



Certificate of Compliance

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 OG: 18/01/2018 15:22:58
 OL: 18/01/2018 15:22:58

Product description APOQUEL 5.4MG 2BI 20CPR GROUP7
 Product code F000206500
 Batch number W15296
 Date of manufacturing 11/08/2017
 Expiry date 12/2019
 DestinationCountry GROL7

USED BULK PRODUCT:

Description APOQUEL 5.4MG CPRV
 Bulk code H000204736
 Batch number W08442

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.

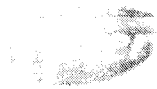
Asco Piceno: _____

signature _____

QP Signature: _____

Identificativo CER - FICATE for COMPLIANCE versione 1.1
 Stampato a partire da ReportingService
 Stampato da: SPS

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 Società diretta e coordinata da Pfizer Inc
 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

FO06206500
 APOQUEL 5.4MG 2BL 20CPR GROUP7

Batch n. W15290

Mfr date NOV-2017

Exp date OCT-2019

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	4.7
TOTAL DEGRADATION PRODUCT	%	N.M.T. 2.0	0.0
PE-05232926 MALEATI 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	97.9

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.
 53100 Ascoli Piceno
 Valeria Cappacucci