



Certificate of Compliance

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OG: 13/06/2019 11:03:33
QL: 13/06/2019 11:03:33

Product description APOQUEL 5.4MG 10BL100CPRGROUP7
Product code F000206501
Batch number AW5511
Date of manufacturing 05/13/2019
Expiry date 04/2021
Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV SIEGFRIED
Bulk code H000204743
Batch number CG7420

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, 1 / 1 / 2019

Signature: _____

QP Signature: _____

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

Pfizer Italia S.r.l.
P.O. Box 50011, Piacenza Plant
Gianluca Panicola
Qualified Person



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

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206501
 APOQUEL 5.4MG 10BL100CPRGROUP7

Batch n. AW5511
 Mfr date MAY-2019
 Exp date APR-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	3.8
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	95.2

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

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

Date: 13-SEP-2019

Quality Operation Product Assurance
 Lot Dispositioned By
 VALENTINA FAINI

Approved by

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