



Certificate of Compliance

Product description APOQUEL 3,6MG 10BL100CPRGROUP7
 Product code 120017100
 Batch number 296DB
 Date of Manufacturing 25/06/2016 (DD/MM/YYYY)
 Expiry date 05/2018

USED BULK PRODUCT:

Description APOQUEL 3,6MG CPRV SIEGFRIED
 Bulk Code 320300036
 Batch Number 296D

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: _____

QP Signature: _____

Pfizer Italia S.r.l.
 PGS Ascoli Piceno Plant
Tommaso Volpicella
 Qualified Person



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

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

120017100-APOQUEL 3,6MG 10BL100CPRGROUP7

Batch n. 296DB
 Mfr date JUN-2016
 Exp date MAY-2018

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 (UPLC)		EXACT	EXACT
WATER	%	N.M.T. 7.0	5.2
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	% I.a.	95.0 - 105.0	99.6

GROUP7 Destination: PT-HU-BG

Q.O RELEASED DATE:
 23-SEP-2016

Date: 27-SEP-2016

Quality Operation Product Assurance
 Lot Dispositioned By
 VALENTINA FAINI

Approved by _____

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