



# Certificate of Compliance

Pagina: 1 di 1  
OG: 28/09/2018 13:15:46  
OL: 28/09/2018 13:15:46

Product description APOQUEL 5,4MG 2BL 20CPR GROUP7

Product code F000206500

Batch number X78318

Date of manufacturing 07/06/2018

Expiry date 06/2020

Destination Country GROU7

### USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV SIEGFRIED

Bulk code H000204743

Batch number X58945

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, 01 OCT 2018

**Pfizer Italia S.r.l.**  
PGS Ascoli Piceno Plant  
Valentina Felini  
Quality Operations  
**Pfizer Italia S.r.l.**  
PGS Ascoli Piceno Plant  
QP Signature: Gianluca Paniccia  
Qualified Person



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

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

Diszpó: PN0804819513 Vevő: DR SZEKELY KFT Erd File név: PN00009776 Egyedi sorszám: PN0000088466 11 másolat  
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0390/18  
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2018.11.09  
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

**CertEx v 3.10**



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

## Pfizer Global Supply (PGS)

### CERTIFICATE OF ANALYSIS

F000206500

APOQUEL 5,4MG 2BL 20CPR GROUP7

Batch n. X78318  
 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	4.2
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	98.6
IDENTITY (HPLC)/UPLC		EXACT	EXACT

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

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

Date: 02-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