



Certificate of Compliance

Product description	APOQUEL 5.4MG FLP 20CPR RU
Product code	F000044846
Batch number	EJ8391
Date of manufacturing	02/2020
Expiry date	01/2023
DestinationCountry	RU

USED BULK PRODUCT:

Description	APOQUEL 5,4MG CPRV
Bulk code	H000204736
Batch number	DM5157

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, 06/11/2020

Signature: _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Valentina Faini
Quality Operations *06/11/2020*

QP Signature: _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Serena Angius
Qualified Person



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

CERTIFICATE OF ANALYSIS

F000044846
APOQUEL 5.4MG FLP 20CPR RU

Pfizer Global Supply (PGS)

Batch n. EJ8391
Mfr date FEB-2020
Exp date JAN-2023

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
WATER	%	N.M.T. 7.0	4.7
DISSOLUTION TEST IN 30'	Q%	N.L.T. 75	COMPLIES
UNIFORMITY OF CONTENT /DOSAGE UNITS		COMPLIES	COMPLIES
TOTAL DEGRADATION PRODUCT	%	N.M.T. 4.0	0.0
EACH INDIV UNSP DEGR PRODUCT	%	N.M.T. 1.0	0.0
PF-05232926 MALEATE CONJUGATE	%	N.M.T. 2.0	0.0
ASSAY AS FREE BASE	% I.a.	90.0 - 110.0	96.6

The batch meets the current analytical specifications.

Q.O. RELEASED DATE:
06-NOV-2020

Date: 09-NOV-2020

Quality Operation Product Assurance
Lot Dispositioned By
SERENA ANGIUS

Approved by


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