

CERTIFICATE OF ANALYSIS

XYLOMETAZOLONI HYDROCHLORIDUM 2,5 g

Lot No.: 24I09-F240117

Authorisation:1890R05441Date Of Analysis:04/10/2024Analytical Reference:Ph.Eur. [01/2008:1162]Production Number:240924-G240151CNK:3490-992Expiry Date:03/2029

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with xylometazoline hydrochloride CRS	Complies
Identification E	Reaction of (a) chlorides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Complies	Complies
Acidity or alkalinity	Complies	Complies
Related substances		
Impurity A	≤ 0.2%	0.002%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Loss on drying	≤ 0.5%	0.04%
Sulfated ash	≤ 0.1%	0.04%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	99.9%

Manufacturer identification code: S/GS/009

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: Maxime Brits

(Signature) 2024.11.18

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