

XYLOMETAZOLINI HYDROCHLORIDUM 2,5 g

Lot No.: 22E12-APR23173

Autorisation :	1890R05441	Date Of Analysis :	17/03/2022
Analytical Reference :	Ph. Eur. 10.6 [01/2008:1162] Corr. 10.1	Production Number :	080623-GS22046
CNK :	3490-992	Expiry Date :	11/2026

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	Clear and not more intensely coloured than reference solution Y ₆	Complies
Acidity or alkalinity	Solution is red	Complies
	≤ 0.2 mL sodium hydroxide (0.01 M)	0.1 mL
Related substances		
Impurity A	≤ 0.2%	< 0.05%
Unspecified impurities	≤ 0.10%	0.06%
Total	≤ 0.5%	0.06%
Loss on drying	≤ 0.5%	0.04%
Sulfated ash	≤ 0.1%	0.09%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	100.8%

Manufacturer identification code: S/GS/009

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:

Joran Smout
(Signature) Digitally signed by Joran Smout (Signature)
Date: 2023.07.11 11:16:54 +02'00'