Certificate of Analysis

CARDURA 2mg TAB 3x10 BLS CL

Destination: Chile

Material No.: F000047928
Batch No.: FP1293
Manufacturing Date: 15-OCT-2021
Expiry Date:30-SEP-2023
Analytical Procedure: H000154404-03

Test	Method	Limit	Result
APPEARANCE			
Result	I 2.02	White, oblong, biconvex tablets with break score and code CN 2 on one side and Pfizer logo on the other side	conforms
IDENTITY DOXAZOSIN			
Result	I 2.373 / TLC	Meets test	conforms
IDENTITY MESYLATE COUNTER-ION			
Result	I 2.379 / HPLC	Shows an HPLC peak with the same retention time and response as the mesylate peak from a reference sample of doxazosin mesylate when both are chromatographed sequentially	conforms
ASSAY DOXAZOSIN			
Result	D 135.041 / HPLC	Average of 10 individual tablets is in the range of 95.0% - 105.0% of label claim.	99.2
IMPURITIES EACH IDENTIFIED AND SPECIFIED DEGRADATION PRODUCTS UK-28,805			
Result	D 135.6 / HPLC	<= 1.0% calculated with respect to doxazosin	< 0.1
UK-2,249			
Result	D 135.6 / HPLC	<= 1.0% calculated with respect to doxazosin	< 0.1
EACH INDIVIDUAL UNIDENTIFIED DEGRADATION PRODUCTS			
Result	D 135.6 / HPLC	<= 0.5% calculated with respect to doxazosin	< 0.1
SUM OF DEGRADATION PRODUCTS			
Result	D 135.6 / HPLC	<= 1.5% calculated with respect to doxazosin	< 0.1
MOISTURE CONTENT			

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Test	Method	Limit	Result
Result	W 1.0	6.0% Maximum	4.6
DISSOLUTION (USP) AFTER 30 MIN.			
Result	USP-NF <711>	Q = 70%	conforms
Average	USP-NF <711>	-	85
Min.	USP-NF <711>	-	83
Max.	USP-NF <711>	-	89
Standard Deviation	USP-NF <711>	-	2.1
Stage	USP-NF <711>	-	1
UNIFORMITY OF DOSAGE UNITS - CONTENT UNIFORMITY			
Result	Ph.Eur. 2.9.40 / U 3.04	Meets Ph. Eur. requirements	conforms
Average	Ph.Eur. 2.9.40 / U 3.04	-	99.2
Min.	Ph.Eur. 2.9.40 / U 3.04	-	95.1
Max.	Ph.Eur. 2.9.40 / U 3.04	-	103.1
Stage	Ph.Eur. 2.9.40 / U 3.04	-	1
Coefficient of Variation	Ph.Eur. 2.9.40 / U 3.04	-	2.2
UNIFORMITY OF MASS OF HALF TABLET			
Result	PH. EUR. 2.9.5	Meets Ph. Eur. requirements	conforms
THEORETICAL WEIGHT OF TABLET			
Result	AP	120 mg	120

Certificate of Compliance

CARDURA 2mg TAB 3x10 BLS CL

Destination: Chile

Material No.:	F000047928
Batch No.:	FP1293
Manufacturing Date:	15-OCT-2021
Expiry Date:	30-SEP-2023
Yield:	7240 EA
Date of Release:	17-JAN-2022
Source Lots:	FL2542

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The corresponding active ingredient was manufactured in compliance with GMP. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. Any investigations, deviations and discrepancies have been approved.

This batch has been released by a Qualified Person.

This certificate was created by a validated system and is valid without manual signature.

Electronic Signature: Birgit Schimanke Lot Release Local Timestamp: 17-JAN-2022 14:21:08 Server Timestamp: 17-JAN-2022 14:21:02

PFIZER MANUFACTURING
DEUTSCHLAND GMBH
BETRIEBSSTÄTTE FREIBURG
MOOSWALDALLEE 1
79090 FREIBURG, GERMANY

Certificate of Analysis and Compliance

Item Code:	H000116032
Description:	DOXAZOSIN MESYLATE BULK
Lot Name:	FA4463
Supplier Lot:	FA4463
Specifications Reference Number:	840110-03
Manufacture Date:	19-Oct-2019
Reevaluation Date:	19-Oct-2021

Test	Specification	Test Method	Result
Description	White or almost white crystalline powder	A 28.0	Conforms
Identification Doxazosin Mesylate (IR)	Conforms	Ph. Eur. 2.2.24	Conforms
Appearance of solution	The solution is clear and not more intensly coloured than reference solution BG_6	Ph. Eur. 2.2.1 / 2.2.2	Conforms
Water / K.F.	Not more than 1.5 %	Ph. Eur. 2.5.12 or W 1.0	0.5 %
Sulfated ash	Not more than 0.1 %	Ph. Eur. 2.4.14	<0.1 %
Related substances Doxazosin Mesylate (HPLC)		Ph. Eur., 2.2.29	
Related Substances: unknown impurities individual	Not more than 0.10 %		<0.05 %
Related Substances: total impurities	Not more than 0.3 %		<0.1 %
Assay Doxazosin Mesylate (HPLC)	98.0 % - 102.0 % (anhydrous substance)	Ph. Eur., 2.2.29	100.4 %
Identification polymorphic form (DSC)	Conforms	I 2.372	Conforms
Iron / Heavy metals		H 2.95 / H 2.95 or 1.07	
Iron	Not more than 20 ppm		<10 ppm
Heavy metals	Not more than 20 ppm		<10 ppm
Particle size		P 47.81 or P 47.89 or P 47.811	
Particle size < 50 %	Less than 11 µm		3 µm

Issued By: Sarah Braun

Date of Issue: 17-Jan-2022 13:42:35

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DEUTSCHLAND GMBH
BETRIEBSSTÄTTE FREIBURG
MOOSWALDALLEE 1
79090 FREIBURG, GERMANY

Certificate of Analysis and Compliance

Item Code:	H000116032
Description:	DOXAZOSIN MESYLATE BULK
Lot Name:	FA4463
Supplier Lot:	FA4463
Specifications Reference Number:	840110-03
Manufacture Date:	19-Oct-2019
Reevaluation Date:	19-Oct-2021

Test	Specification	Test Method	Result
Particle size < 90 %	Less than 34 µm		10 µm
Residual solvents Acetone	Not more than 0.1 %	D 24.18	<0.1 %
Residual solvents Amyl acetate / N,N -Dimethylformamide		D 24.18 or A 54.1 or A 54.2 / D24.16 or A 54.2	
Residual solvents: Amyl acetate	Not more than 0.1 %		<0.1 %
Residual solvents: N,N-Dimethylformamid	Not more than 0.088 %		0.020 %
Certificate of supplier	Present	AP	Conforms

I hereby certify that the above information is authentic and accurate.

Disposition Value:	Released
Dispositioned By:	Holger Omyla
Disposition Date:	04-Oct-2021 15:58:27
	This certificate was created by a validated system and is valid without manual signature

Issued By: Sarah Braun

Date of Issue: 17-Jan-2022 13:42:35

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