more than 20 ppm

Date of Approval: 29/11/19

	Prepared by	Checked by	Approved by
Sign / Date	 26/12/19	 26/12/19	 26/12/19
Name:	Ankur Sheth	Mahendra Ravalji	Nikunj Patel
Designation:	Executive (QC)	Asst. Manager (QC)	Dy. Manager (QC)

Format No.: QCD/GEN/033/F1-01



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8.0	Loss on drying	0.21 %w/w	Not more than 0.5% w/w
9.0	Sulphated ash	0.04 %w/w	Not more than 0.1% w/w
10.0	Assay (By HPLC) (On dried basis)	99.1 %w/w	Not less than 98.0 % and not more than 102.0 %
Additional tests			
11.0	Residual solvent by GC		
	a) Methanol	Not detected	a) Not more than 100 ppm
	b) Acetone	145 ppm	b) Not more than 5000 ppm
	c) Toluene	Not detected	c) Not more than 890 ppm

SO No.: 00298

Remarks: The product complies with EP - 9.2 and customer specification (* Indis NV).

Approved / Rejected

Date of Approval: 29/11/19

Sign / Date	Prepared by	Checked by	Approved by
	<i>A. Sheth</i>	<i>M. Ravalji</i>	<i>N.R. Patel</i>
Name:	Ankur Sheth	Mahendra Ravalji	Nikunj Patel
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