



Certificate of Compliance

Pagina: 1 di 1
OG: 10/02/2020 13:57:51
OL: 10/02/2020 13:57:51

Product description APOQUEL 16MG 10BL100CPR GROUP7
Product code F000206503
Batch number DC5198
Date of manufacturing 11/09/2019
Expiry date 10/2021
Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 16MG CPRV
Bulk code H000204734
Batch number DD1230

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, 25 FEB 2020

Signature: _____

QP Signature: _____

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

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

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



Pfizer Italia S.r.l.
 Località Marino del Tronto
 63100 Ascoli Piceno (AP).
 Tel. +39 0736 305.111 Fax +39 0736 305.263 www.pfiaci.it
 Società diretta e coordinata da Pfizer Inc.
 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206503
 APOQUEL 16MG 10BL100CPR GROUP7

Batch n. DC5198
 Mfr date NOV-2019
 Exp date OCT-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	4.3
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	98.4

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

Q.O. RELEASED DATE:
 25-FEB-2020

Date: 26-FEB-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 Elisabetta Carluccio

Approved by

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