



# Certificate of Compliance

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OG: 04/03/2020 16:17:09  
OL: 04/03/2020 16:17:09

Product description APOQUEL 16MG 2BL 20CPR GROUP7

Product code F000208502

Batch number DN9526

Date of manufacturing 09/10/2019

Expiry date 08/2021

Destination Country GROU7

### USED BULK PRODUCT:

Description APOQUEL 16MG CPRV

Bulk code H000204734

Batch number CW4686

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**  
Quality Operations

Ascoli Piceno, 11/03/2020

Signature: \_\_\_\_\_

QP Signature: \_\_\_\_\_

**Pfizer Italia S.r.l.**

PGM: Ascoli Plant  
**Gianluca Panico**  
Qualified Person

Stampato da: Automotiva

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

F000206502  
 APOQUEL 16MG 2BL 20CPR GROUP7

Batch n. DN9526  
 Mfr date SEP-2019  
 Exp date AUG-2021

**Description:**

White to off-white caplet shaped tablet with AQ, single score line and L 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	4.6
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	97.5

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

Q.O. RELEASED DATE:  
 12-MAR-2020

Date: 13-MAR-2020

Quality Operation Product Assurance  
 Lot Dispositioned By  
 Elisabetta Carluccio

Approved by

PGS Ascoli Plant  
 Michela Giordani  
 Quality Operations