



# Certificate of Compliance

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OG: 16/01/2018 09:14:23

OL: 16/01/2018 09:14:23

Product description APOQUEL 5.4MG 10BL100CPRGROUP7

Product code F000206501

Batch number T95380

Date of manufacturing 11/08/2017

Expiry date 10/2019

Destination Country GROU7

### USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV

Bulk code H000204736

Batch number W08438

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**

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

Signature: \_\_\_\_\_  
Quality Operations

QP Signature: \_\_\_\_\_  
Quality Operations

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

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



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 Stabilimento di Ascoli Piceno

## Pfizer Global Supply (PGS)

### CERTIFICATE OF ANALYSIS

F000206501  
 APOQUEL 5,4MG 10BL100CPRGROUP7

Batch n. T95380  
 Mfr date NOV-2017  
 Exp date OCT-2019

**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
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	4.7
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	% Ia.	95.0 - 105.0	96.8

GROUP7 Destination: PT-HU-BG

Q.O. RELEASED DATE:  
 22-JAN-2018

Date: 23-JAN-2018

Quality Operation Product Assurance  
 Lot Dispositioned By  
 VALENTINA FAINI

Approved by \_\_\_\_\_

**Pfizer Italia S.r.l.**  
 PGS Ascoli Piceno Plant  
 Patrizia Capparucci  
 Quality Operations