



Certificate of Compliance

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OG: 27/08/2020 15:10:03
OL: 27/08/2020 15:10:03

Product description APOQUEL 5,4MG 10BL100CPRGROUP7

Product code F000206501

Batch number ED6027

Date of manufacturing 13/12/2019

Expiry date 11/2021

Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV

Bulk code H000204736

Batch number DG4008

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.

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

Ascoli Piceno, 31/12/2020

Signature: _____

QP Signature **Pfizer Italia S.r.l.**
PGS Ascoli Piceno Plant

Serena Angius
Qualified Person

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



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 Stabilimento di Ascoli Piceno

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206501
 APOQUEL 5.4MG 10BL100CPRGROUP7

Batch n. ED6027
 Mfr date DEC-2019
 Exp date NOV-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 (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	4.0
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	96.7

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

Q.O. RELEASED DATE:
 31-AUG-2020

Date: 01-SEP-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 SERENA ANGIUS

Approved by

Michela Giordani

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