



Certificate of Compliance

Pagina: 1 di 1
DG: 16/04/2020 16:00:48
OL: 16/04/2020 16:00:48

Product description APOQUEL 3,6MG 2BL 20CPR GROUP7
Product code F000206498
Batch number DR8727
Date of manufacturing 09/20/2019
Expiry date 08/2021
Destination Country GROU7

USED BULK PRODUCT:

Description APOQUEL 3,6MG CPRV SIEGFRIED
Bulk code H000204742
Batch number CW8347

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, 17/08/2020

Signature: _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Valentina Faini
Quality Operations

QP Signature: _____

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Serenia Angiolini
Qualified Person

Rockwell
Automation

Identificativo: CERTIFICATE_OF_COMPLIANCE, versione: 1.1
Stampato a partire da: ReportingService
Stampato da: <SYS>

Data: 20200720 16:00:48 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

F000206498
 APOQUEL 3.6MG 2BL 20CPR GROUP7

Batch n. DR8727
 Mfr date SEP-2019
 Exp date AUG-2021

Description:

White to off-white caplet shaped tablet with AQ, single score line and S on both sides.

<-----TEST----->	U.N	<---SPECIFICATION--->	<---RESULT--->
APPEARANCE		Same as description	COMPLIES
IDENTITY (HPLC)/UPLC		EXACT	EXACT
WATER		N.M.T. 7.0	5.7
DISSOLUTION TEST IN 30'	%	N.L.T. 75	COMPLIES
UNIFORMITY OF CONTENT /DOSAGE UNITS	Q%	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.B.	95.0 - 105.0	99.7

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

Q.O. RELEASED DATE:
 17-APR-2020

Date: 20-APR-2020

Quality Operation Product Assurance
 Lot Dispositioned By
 VALENTINA FAINI

Approved by
~~Pfizer Italia S.r.l.~~
 PGS Ascoli Piceno Plant
Serena Angius
 Qualified Person

Approved by
~~Pfizer Italia S.r.l.~~
 PGS Ascoli Plant
Michela Giordani
 Quality Operations

Capitale Sociale €1.000.000.000,00 i.v.
 Part. IVA 01781570593
 Cod. Fisc. B Registro Imprese: Laura 0954780157
 R.B.A. Numero n. 110637
 Sede Legale: 01100 Ascoli Piceno - Via Firenze, 71
 Sede Amministrativa: 02188 Roma - Via Volturno, 111