

Issued by:

GlaxoSmithKline
Harmire Road
BARNARD CASTLE
Durham DL12 8DT
UNITED KINGDOM



Tel: +44(0)1833 690600 Fax: +44(0)1833 692300

Batch Certificate

Certificate Date	Certificate Number
21-Jan-2020	BCI_0000000670
Page	1 of 2

Material Description: ALENYS NASAL SPRAY 0.05%120SPRX1 CL-ETEX

Material Number: 10000000068114

Dosage Form:

Liquid Suspension

Package size / type: 120 Dose Bottle

Strength:

0.05 %w/w

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:

688N

Date of Expiry

DEC-2021

Date of Manufacture:

DEC-2019

Importing Country:

Chile

Description	Specification	Results
Description - Form	Uniform Suspension	Complies
Description - Colour	White	Complies
Container	Complies with test	Complies
Fluticasone furoate identity (IR)	Concordant with reference spectrum	Complies
Fluticasone furoate content (HPLC) %LC	>=95 and <=105 %LC	101
Benzalkonium chloride content %LC	>=90 and <=110 %LC	100
Edetate disodium content (HPLC) %LC	>=90 and <=110 %LC	101
pH	>=5.0 and <=7.0	6.0
Mean dose delivered – start bottle µg/spray	>=23.4 and <=31.6 µg/spray	27.5
Mean dose delivered – end bottle µg/spray	>=23.4 and <=31.6 µg/spray	29.2
Dose Uniformity – L@ 85% coverage	<=20 %	11
Dose Uniformity – L@ 99% coverage	<=25 %	17
Weight of contents g	>=9.5 and <=10.5 g	10.0
Number of Medicated Sprays	>=120	Complies
Droplet Size Distribution: D10 µm	>=20 and <= 40 µm	30
Droplet Size Distribution: D50 µm	>=40 and <=110 µm	71
Mean % of droplets < 10µm %	<1.5 %	0.2
Total viable aerobic count cfu/mL	<=100 cfu/mL	<3.3

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Description	Specification	Results
Total viable aerobic count cfu/g	≤ 100 cfu/g	< 3.3
Total yeast and mould count cfu/mL	≤ 10 cfu/mL	< 3.3
Total yeast and mould count cfu/g	≤ 10 cfu/g	< 3.3
Ps. aeruginosa	Absent	Complies
S. aureus	Absent	Complies

Qualified Person

Signature AKWEAR

Name AKWEAR

Date 22 Jan 2020