



Certificate of Compliance

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 OG: 29/08/2019 12:07:26
 OL: 29/05/2019 12:07:26

Product description	APOQUEL 5,4MG 2BL 20CPR GROUP7
Product code	F000206500
Batch number	CK5826
Date of manufacturing	07/03/2019
Expiry date	06/2021
Destination Country	GROU7
USED BULK PRODUCT:	
Description	APOQUEL 5.4MG CPRV SIEGFRIED
Bulk code	H000204743
Batch number	CL7329

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.
- (x) 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.

Pfizer Italia S.r.l.
 PGM Ascoli Plant
 Elisabetta Carluccio
 Quality Operations

Ascoli Piceno, 29/11/2019

Signature: _____

QP Signature: _____

Pfizer Italia S.r.l.
 PGM Ascoli Piceno Plant
 Gianluca Paniceà
 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

F000206500
 APOQUEL 5,4MG 2BL 20CPR GROUP7

Batch n. CK5626
 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	4.6
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	% La.	95.0 - 105.0	97.2

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

Q.O. RELEASED DATE:
 16-SEP-2019

Date: 17-SEP-2019

Quality Operation Product Assurance
 Lot Dispositioned By
 Elisabetta Carluccio

Approved by: *[Signature]*

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