

CERTIFICATE OF ANALYSIS

TOPIRAMATE USP

INSPECTION LOT NO. : 40000620415

DATE OF RELEASE : 08.07.2019

BATCH NO. : FDP190123

MFG. DT. : Dec 2018

QTY : 35.0 KG

RETEST DT. : Nov 2020

MFG. BATCH/LOT : FDC180547

LIMS LOT NO. : 3116012

TEST	REFERENCE	UNIT	STANDARD	RESULT
DESCRIPTION	USP			Meets the requirement
Observation		-	White to off-white powder.	Complies
SOLUBILITY	USP			Meets the requirement
Observation		-	Freely soluble in Dichloromethane.	Complies
IDENTIFICATION A (BY IR)	USP			Meets the requirement
Observation		-	The infrared spectrum of the sample is concordant with the spectrum obtained from the similar determination of USP Topiramate RS.	Complies
IDENTIFICATION B (BY HPLC)	USP			Meets the requirement
Observation		-	The retention time of the major peak of the Sample Solution corresponds to that of the Standard Solution as obtained in the Assay.	Complies
ASSAY (BY HPLC) (ON ANHYDROUS BASIS)	USP			Meets the requirement
Assay		%	NLT 98.0 NMT 102.0	99.8
RESIDUE ON IGNITION	USP			Meets the requirement
Residue on Ignition		%	NMT 0.10	0.02

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TEST	REFERENCE	UNIT	STANDARD	RESULT
ORGANIC IMPURITIES (BY HPLC) PROCEDURE 2	USP			Meets the requirement
Fructose		%	NMT 0.30	Not Detected
Topiramate Related Compound A		%	NMT 0.20	Below LOQ (0.02)
Topiramate Impurity I		%	NMT 0.10	Not Detected
TP2 Compound		%	NMT 0.10	Not Detected
Individual unknown impurity		%	NMT 0.10	Below LOD (0.009)
Total Impurities		%	NMT 0.50	Below LOQ
OPTICAL ROTATION, SPECIFIC ROTATION (ON ANHYDROUS BASIS)	USP			Meets the requirement
Optical Rotation, Specific Rotation		°	Between -29.00 to -35.00	-31.37
WATER DETERMINATION (BY KARL FISCHER)	USP			Meets the requirement
Water determination		%	NMT 0.50	0.01
LIMIT OF SULFAMATE AND SULFATE (BY IC)	USP			Meets the requirement

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TEST	REFERENCE	UNIT	STANDARD	RESULT
LIMIT OF SULFAMATE AND SULFATE (BY IC)	USP			Meets the requirement
Sulfamate		%	NMT 0.10	Not Detected
Sulfate		%	NMT 0.10	Not Detected
MELTING RANGE	INHOUSE			Meets the requirement
Melting range		°C	NLT 120.0 NMT 130.0	124.8 - 126.1
RESIDUAL SOLVENTS METHOD A (BY GC)	USP INHOUSE			Meets the requirement
Acetone		ppm	NMT 1500	Not Detected
Isopropyl alcohol		ppm	NMT 5000	1487
Methylene chloride		ppm	NMT 250	Not Detected
n-Hexane		ppm	NMT 200	Not Detected
Ethyl Acetate		ppm	NMT 2000	Not Detected
Toluene		ppm	NMT 890	Not Detected
Other Class 1, 2, 3 residual solvents and other organic solvents		-	Meets the requirement of other Class 1, 2, and 3 residual solvents as per USP Chapter <467> and no other organic solvents are present.	Complies
RESIDUAL SOLVENTS (BY GC) METHOD B	USP INHOUSE			Meets the requirement
Triethylamine		ppm	NMT 320	Not Detected

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TEST	REFERENCE	UNIT	STANDARD	RESULT
RESIDUAL SOLVENTS (BY GC) METHOD B	USP INHOUSE	-	Meets the requirement of other Class 1, 2, 3 Residual Solvents as per USP Chapter <467> and no other organic solvents are present.	Meets the requirement Complies
RESIDUAL SOLVENTS (BY HPLC) METHOD C	INHOUSE			Meets the requirement
Acetic Acid		ppm	NMT 5000	Not Detected

REMARK : COMPLIES WITH USP42 AND INHOUSE STANDARDS.

QUALITY CONTROL

Name : Surendrakumar T (3308)
(Head Unit Quality Control)

Date : 05.07.2019 14:27:42

QUALITY ASSURANCE

Name : Shakuntala B (30407)
(Head Unit Quality Assurance)

Date : 09.07.2019 15:48:01

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