



Certificate of Compliance

Pagina: 1 di 1
OG: 03/07/2018 16:27:12
QL: 03/07/2018 16:27:12

Product description	APOQUEL 3,6MG 2BL 20CPR GROUP7
Product code	F000206498
Batch number	X04659
Date of manufacturing	03/05/2018
Expiry date	02/2020
Destination Country	GROU7
USED BULK PRODUCT:	
Description	APOQUEL 3,6MG CPRV SIEGFRIED
Bulk code	H000204742
Batch number	W71024

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, 06 JUL 2018

Signature: _____

QP Signature: _____

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

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

Barcode

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

Database: ASCP2018070301 Pfizer.com: 1521/prnxpro.pfizer.com



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 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206498

APOQUEL 3,6MG 2BL 20CPR GROUP7

Batch n. X04659
 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	4.6
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	100.4


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

Q.O. RELEASED DATE:
 06-JUL-2018

Date: 09-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