



Certificate of Compliance

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OG: 18/04/2019 16:11:58
OL: 18/04/2019 16:11:58

Product description APOQUEL 3,6MG 10BL100CPRGROUP7
Product code F000206499
Batch number AW1921
Date of manufacturing 01/10/2019
Expiry date 12/2020
Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 3,6MG CPRV SIEGFRIED
Bulk code H000204742
Batch number AK5503

I hereby certify that this batch has been manufactured, packed and tested under GMP conditions in accordance with EC Guide to Good Manufacturing Practices for Medicinal Products, using current Manufacturing Instructions and Test Instructions.

The documentation of the manufacturing and packaging process and testing is complete and has been reviewed and approved.

During the course of manufacturing, packaging and testing there were:

- No deviations that may influence the release of the Products.
- Deviations which may influence the release of the Product. These have been reviewed and approved in accordance with an established deviation procedure.
- Additional relevant information regarding the quality of Product is attached.

The Product batch conforms with the agreed specifications and can be released for sale.

Ascoli Piceno, 18/07/2019

Pfizer Italia S.r.l.
PGM/Ascoli Plant
Elisabetta Ceruccio
Quality Operations

Signature: _____

Pfizer Italia S.r.l.
PGS/Ascoli Piceno Plant
Gianluca Paniccià
Qualified Person

QP Signature: _____

Rockwell
Performance

Identificativo: CERTIFICATE_OF_COMPLIANCE, versione: 1.1
Stampato a partire da: ReportingService
Stampato da: <SYS>

Database: AQP20205PROD:pfizer.com:1521/pmxpro.pfizer.com



Pfizer Italia S.r.l.
 Località Marino del Tronto
 63100 Ascoli Piceno (AP).
 Tel. +39 0736 305.111 – Fax +39 0736 305.263 www.pfizer.it
 Società diretta e coordinata da Pfizer Inc.
 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206499
 APOQUEL 3,6MG 10BL100CPRGROUP7

Batch n. AW1921
 Mfr date JAN-2019
 Exp date DEC-2020

Description:

White to off-white caplet shaped tablet with AQ, single score line and S on both sides.

<-----TEST----->	U.M	<---SPECIFICATION--->	<---RESULT--->
APPEARANCE		Same as description	COMPLIES
IDENTITY (HPLC)/UPLC		EXACT	EXACT
WATER	%	N.M.T. 7.0	4.3
DISSOLUTION TEST IN 30'	Q%	N.L.T. 75	COMPLIES
UNIFORMITY OF CONTENT /DOSAGE UNITS		COMPLIES	COMPLIES
TOTAL DEGRADATION PRODUCT	%	N.M.T. 2.0	0.0
EACH INDIV UNSP DEGR PRODUCT	%	N.M.T. 1.0	0.0
PF-05232926 MALEATE CONJUGATE	%	N.M.T. 1.0	0.0
ASSAY AS FREE BASE	% I.a.	95.0 - 105.0	98.3

GROUP7 Destination: PT-HU-BG.
 The batch meets the current analytical specifications.

Q.O. RELEASED DATE:
 26-APR-2019

Date: 29-APR-2019

Quality Operation Product Assurance
 Lot Dispositioned By
 Elisabetta Carluccio

Approved by

Pfizer Italia S.r.l.

Tiziana Mecozzi
 Laboratory Operations Manager
 Ascoli Piceno Plant

Approved by

Pfizer Italia S.r.l.

PGS Ascoli Plant
 Michela Giordani
 Quality Operations