

SULPIRIDUM 250 g
Lot No.: 24E13-APR24098

Autorisation :	1890R05438	Date Of Analysis :	29/01/2024
Analytical Reference :	Ph. Eur. 10.6 [01/2017 :1045]	Production Number :	130524-GS24008
CNK :	3490-893	Expiry Date :	10/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the reference spectrum obtained with sulpiride CRS	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution Y ₆	Complies
Impurity A	≤ 0.1%	Complies
Related substances		
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.3%	< 0.05%
Chlorides	≤ 100 ppm	Complies
Iron	≤ 10 ppm	Complies
Loss on drying	≤ 0.5%	0.04%
Sulfated ash	≤ 0.1%	0.04%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.5% to 101.0% (dried substance)	100.1%
Manufacturer identification code: S/GS/058		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: