Pharmathen
Innovation inspired by life

CERTIFICATE OF ANALYSIS

VENLAVITAE 75mg XR CAPSULES

Man. Date: 07-10-2020	**Expiry Date: 10-2023**	**Pack Lot: 0007154**
Manuf. Lot: 0005873		**Batch Size: 300.000 caps**
Active Ingredient Lot: 2002006129		**Active Ingredient Supplier: ALEMBIC**
Man. Site: Pharmathen S.A		**Pkg. Site: Pharmathen S.A**
Deviation Report: ☑ **NO**		☐ **YES** *(the deviation report is attached)*

Controls	Specifications	Results
Appearance	Flesh opaque-Flesh opaque size 0 hard gelatin capsules non-printed, containing two white, round biconvex 37.5mg film coated tablets	Conforms
Identification	HPLC Chromatogram of assay must be in accordance to standard.	Positive
Uniformity of dosage units	Complies with Pharmacopeia (Ten capsules, acceptance value, AV: Not more than 15,0)	AV: 2.1
Assay	HPLC/Wst Theoretical: 75,0 mg/capsule Range: 71,25 – 78,75 mg/capsule	75.22mg/capsule
Related substances	HPLC Impurity A : ≤ 0.10% Impurity F : ≤ 0.10% Venamidol (in house) : ≤ 0.10% Individual unknown impurities : ≤ 0.20% Total impurities: ≤ 0. 50%	Impurity A: BQL(LOQ=0.015%) Impurity F: BDL Venamidol: BDL Individual unknown: 0.06% Total impurities: 0.11%
Dissolution	500 ml dissolution media a) for first 2 hours + 500 ml of dissolution media b)during the rest of assay =1000 ml 37°C ± 0.5 °C 24 h 100 rpm , apparatus Paddles< 25% in 1 hour <25% in 1 hour 35-55% in 4 hours 55-75% in 8 hours > 80% in 24 hours	1 hour:19% 4 hours:45% 8 hours:64% 24 hours:86%
Microbiological test	Total aerobic < 1000 cfu/g Total aerobic yeast and mould count < 100 cfu/g E. coli absence in 1g	TAMC:<10cfu/g TYMC:<10cfu/g E Coli: Absence
Packaging	Cardboard box with white opaque PVC-PEPVDC/ Aluminium blister. All sealed with package leaflet.	Conforms
Responsible for Quality Control		**Release Date: 04-12-2020**

Panagiotis Ivopoulos
Quality Control Senior Manager/QP
Pharmathen S.A.
04/12/20

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: Vasiliki Papadopoulou

Pharmathen
Innovation inspired by life

CERTIFICATE OF CONFORMANCE FOR FINISHED PRODUCT

NAME OF PRODUCT:	VENLAVITAE 75mg XR CAPSULES
DOSAGE FORM:	CAPSULES **STRENGTH:** 75mg
PACK SIZE AND TYPE:	BTX3BLISTERX10CAPS
QUANTITY:	9.762BT
IMPORTING COUNTRY:	GALENICUM CHILE
BATCH NUMBER BULK:	0005873
BATCH NUMBER FIN:	0007154
MANUFACTURE DATE:	07-10-2020 **EXPIRY DATE:** 10-2023
MANUFACTURING SITE:	Pharmathen S.A
PACKAGING SITE:	Pharmathen S.A
BATCH NUMBER OF API:	2002006129_ALEMBIC
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: 4/12/2020

Date of Release: 04-12-2020

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 Papadopoulou