



# Certificate of Compliance

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 OG: 09/03/2019 13:15:45  
 OL: 09/03/2019 13:15:45

Product description APOQUEL 16MG 10BL100CPR GROUP7  
 Product code F000206503  
 Batch number AM9162  
 Date of manufacturing 02/15/2019  
 Expiry date 01/2021  
 Destination Country GROU7

### USED BULK PRODUCT:

Description APOQUEL 16MG CPRV SIEGFRIED  
 Bulk code H000204741  
 Batch number AP3723

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, 15/03/2019

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

QP Signature: 

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

**Pfizer Italia S.r.l.**  
 PGS Ascoli Piceno Plant  
**Gianluca Paniccià**  
 Qualified Person



Identificativo: CERTIFICATE\_OF\_COMPLIANCE, versione: 1.1  
 Stampato a partire da: ReportingService  
 Stampato da: <SYS>



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

## Pfizer Global Supply (PGS)

### CERTIFICATE OF ANALYSIS

F000206503  
APOQUEL 16MG 10BL100CPR GROUP7

Batch n. AM9162  
Mfr date FEB-2019  
Exp date JAN-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 (HPLC)/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	3.5
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	99.6


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

Q.O. RELEASED DATE:  
19-MAR-2019

Date: 20-MAR-2019

Quality Operation Product Assurance  
Lot Dispositioned By  
VALENTINA FAINI

Approved by

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