



# Certificate of Compliance

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 OL: 08/10/2018 16:28:36

Product description APOQUEL 3,6MG 2BL 20CPR GROUP7

Product code F000206498

Batch number AA0609

Date of manufacturing 06/05/2018

Expiry date 05/2020

Destination Country GROU7

**USED BULK PRODUCT:**

Description APOQUEL 3,6MG CPRV SIEGFRIED

Bulk code H000204742

Batch number X38511

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.**  
 PGS Ascoli Piceno Plant  
 Valentina Faini  
 Quality Operations

Ascoli Piceno, \_\_\_/\_\_\_/\_\_\_

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

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

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

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

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Pfizer Italia S.r.l.  
 Località Marino del Tronto  
 63100 Ascoli Piceno (AP).  
 Tel. +39 0736 305.111 Fax +39 0736 305.263 www.pfizer.it  
 Società diretta e coordinata da Pfizer Inc.  
 Stabilimento di Ascoli Piceno

## Pfizer Global Supply (PGS)

### CERTIFICATE OF ANALYSIS

F000206498

APOQUEL 3,6MG 2BL 20CPR GROUP7

**Batch n.** AA0609

**Mfr date** JUN-2018

**Exp date** MAY-2020

**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	4.8
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	% Ia.	95.0 - 105.0	99.3

GROUP7 Destination: PT-IIU-BG.

The batch meets the current analytical specifications.

Q.O. RELEASED DATE:  
15-OCT-2018

Date: 16-OCT-2018

Quality Operation Product Assurance

Lot Dispositioned By  
VALENTINA FAINI

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)  
Quality Operations Site Leader