

Geldig van 27 DEC 2018
tot 27 DEC 2021

QUALITY CONTROL DEPARTMENT

MOMETASONI FUROAS
ANALYSIS REPORT: 21I03-APR21190

AUTHORISATION	1890R05507	DATE OF ANALYSIS	28/07/2021
LOT NUMBER	21I03-APR21190	EXPIRY DATE	03/2026
PRODUCTION NUMBER	130921-GS21053	ANALYTICAL REFERENCE	PH. EUR. 10.4 [04/2020:1449]

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with mometasone furoate CRS	Complies
Identification D	Chromatogram complies	Complies
Identification E	≤ 0.5%	Complies
TESTS	SPECIFICATION	RESULT
Specific optical rotation	+ 50 to + 55 (dried substance)	+ 50
Related substances		
Impurity J	≤ 0.15%	0.09%
Unspecified impurities	≤ 0.10%	0.07%
Total	≤ 0.3%	0.2%
Loss on drying	≤ 0.5%	0.2%
ASSAY	SPECIFICATION	RESULT
LC	98.0% to 102.0% (dried substance)	99.4%

CONCLUSION: *Complies*

RESPONSIBLE PHARMACIST:


DATE: *01-10-2021*