

CERTIFICATE OF ANALYSIS

LEVEVITAE 500mg f.c. tablets

Man. Date: 29-07-2020

Expiry Date: 07-2023

Pack. Lot: 0005604

Manuf. Lot : 0004441

Batch Size : 100.000 Tabs

Active Ingredient Lot : LTI0520167

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	Yellow, oblong, biconvex tablets with no defects Dimensions: 19.4±0.1mm x 7.8±0.1mm Thickness: 5.1±0.2mm	Conforms 7.9mmX19.5mmX5.2mm
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. Positive RRT=1.0 2. Positive
Average mass	680.0mg ± 5%mg (646.0-714.0)mg	689.2mg
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:670.2mg Max:706.5mg Conforms
Uniformity of dosage units (Mass Variation)	Acceptance Value (of 10 tablets) ≤ 15.0	3.3
Loss on drying	NMT 4.0%	1.4%
Hardness	NLT 60N	177N Min:171N Max:192N
Assay	95.0 - 105.0% of the stated amount	98.4%
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: 0.03% Total: 0.03%
Enantiomeric purity	NMT 0.50%	BDL
Disintegration	Max. 30 min in water at 37°C ± 1°C Apparatus II paddles, 50rpm, Comply with Ph.Eur current edition (introducing S1,S2) % Dissolved: Q=85% of the stated amount in 20 min	00'.45'' - 02'.03''
Dissolution		98% Min:96% Max:100%
Identification of Titanium Dioxide	Red-Orange colour is produced	Positive
Identification of Quinoline yellow	Sample and standard similar	Positive
Residual solvents	Ethanol: NMT 2500µg/tablet	429µg/tab
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/g TYMC:<10cfu/g Ecoli: 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	SAPALIDIS GEORGE QC SUPERVISOR-QP	Release Date: 02-10-2020

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: Vasiliki Papadopolou

**CERTIFICATE OF CONFORMANCE
FOR FINISHED PRODUCT**

NAME OF PRODUCT:	LEVEVITAE 500mg f.c. tablets		
DOSAGE FORM:	TABLETS	STRENGTH:	500MG/TAB
PACK SIZE AND TYPE:	BTX3BLISTERX10TABS		
QUANTITY:	3.137BT		
IMPORTING COUNTRY:	GALENICUM CHILE		
BATCH NUMBER BULK:	0004441		
BATCH NUMBER FIN:	0005604		
MANUFACTURE DATE:	29-07-2020	EXPIRY DATE:	07-2023
MANUFACTURING SITE:	Pharmathen S.A		
PACKAGING SITE:	Pharmathen S.A		
BATCH NUMBER OF API:	LTI0520167/NEULAND		
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: SAPALIDIS GEORGE
QC SUPERVISOR-QP

Signature of

Qualified Person:

 02/10/2020

Date of Release: 02-10-2020

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