



CERTIFICATE OF ANALYSIS

BACLOFENUM 5 g

Lot No.: 24B06-APR24032

 Autorisation:
 1890R05503
 Date Of Analysis:
 13/12/2023

 Analytical Reference:
 Ph. Eur. 10.6 [01/2008:0653]
 Production Number:
 140224-GS23128

CNK: 3489-713 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 colution	Not more opalescent than reference suspension II	Complies
Appearance of solution	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: