



Certificate of Compliance

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 OG: 26/07/2019 15:07:42
 CL: 26/07/2019 15:07:42

Product description APOQUEL 5.4MG 10BL100CPRGROUP7
 Product code F000206501
 Batch number CL8805
 Date of manufacturing 07/02/2019
 Expiry date 08/2021
 Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 5.4MG CPRV SIEGFRIED
 Bulk code H000204743
 Batch number CL7327

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, 07 Aug 2019

Pfizer Italia S.r.l.
 PGS Ascoli Piceno Piz
 Valentina Pizzini
 Quality Operator
 Signature: [Signature]
 Pfizer Italia S.r.l.
 PGS Ascoli Piceno Plant
 QP Signature: Gianluca Panissio
 Qualified Person

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

Database: ASCP2C208PROD pfizer.com:1521/pmspro.pfizer.com



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 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206501
 APOQUEL 5,4MG 10BL100CPRGROUP7

Batch n. CL8605
 Mfr date JUL-2019
 Exp date JUN-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 (HPLC)/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	3.9
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	97.7

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

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

Date: 08-AUG-2019

Quality Operation Product Assurance
 Lot Dispositioned By
 VALENTINA FAINI

Approved by

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