



Certificate of Compliance

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OG: 13/06/2018 16:23:30
OL: 13/06/2018 16:23:30

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

Product code F000206500

Batch number X04581

Date of manufacturing 03/21/2018

Expiry date 02/2020

DestinationCountry GROU7

USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV

Bulk code H000204736

Batch number W80184

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, 13/06/2018

Signature: _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Valentina Faïni
Quality Operations

QP Signature: _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Gianluca Paniccia
Qualified Person

Recibo
Stampato a partire da: ReportingService

Identificativo: CERTIFICATE_OF_COMPLIANCE, versione 1.1
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. X04581
 Mfr date MAR-2018
 Exp date FEB-2020

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	3.6
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	96.5

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

Q.O. RELEASED DATE:
 25-JUN-2018

Date: 26-JUN-2018

Quality Operation Product Assurance
 Lot Dispositioned By
 VALENTINA FAINI

Approved by _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
 Patrizia Cappanacci
 Quality Operations