



Certificate of Compliance

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OG: 19/10/2018 14:55:38
OL: 19/10/2018 14:55:38

Product description APOQUEL 16MG 10BL100CPR GROUP7
Product code F000206503
Batch number AF2629
Date of manufacturing 07/11/2018
Expiry date 06/2020
Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 16MG CPRV
Bulk code H000204734
Batch number X63261

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.
- (X) 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, 19/10/2018

Signature: _____

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

QP Signature: _____

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

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

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Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206503

APOQUEL 16MG 10BL100CPR GROUP7

Batch n. AF2629
Mfr date JUL-2018
Exp date JUN-2020

Description:

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

<-----TEST----->	U.M	<---SPECIFICATION--->	<---RESULT--->
APPEARANCE		Same as description.	COMPLIES
IDENTITY (UPLC)		EXACT	EXACT
UNIFORMITY OF CONTENT /DOSAGE UNITS		COMPLIES	COMPLIES
DISSOLUTION TEST IN 30'	Q%	N.L.T. 75	COMPLIES
WATER	%	N.M.T. 7.0	3.9
TOTAL DEGRADATION PRODUCT	%	N.M.T. 2.0	0.0
PF-05232926 MALEATE CONJUGATE	%	N.M.T. 1.0	0.0
EACH INDIV UNSP DEGR PRODUCT	%	N.M.T. 1.0	0.0
ASSAY AS FREE BASE	% I.a.	95.0 - 105.0	99.3

GROUP7 Destination: PT-HU-BG.

The batch meets the current analytical specifications.

Q.O. RELEASED DATE:

09-NOV-2018

Date: 12-NOV-2018

Quality Operation Product Assurance
Lot Dispositioned By
VALENTINA FAINI

Approved by



Pfizer Italia S.r.l.
PGS Ascoli Plant
Michela Giordani
Quality Operations