

CERTIFICATE OF ANALYSIS

PULMICORT 400 UG/DOS TURBUHALER 1X50 DOSER GB

Batch Number: GAET
Date of Manufacture: Nov-2019
Date of Expiry: Oct-2021
Importing Country: United Kingdom

TEST/PROCEDURE	ACCEPTANCE CRITERIA	RESULT
Appearance	A specially designed powder inhaler made of plastic materials. The colour of the turning grip is dark brown. On the bottom of the turning grip, Budesonide 400, is embossed. The contents are white to off-white rounded granules, which disintegrate to a fine powder upon slight pressure. A powder fraction may be present.	Complies
Budesonide (Identity)	Positive identity.	Positive
Weight of contents	Not less than 50 mg.	Complies
Dose measurements		
Metered dose	Average of 10 single doses from each of 10 inhalers, with the mouthpiece removed. 0.30-0.50 mg/dose	0.44 mg/dose
Metered dose	The standard deviation of the single doses. ≤ 0.12 mg/dose	0.03 mg/dose
Particle measurements		
Particle measurement	Deposition in stages 3 plus 4 of the Multi-stage Liquid Impinger at an airflow of 60 l/min (average of 3 inhalers). ≥ 120 μg /dose	162 μg /dose

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Deposition	The deposition in the mouthpiece at an airflow of 60 l/min (average of 3 inhalers). ≤ 0.12 mg/dose	0.11 mg/dose

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 : Maria Thalen Qualified Person

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

Released On : 11-Dec-2019

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