



# Certificate of Compliance

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OG: 15/07/2020 15:04:25

OL: 15/07/2020 15:04:25

Product description APOQUEL 5,4MG 2BL 20CPR GROUP7

Product code F000206500

Batch number EC0549

Date of manufacturing 11/12/2019

Expiry date 11/2021

Destination Country GROU7

### USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV

Bulk code H000204736

Batch number DG4004

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.**

PGM Ascoli Plant

**Elisabetta Carluccio** *16/07/2020*

Quality Operations

Ascoli Piceno, 16/07/2020

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>

Salvo approvazione di: D.pfizer.com:1521/pmxpro.pfizer.com

Diszpó: PN0810515725

Vevő: DR SZEKELY KFT Erd

File név: PN00010618

Egyedi sorszám: PN0000096156

1 másolat

Szállító: Zoetis Hungary Kft.

Oldal/Lap 2 / 1

Anyaglap: PN0329/20

Az eredetiről készült hiteles másolat.

Nyomtatás dátuma: 2020.10.15

Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

**CertEx v3.10**



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Stabilimento di Ascoli Piceno

## Pfizer Global Supply (PGS)

### CERTIFICATE OF ANALYSIS

F000206500  
APOQUEL 5.4MG 2BL 20CPR GROUP7

Batch n. EC0549  
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	3.1
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	% Ia.	95.0 - 105.0	98.9

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

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

Date: 17-JUL-2020

Quality Operation Product Assurance  
Lot Dispositioned By  
SERENA ANGIUS

Approved by

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