Pharmathen
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CERTIFICATE OF ANALYSIS

LEVEVITAE 1000mg f.c. tablets

Man. Date :28-08-2020 **Expiry Date : 08-2023** **Pack Lot :0005663**

Manuf. Lot : 0004855 **Batch Size : 100.000 Tabs**

Active Ingredient Lot : LTI0520168-LTI0319084 **Active Ingredient Supplier: NEULAND**

Man. Site: PHARMATHEN S.A **Pkg. Site: PHARMATHEN S.A**

Deviation Report: ☑ **NO** ☐ **YES** *(the deviation report is attached)*

Controls	Specifications	Results
Appearance	White, oblong, biconvex tablets with no defects Dimensions: 22.9±0.1mm x 11.1mm Thickness: 6.7±0.2mm	Conforms 22.9mmX11.1mmX6.7mm
Identification	1.The relative retention time of Levetiracetam peak in the sample solution in relation to the reference solution is RRT = 1.0 ± 0.1 2.UV spectrum of standard correspond to UV spectrum of sample (HPLC – PDA)	1. RRT=1.0 2. Positive
Average mass	1360.0± 5%mg (1292.0–1428.0)mg	1346.8mg
Uniformity of mass	Not more than 2 tablets deviate in mass more than 5% of the reported average mass obtained No tablets deviate in mass more than 10% of the average mass obtained	Min:1321.5mg Max:1374.5mg Conforms
Uniformity of dosage units (Mass Variation)	Acceptance Value (of 10 tablets) ≤ 15.0	1.1
Loss on drying	NMT 4.0%	1.9%
Hardness	NLT 60N	136N Min:123N Max:152N
Assay	95.0 – 105.0% of the stated amount	99.7%
Related substances And Degradation products	Levetiracetam acid NMT 0.10% Any single impurity NMT 0.10% Total NMT 0.50%	Levetiracetam acid: BDL Any single impurity: BQL(LOQ=0.005%) Total: BQL
Enantiomeric purity	NMT 0.50%	BDL
Disintegration	Max. 30 min in water at 37°C ± 1°C	03'.50''- 04'.26''
Dissolution	Apparatus II paddles, 50rpm, Comply with Ph.Eur current edition (introducing S1,S2) % Dissolved: Q=85% of the stated amount in 20 min	93% Min:91% Max:96%
Identification of Titanium Dioxide	Red-Orange colour is produced	Positive
Residual solvents	Ethanol: NMT 2500μg/tablet	283μg/tablet
Microbial contamination	Total Aerobic Microbial count: NMT 1000 cfu/1g Total Yeast and Mould Count: NMT 100 cfu/1g E. Coli: NMT 0 cfu/1g	TAMC:<10cfu/1g TYMC:<10cfu/1g E coli: Absence
Blister tightness	Air and water tight after 30 sec. in 1% methylene blue solution, 160 mmHg pressure	Tight
Packaging	Cardboard box contains the appropriate number of blisters of opaque white PVC / PE / PVDC/Aluminium with the appropriate number of tablets and an instruction leaflet and is printed with Lot, Exp.	Conforms
Responsible for Quality Control	Panagiotis Ivopoulos Quality Control Senior Manager / QP Pharmathen S.A 06/10/20	**Release Date :06-10-2020**

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

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CERTIFICATE OF CONFORMANCE FOR FINISHED PRODUCT

NAME OF PRODUCT:	LEVEVITAE 1000mg f.c. tablets		
DOSAGE FORM:	TABLETS	**STRENGTH:**	1000MG/TAB
PACK SIZE AND TYPE:	BTX3BLISTERX10TABS		
QUANTITY:	3.221BT		
IMPORTING COUNTRY:	GALENICUM CHILE		
BATCH NUMBER BULK:	0004855		
BATCH NUMBER FIN:	0005663		
MANUFACTURE DATE:	28-08-2020	**EXPIRY DATE:**	08-2023
MANUFACTURING SITE:	Pharmathen S.A		
PACKAGING SITE:	Pharmathen S.A		
BATCH NUMBER OF API:	LTI0520168-LTI0319084_NEULAND		
RESULT OF ANALYSIS:	Certificate of analysis of finished product attached.		
COMMENTS/REMARKS:	-N/A-		
DEVIATIONS:	☐ YES	☑ 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: Panagiotis Ivopoulos
Quality Control Senior Manager / QP
Pharmathen S.A

Signature of Qualified Person:

Date of Release : 06-10-2020

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