

Issued by:

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Batch Certificate

Certificate Date	Certificate Number
30-APR-2020	1000300276
Page	1 of 1

Material Description: AEROLIN SOL RESPIRADOR 20ML +DPR CL-GSK

Material Number: 1308203

Dosage form: Solution

Package size / type: 20mL Bottle

Strength: 0.5 %w/v

Manufacturing Authorisation Number: MIA4

Regulatory Statement:

Manufacturer's GMP Certificate Number: GMP/IMP 4/3848

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the EU and the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country / product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU GMP

Lot/Batch: WX7M

Date of Expiry

APR-2023

Date of Manufacture APR-2020

Importing Country:

Chile

Description	Specification	Results
Description - Form	Mobile liquid	Complies
Description - Colour	Colourless to pale yellow	Complies
Description - Clarity	Clear	Complies
Salbutamol identity (HPLC)	Similar to reference chromatogram	Complies
pH	≥ 3.4 and ≤ 4.0	3.6
Salbutamol content (HPLC) %w/v	≥ 0.485 and ≤ 0.515 %w/v	0.506
Benzalkonium chloride cont. %w/v	≥ 0.008 and ≤ 0.012 %w/v	0.011

Qualified Person.

Signature AKW

Name AKW

Date 13 May 2020