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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. CD5421
 Mfr date MAR-2019
 Exp date FEB-2021

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 (HPLC)/UPLC		EXACT	EXACT
WATER	%	N.M.T. 7.0	4.4
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	100.8

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

Q.O. RELEASED DATE:
 07-MAY-2019

Date: 07-MAY-2019

Quality Operation Product Assurance
 Lot Dispositioned By
 Elisabetta Carluccio

Approved by

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