



Certificate of Compliance

Pagina: 1 di 1
OG: 20/03/2020 12:20:17
OL: 20/03/2020 12:20:17

Product description	APOQUEL 16MG 10BL100CPR GROUP7
Product code	F000206503
Batch number	DN9137
Date of manufacturing	12/03/2019
Expiry date	11/2021
Destination Country	GROU7
USED BULK PRODUCT:	
Description	APOQUEL 16MG CPRV
Bulk code	H000204734
Batch number	DF8705

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

Ascoli Piceno, 21/04/2020

Signature: _____

QP Signature: _____

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

Flowchart
su:2020-03-18

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. DN9137
 Mfr date DEC-2019
 Exp date NOV-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	3.8
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	98.3

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

Q.O. RELEASED DATE:
 23-MAR-2020

Date: 24-MAR-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 Elisabetta Cartuccio

Approved by

Michele Giordani

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