



**Certificate of Compliance**

Product description      APOQUEL 16MG 10BL100CPR GROUP7  
 Product code              120017700  
 Batch number              162DD  
 Date of Manufacturing    07/06/2016              (DD/MM/YYYY)  
 Expiry date                05/2018

**USED BULK PRODUCT:**

Description                APOQUEL 16MG CPRV  
 Bulk Code                  320100016  
 Batch Number              162D

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 completed 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, \_\_\_/\_\_\_/\_\_\_

Signature:

*Pfizer Italia S.r.l.*  
 PGS Ascoli Piceno Plant  
*Valentina Pato*  
 Quality Specialist

QP Signature:

*Pfizer Italia S.r.l.*  
 PGS Ascoli Piceno Plant  
*Annalisa Volpato*  
 Qualified Person



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](http://www.pfizer.it)  
 Società diretta e coordinata da Pfizer Inc.  
 Stabilimento di Ascoli Piceno

## Pfizer Global Supply (PGS)

### CERTIFICATE OF ANALYSIS

120017700-APOQUEL 16MG 10BL100CPR GROUP7

Batch n. 162DD

Mfr date JUN-2016

Exp date MAY-2018

**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 (UPLC)		EXACT	EXACT
UNIFORMITY OF CONTENT /DOSAGE		COMPLIES	COMPLIES
UNITS			COMPLIES
DISSOLUTION TEST IN 30'	Q%	N.L.T. 75	5.2
WATER	%	N.M.T. 7.0	0.0
TOTAL DEGRADATION PRODUCT	%	N.M.T. 2.0	0.0
PF-05232926 MALEATE CONJUGATE	%	N.M.T. 1.0	0.0
LACII INDIV UNSP DEGR PRODUCT	%	N.M.T. 1.0	0.0
ASSAY AS FREE BASE	% La.	95.0 - 105.0	98.6

GROUP7 Destination: PT-HU-BG

The batch meets the current analytical specifications

Q.O. RELEASED DATE:

14-JUL-2016

Date:15-JUL-2016

Quality Operation Product Assurance

Lot Dispositioned By

VALENTINA FAINI

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

**Pfizer Italia S.r.l.**

PGS Ascoli Piceno Plant

Patrizia Cappaccioli

Quality Operation

Page 1 of 1

Capitale Sociale €1.000.000.000,00 i.v.  
 Part. IVA 01781570591  
 Cod. Fisc. E Registro Imprese Latina 06954380157  
 R.F.A. Latina s. 110637  
 Sede Legale: 04100 Lancia - Via Isanzo, 71  
 Sede Amministrativa - 00188 Roma - Via Valbenedetto, 113

Diszpó: PN0802558818 Vevő: DR SZEKELY KFT Erd File név: PN00008890 Egyedi sorszám: PN000085562 39 másolat  
 Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 2 Anyaglap: PN0251/16  
 Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2018.01.09  
 Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

**CertEx v3.03a**