



Certificate of Compliance

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OG: 27/02/2020 14:16:06
OL: 27/02/2020 14:16:06

Product description APOQUEL 5,4MG 2BL 20CPR GROUP7

Product code F000206500

Batch number DE3953

Date of manufacturing 10/17/2019

Expiry date 09/2021

Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV

Bulk code H000204736

Batch number DA8706

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, 02/11/2020

Signature: _____

QP Signature: _____

Pfizer Italia S.r.l.

PGM Ascoli Plant

Elisabetta Carluccio

Quality Operations

Pfizer Italia S.r.l.

PGS Ascoli Piceno Plant

Gianluigi Paniccò

Qualified Person



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

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



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 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206500
 APOQUEL 5,4MG 2BL 20CPR GROUP7

Batch n. DE3953
 Mfr date OCT-2019
 Exp date SEP-2021

Description:

White to off-white caplet shaped tablet with AQ, single score line and M 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	4.0
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	% Ia.	95.0 - 105.0	99.1

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

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

Date: 05-MAR-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 Elisabetta Carluccio

Approved by

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