



Certificate of Compliance

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OG: 27/03/2020 14:23:49

OL: 27/03/2020 14:23:49

Product description DOSTINEX 0.5mg TAB 1x2 GBTL BY

Product code F000121306

Batch number DN5296

Date of manufacturing 02/2020

Expiry date 01/2022

Destination Country BY

USED BULK PRODUCT:

Description CABERGOLINA 0,5MGX2CPR FL ANON

Bulk code H000204689

Batch number DN5632

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:

(X) 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, 30 MAR / 2020

Signature: _____

QP Signature: _____

Pfizer Italia S.r.l.
PGM Ascoli Plant
Elisabetta Carluccio
Quality Operations

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

Rockwell
Automation

Identificativo: CERTIFICATE_OF_COMPLIANCE, versione: 1.1

Stampato a partire da: ReportingService

Stampato da: <SYS>

Database: ASCP2CZ0BPROD.pfizer.com;1521/pmxpro.pfizer.com



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Stabilimento di Ascoli Piceno.

Pfizer Global Supply (PGS)

CERTIFICATE OF ANALYSIS

F000121306

DOSTINEX 0.5MG TAB 1X2 GBTL BY

Batch n. DN5296

Mfr date FEB-2020

Exp date JAN-2022

Description:

White, flat, oblong, with engraving "PU" divided by a score on one side; engraving "700" and light score above and below the central "0" on other side.

<-----TEST----->		U.M	<---SPECIFICATION---	<---RESULT---
APPEARANCE			Same as description.	COMPLIES
IDENTITY(TLC)			Rf of the sample matches standard.	EXACT
IDENTITY CABERGOLINE (HPLC)			Same retention time as cabergoline working standard.	EXACT
TOTAL RELATED COMPOUNDS (HPLC)	%		N.M.T. 1.5	0.3
CABERGOLINE ACID (HPLC)	%		N.M.T. 0.5	0.1
N-OXIDE CABERGOLINE (HPLC)	%		N.M.T. 0.3	0.0
RELATED COMPOUNDS, EACH UNKNOWN <= 0.3%			COMPLIES	COMPLIES
DISSOLUTION TEST IN 15'	Q%		N.L.T. 75	COMPLIES
UNIFORMITY OF CONTENT (PH.EUR)			COMPLIES	COMPLIES
ASSAY CABERGOLINE (HPLC)	mg/tbl		0.475 - 0.525	0.500
TAMC	CFU/g		N.M.T. 2000	0
TYMC	CFU/g		N.M.T. 200	0
ESCHERICHIA COLI	/g		ABSENT	ABSENT

The batch meets the current analytical specifications.

Q.O. RELEASED DATE:

30-MAR-2020

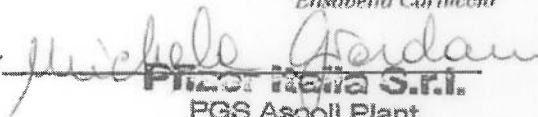
Date: 31-MAR-2020

Quality Operation Product Assurance

Lot Dispositioned By

Elisabetta Carluccio

Approved by


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