



QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

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

Batch No.:	CAR/2007B/0151	A.R. No.:	FP/20/01403/06
Batch size:	355.15 kg	Date of sampling:	02/08/20
Mfg date:	JUL - 2020	Exp date:	JUN - 2025

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	190°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 standard.
4.0	Acidity or alkalinity	0.24 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.
		0.26 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	Not detected	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
8.0	Loss on drying	0.26 %w/w	Not more than 0.5% w/w

Date of Approval: 08/08/20

	Prepared by	Checked by	Approved by
Sign / Date	<i>A. Sheth</i> 16/09/20	<i>M. Ravalji</i> 16/09/20	<i>N.R. Patel</i> 16/09/20
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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9.0	Sulphated ash	0.03 %w/w	Not more than 0.1% w/w
10.0	Assay (By HPLC)	99.5 %w/w	Between 98.0% and 102.0% w/w(On dried basis)
Additional Test			
11.0	Residual solvent		
	a) Methanol	Not detected	Not more than 100 ppm
	b) Acetone	127 ppm	Not more than 5000 ppm
	c) Toluene	Not detected	Not more than 890 ppm

SO No.: 00193

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

Approved / Rejected

			Date of Approval: 08/08/20
Sign / Date	Prepared by <i>A. Sheth</i> 16/09/20	Checked by <i>M. Ravalji</i> 16/09/20	Approved by <i>N. R. Patel</i> 16/09/20
Name:	Ankur Sheth	Mahendra Ravalji	Nikunj Patel
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