



# Certificate of Compliance

Pagina: 1 di 1  
 OG: 07/09/2018 15:03:04  
 OL: 07/09/2018 15:03:04

Product description	APOQUEL 5,4MG 10BL100CPRGROUP7
Product code	F000206501
Batch number	X64560
Date of manufacturing	07/05/2018
Expiry date	06/2020
Destination Country	GROU7
<i>USED BULK PRODUCT:</i>	
Description	APOQUEL 5,4MG CPRV SIEGFRIED
Bulk code	H000204743
Batch number	X58944

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, 07/09/2018

Signature:   
**Pfizer Italia S.r.l.**

QP Signature:   
 PGS Ascoli Piceno Plant  
**Gionluca Paniccia**  
 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

F000206501

APOQUEL 5,4MG 10BL100CPRGROUP7

Batch n. X64560  
 Mfr date JUL-2018  
 Exp date JUN-2020

**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
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 ASSAY	%	N.M.T. 1.0	0.0
AS FREE BASE	% I.a.	95.0 - 105.0	98.7
IDENTITY (HPLC)/UPLC		EXACT	EXACT

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

Q.O. RELEASED DATE:  
 11-SEP-2018

Date: 12-SEP-2018

Quality Operation Product Assurance  
 Lot Dispositioned By  
 Emanuela Iurlaro

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