ASTRAZENECA DUNKERQUE PRODUCTION
224 avenue de la Dordogne
DUNKERQUE
59640
France

Tel. 03 28 58 48 00

CERTIFICATE OF ANALYSIS

VANNAIR 160/4.5 MCG/ACTIVATION (120)

Batch Number:	3002307E00
Date of Manufacture:	May-2020
Date of Expiry:	Apr-2022
Importing Country:	Chile

TEST/PROCEDURE	ACCEPTANCE CRITERIA	RESULT
Description of inhaler	The canister is enclosed within a red actuator with a white mouthpiece and a grey actuation counter module. The actuator is fitted with an integral cap retaining strap and a grey dust cap.	Complies
Description of primary pack	The contents are held in a metal can fitted with a plastic stemmed metering valve. The external and internal can and valve surfaces are free from corrosion and obvious defects.	Complies
Description of canister contents	The residue after evaporation of the propellant is a white solid, free from visible contaminants.	Complies
Identity of budesonide and formoterol by HPLC retention time	The retention times of the peaks due to budesonide and formoterol in the sample chromatogram correspond with the retention times of the peaks due to budesonide and formoterol in the reference standard chromatogram similarly prepared and run	Complies
Delivered dose and uniformity of delivered dose for budesonide within batch		
Mean	85 - 115 % of nominal	101 % of nominal

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TEST/PROCEDURE	ACCEPTANCE CRITERIA	RESULT
Number of results outside 75-125 % mean	<= 1	0
Number of results outside 65-135 % mean	0	0
Delivered dose and uniformity of delivered dose for formoterol fumarate dihydrate within batch		
Mean	85 - 115 % of nominal	103 % of nominal
Number of results outside 75-125 % mean	<= 1	0
Number of results outside 65-135 % mean	0	0
Fine particle dose of budesonide		
Mean fine particle dose (<4.7 µm)	58 - 106 µg/actuation	68 µg/actuation
Fine particle dose of formoterol fumarate dihydrate		
Mean fine particle dose (<4.7 µm)	1.8 - 3.4 µg/actuation	2.4 µg/actuation
Water content		
Maxi individuals	<= 0.02 % w/w	0.01 % w/w
Number of deliveries per inhaler	Not less than 120	Complies

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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 batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Released by : LEONTINE GOURDIN PHARMACIST

Qualified Person according to the requirements of Directive 2001/83/EC

Released On : 11-Aug-2020

(This electronic signature is the legally binding equivalent of a hand written signature)

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