



Certificate of Compliance

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OG: 24/01/2019 11:35:34

OL: 24/01/2019 11:35:34

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

Product code F000206500

Batch number AK9122

Date of manufacturing 12/06/2018

Expiry date 11/2020

DestinationCountry GROU7

USED BULK PRODUCT:

Description APOQUEL 5,4MG CPRV SIEGFRIED

Bulk code H000204743

Batch number AJ8350

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, 01/07/2019

Signature: Valentina Faini

QP Signature: Gianluca Paniccia

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

Pfizer Italia S.r.l.
PGS Ascoli Piceno Plant
Gianluca Paniccia
Qualified Person

Hochwaller

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

Database: ASCP 2020 BPR 09/19 Pfizer.com:1521/pmipro.pfizer.com



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
 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. AK9122
 Mfr date DEC-2018
 Exp date NOV-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 |
| IDENTITY (HPLC)/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 | 3.9 |
| 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 | % I.a. | 95.0 - 105.0 | 99.4 |

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

Q.O. RELEASED DATE:
 01-FEB-2019

Date: 04-FEB-2019

Quality Operation Product Assurance
 Lot Dispositioned By
 VALENTINA FAINI

Approved by

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