

CERTIFICATE OF ANALYSIS

TOPIVITAE 25mg FILM-COATED TABLETS

Man. Date : 24-07-2020
Expiry Date : 07-2022
Pack Lot : 0005207
Manuf. Lot : 0004315
Batch Size :500.000 Tabs
Active Ingredient Lot : TPA1AVCA4D
Active Ingredient Supplier: CADILA
Man. Site: Pharmathen S.A.
Pkg. Site: Pharmathen S.A.
Deviation Report: ☒ NO
☐ YES (the deviation report is attached)

Controls	Specifications	Results
Appearance and measures	White round, biconvex, film coated tablet. Measures: 6.1 ± 0.1 mm diameter and 3.3 ± 0.2 mm in thickness.	Conforms (6.1mmX3.3mm)
Identification Topiramate	Chromatogram HPLC according to standard	Positive
Uniformity of dosage units	Complies to the test of mass variation Acceptance: no more than 15.0	AV: 4.1
Water Content	Max 3%	2.5%
Hardness	Min 40N	79N Min:61N Max:96N
Average mass	Theoretical weight: 102.0 mg Range: 94.4 – 109.6 mg ($\pm 7.5\%$)	Aver:99.6mg Min:96.0mg Max:107.3mg Only one tab deviates more than 7.5% of the reported average mass
Assay Topiramate	Theoretical: 25 mg/tablet Range: 23.75 – 26.5 mg/tablet (95.0 – 105.0%)	103.2% 25.80mg
Related substances	ATE-1: NMT 0.15% ATE-2: NMT 0.10% Unknown: NMT 0.125% Total: NMT 0.50%	ATE-1: BDL ATE-2: BDL Unknown: BDL Total: BDL
Disintegration	Max. 30 min in water at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$	01'.10'' - 02'.45''
Dissolution Apparatus II (Paddle) 75 rpm HCl 0.01 N 500 ml, $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ 30 min	Complies with Ph.Eur current edition (S1 introduction, S2) % dissolved: NLT Q + 5%, Q=80% 30 min	101% Min:100% Max:104%
Residual solvents	Ethanol: NMT 510mcg/tablet Acetone: NMT 510mcg/tablet	Ethanol: 112µg/tablet Acetone: 121µg/tablet
Microbiological test	Total aerobic: ≤ 1000 cfu/g Mould and yeast: ≤ 100 ufc/g Pathogens: Absent	TAMC: <10cfu/g TYMC: <10cfu/g E Coli: Absence
Package material	White opaque PVC-PEPVC/ Aluminium blister or white opaque polyethylene high density container with tamper- evident closures, desiccant sachet and package leaflet.	Conforms
Responsible for Quality Control		Release Date : 17-09-2020

Panagiotis Ivoopoulos
Quality Control Senior Manager / OP
Pharmathen S.A.

17/9/20

Pharmathen S.A.

Headquarters: 44 Kifissias Avenue, 151 25 Marousi, Athens Greece, t +30 210 6604 300, f +30 210 6666 749

Manufacturing site-Registered seat: 6 Dervenakion str., 153 51 Pallini, Athens Greece, t +30 210 6604 300, f +30 210 6604 583

www.pharmathen.com

Prepared by: Athina Tzanakou

**CERTIFICATE OF CONFORMANCE
FOR FINISHED PRODUCT**

NAME OF PRODUCT:	TOPIVITAE 25mg FILM-COATED TABLETS		
DOSAGE FORM:	Tablets	STRENGTH:	25mg
PACK SIZE AND TYPE:	BTX2BLISTERSX14TABS		
QUANTITY:	15.697BT		
IMPORTING COUNTRY:	GALENICUM CHILE		
BATCH NUMBER BULK:	0004315		
BATCH NUMBER FIN:	0005207		
MANUFACTURE DATE:	24-07-2020	EXPIRY DATE:	07-2022
MANUFACTURING SITE:	Pharmathen S.A		
PACKAGING SITE:	Pharmathen S.A		
BATCH NUMBER OF API:	TPA1AVCA4D/CADILA		
RESULT OF ANALYSIS:	Certificate of analysis of finished product attached.		
COMMENTS/REMARKS:	N/A		
DEVIATIONS:	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
	Attached number of documents:		

I hereby certify that the above information is authentic and accurate.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

This batch of product, including API, has been manufactured, including packaging and quality control at the above mentioned sites in full compliance with the GMP requirements and the local Regulatory Authority and with the specifications of the Marketing Authorization and is released.

**Name of
Qualified Person:**

**Signature of
Qualified Person:**

Panagiotis Ivopoulos
Quality Control Senior Manager / QP
Pharmathen S.A

X. 17/9/2020

Date of Release : 17-09-2020

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