



Certificate of Compliance

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 OG: 23/01/2018 16:07:37
 OL: 23/01/2018 16:07:37

Product description APOQUEL 16MG 2BL 20CPR GROUP7
 Product code F000206502
 Batch number W15310
 Date of manufacturing 11/21/2017
 Expiry date 10/2019
 Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 16MG CPRV
 Bulk code H000204734
 Batch number W13544

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, 23/01/2018

Signature: _____

QP Signature: _____

Pfizer Italia S.r.l.
 PGS Ascoli Piceno Plant
 Valentiniano
 Quality Director

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

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



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 Società diretta e coordinata da Pfizer Inc.
 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206502
 APOQUEL 16MG 2BL 20CPR GROUP7

Batch n. W15310
Mfr date NOV-2017
Exp date OCT-2019

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	4.6
TOTAL DEGRADATION PRODUCT	%	N.M.T. 2.0	0.3
PF-05232926 MALEATE CONJUGATE	%	N.M.T. 1.0	0.0
EACH INDIV UNSP DEGR PRODUCT	%	N.M.T. 1.0	0.3
ASSAY AS FREE BASE	% I.a.	95.0 - 105.0	99.5

GROUP7 Destination: PT-HU-BG

Q.O. RELEASED DATE:
 06-FEB-2018

Date: 07-FEB-2018

Quality Operation Product Assurance
 Lot Dispositioned By
 VALENTINA FAINI

Approved by _____

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