



Certificate of Compliance

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 OL: 26/06/2020 13:47:29

Product description APOQUEL 16MG 10BL100CPR GROUP7
 Product code F000206503
 Batch number EA6650
 Date of manufacturing 31/01/2020
 Expiry date 12/2021
 Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 16MG CPRV
 Bulk code H000204734
 Batch number DH6939

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.

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

01/07/2020

Ascoli Piceno. 01/07/2020

Signature: _____

QP Signature: _____

Pfizer Italia S.r.l.
 PGM Ascoli Piceno Plant
 Serena Angius
 Qualified Person

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

Database: ASOCPicenoPlant - Server: csm 1521/pmxpro.pfizer.com



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 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

FG00206503
 APOQUEL 16MG 10BL100CPR GROUP7

Batch n. EA6650
 Mfr date JAN-2020
 Exp date DEC-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	3.7
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	% La	95.0 - 105.0	97.7

GROUP7 Destination: PT-HU-BG1.
 The batch meets the current analytical specifications.

Q.O. RELEASED DATE:
 01-JUL-2020

Date: 02-JUL-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 SERENA ANGIUS

Approved by

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