



Certificate of Compliance

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OG: 09/07/2020 16:24:15
OL: 09/07/2020 16:24:15

Product description	APOQUEL 3,6MG 10BL100CPRGROUP7
Product code	F000206499
Batch number	EA7745
Date of manufacturing	18/09/2019
Expiry date	08/2021
Destination Country	GROU7
USED BULK PRODUCT:	
Description	APOQUEL 3,6MG CPRV SIEGFRIED
Bulk code	H000204742
Batch number	CW8344

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, 17/08/2020

Signature: _____

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

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>

Database: ASCP2C2DBPROD.pfizer.com:1521/pmxpro.pfizer.com



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

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000206499
 APOQUEL 3,6MG 10BL100CPRGROUP7

Batch n. EA7745
 Mfr date SEP-2019
 Exp date AUG-2021

Description:

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

<-----TEST----->	U.M	<---SPECIFICATION--->	<---RESULT--->
APPEARANCE		Same as description	COMPLIES
IDENTITY (HPLC)/UPLC		EXACT	EXACT
WATER	%	N.M.T. 7.0	4.6
DISSOLUTION TEST IN 30'	Q%	N.L.T. 75	COMPLIES
UNIFORMITY OF CONTENT /DOSAGE UNITS		COMPLIES	COMPLIES
TOTAL DEGRADATION PRODUCT	%	N.M.T. 2.0	0.0
EACH INDIV UNSP DEGR PRODUCT	%	N.M.T. 1.0	0.0
PF-05232926 MALEATE CONJUGATE	%	N.M.T. 1.0	0.0
ASSAY AS FREE BASE	% I.a.	95.0 - 105.0	99.3

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

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

Date: 18-AUG-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 SERENA ANGIUS

Approved by

Pfizer Italia S.r.l.
 Tiziana Mecozzi
 Laboratory Operations Manager
 Ascoli Piceno Plant

Approved by

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