

FUROSEMIDUM 10 g

Lot No.: 24A31-AP24213

Autorisation :	1890IR05372	Date Of Analysis :	31/01/2024
Analytical Reference :	Ph. Eur. [04/2018:0391]	Production Number :	300924-0191223
CNK :	3477-445	Expiry Date :	07/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with furosemide CRS	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution BY ₅	Complies
Related substances		
Impurity C	≤ 0.2%	< 0.05%
Impurity D	≤ 0.15%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Chlorides	≤ 200 ppm	< 200 ppm
Sulfates	≤ 300 ppm	< 300 ppm
Loss on drying	≤ 0.5%	0.1%
Sulfated ash	≤ 0.1%	0.02%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.5% to 101.0% (dried substance)	100.1%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: