



Certificate of Compliance

Product description	APOQUEL 5,4MG 10BL100CIPRGROUP7
Product code	F000206501
Batch number	EA6708
Date of manufacturing	19/10/2019
Expiry date	09/2021
DestinationCountry	GROU7
USED BULK PRODUCT:	
Description	APOQUEL 5,4MG CPRV
Bulk code	H000204736
Batch number	DA8708

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, 20/7/2020

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Signature: Valentina Falini *28/8/2020*
Quality Operations

QP Signature: [Signature]
Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Gianluca Paniccà
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. EA6708
 Mfr date OCT-2019
 Exp date SEP-2021

Description:

White to off-white caplet shaped tablet with AQ, single score line and M on both sides.

TEST	U.N	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
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	97.8

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

Q.O. RELEASED DATE:
 29-JUL-2020

Date: 30-JUL-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 GIANLUCA PANICCLA

Approved by

Michela Giordani

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