

BACLOFENUM 100 g
Lot No.: 24B06-APR24031

Autorisation :	1890R05503	Date Of Analysis :	13/12/2023
Analytical Reference :	Ph. Eur. 10.6 [01/2008 :0653]	Production Number :	130224-GS23128
CNK :	4413-050	Expiry Date :	04/2026

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with baclofen CRS	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Not more opalescent than reference suspension II	Complies
	Not more intensely coloured than reference solution BY ₅	Complies
Related substances		
Impurity A	≤ 1.0%	Not detected
Total	≤ 2.0%	Not detected
Water	≤ 1.0%	0.07%
Sulfated ash	≤ 0.1%	0.1%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.0% to 101.0% (anhydrous substance)	99.4%
Manufacturer identification code: S/GS/020		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: