Pharmathen
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CERTIFICATE OF ANALYSIS

ONDANVITAE 8mg FILM-COATED TABLETS

Man. Date : 23-06-2020	**Expiry Date :06-2023**	**Pack Lot :0004549**
Manuf. Lot :0003466		**Batch Size : 400.000 tabs**
Active Ingredient Lot : ADMH002122		**Active Ingredient Supplier: DR REDDY'S**
Man. Site: PHARMATHEN S.A		**Pkg Site: PHARMATHEN S.A**
Deviation Report: ☑ **NO**		☐**YES** *(the deviation report is attached)*

Controls	Specifications	Results
Appearance	Pale yellow round biconvex film-coated tablets, with "42" embossed on one side and dimensions about 9.2 ± 0.1 mm diameter and thickness about 4.2 ± 0.2 mm	Conforms 9.2mmX4.0mm
Identification of Ondansetron (HPLC)	Positive with reference to standard chromatogram used	Positive
Water content (KF)	No more than 6.0%	5.7%
Loss on drying	No more than 4.0%	2.0%
Average weight for uniformity of mass	Theoretical weight: 262.0mg Range: 248.9–275.10mg (± 5%)	Aver:262.9mg Min:257.5mg Max:268.9mg
Disintegration	No more than 30 minutes	00'.25"- 00'.36"
Assay Ondansetron (HPLC)	Theoretical:8.0mg/Tablet Range:7.6–8.4mg/Tablet (95%-105.0%)	7.7mg/tablet (96%)
Uniformity of dosage units (HPLC)	Complies with the test of content uniformity Level L1: A.V.≤15	5.3
Hardness	40-100 Newton	80N Min:70N Max:88N
Dissolution **Apparatus: II (paddle)** **Dissolution medium: 500ml HCl 0.1 N** **Rotation speed: 50rpm** **Temperature: 37°C ± 0.5°C** **Time: 30 minutes**	>85% of the stated amount in no more than 30 minutes	101% Min:98% Max:105%
Related substances (HPLC)	Impurity A: ≤ 0.10% Impurity C: ≤ 0.20% Impurity D: ≤ 0.10% Impurity E: ≤ 0.20% Impurity F: ≤ 0.20% Impurity G (HD-V): ≤0.10% Impurity H: ≤ 0.10% Any unknown impurity: ≤ 0.20%	Impurity A: BDL Impurity C : BDL Impurity D : BDL Impurity E: BDL Impurity F: BDL Impurity G (HD-V): BDL Impurity H: BDL Any unknown impurity: BDL
Impurity B (HPLC, TLC)	≤ 0.4%	Impurity B: BDL
Microbiological test **TAMC** **TYMC** **Escherichia coli**	$< 10^3$ UFC/g $< 10^2$ UFC/g Absent 1/g	TAMC:<10cfu/g TYMC:<10cfu/g Ecoli: Absence
Packaging material	White opaque blister in PVC/ Al cardboard box. All duly printed, sealed and with package leaflet	Conforms
Responsible for Quality Control		**Release Date : 26-08-2020**

Panagiotis Ivoppulos
Quality Control Senior Manager / QP
Pharmathen S.A
26/3/20

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CERTIFICATE OF CONFORMANCE FOR FINISHED PRODUCT

NAME OF PRODUCT:	ONDANVITAE 8mg FILM-COATED TABLETS
DOSAGE FORM:	TABLETS **STRENGTH:** 8MG
PACK SIZE AND TYPE:	BTX1BLISTERX10TABS
QUANTITY:	39.039BT
IMPORTING COUNTRY:	GALENICUM CHILE
BATCH NUMBER BULK:	0003466
BATCH NUMBER FIN:	0004549
MANUFACTURE DATE:	23-06-2020 **EXPIRY DATE:** 06-2023
MANUFACTURING SITE:	Pharmathen S.A
PACKAGING SITE:	Pharmathen S.A
BATCH NUMBER OF API:	ADMH002122/DR REDDY'S
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: 26-08-2020