



Certificate of Compliance

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OG: 08/08/2019 13:53:55

OL: 08/08/2019 13:53:55

Product description APOQUEL 16MG 2BL 20CPR GROUP7

Product code F000206502

Batch number CK5581

Date of manufacturing 06/29/2019

Expiry date 05/2021

Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 16MG CPRV

Bulk code H000204734

Batch number CK6594

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, 21 / Aug / 2019

Signature: _____

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

QP Signature: _____

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

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

Database: ASCP2C2DBPROD.pfizer.com:1521/pmxpro.pfizer.com



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Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206502
APOQUEL 16MG 2BL 20CPR GROUP7

Batch n. CK5581
Mfr date JUN-2019
Exp date MAY-2021

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	4.6
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	% l.a.	95.0 - 105.0	98.2

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

Q.O. RELEASED DATE:
21-AUG-2019

Date: 22-AUG-2019

Quality Operation Product Assurance
Lot Dispositioned By
Elisabetta Carluccio

Approved by

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
(Serena Angius)
Quality Operations Site Leader