



Certificate of Compliance

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OG: 16/07/2018 15:49:40
OL: 16/07/2018 15:49:40

Product description APOQUEL 3,6MG 10BL100CPRGROUP7
Product code F000206499
Batch number X37098
Date of manufacturing 03/06/2018
Expiry date 02/2020
Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 3,6MG CPRV SIEGFRIED
Bulk code H000204742
Batch number W71027

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, 11/1/2018

Signature: _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Valentina Faini
Quality Operation

QP Signature: _____

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

Rec.Fwv#
Aut. 0000000000

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

PGS Ascoli Piceno Plant Pfizer.com:1521/pmxpro.pfizer.com



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 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206499

APOQUEL 3,6MG 10BL100CPRGROUP7

Batch n. X37098
 Mfr date MAR-2018
 Exp date FEB-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	4.1
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	100.8

GROUP7 Destination: PT-HU-BG.

The batch meets the current analytical specifications.

Q.O. RELEASED DATE:

18-JUL-2018

Date: 19-JUL-2018

Quality Operation Product Assurance

Lot Dispositioned By

VALENTINA FAINI

Approved by



Pfizer Italia S.r.l.

PGS Ascoli Piceno Plant

(Serena Angius)

Quality Operations Site Leader