

BACLOFENUM

Lot No.: 24K28-F250016

Authorisation:	1890R05503	Date Of Analysis:	05/09/2024
Analytical Reference:	Ph.Eur. [01/2008:0653]	Production Number:	170125-G240068
CNK:	4413050	Expiry Date:	12/2026

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 and 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%	0.2%
Sulfated ash	≤ 0.1%	< 0.1%
ASSAY		RESULT
Potentiometric titration	98.0% to 101.0%	100.3%

Manufacturer identification code: S/GS/020

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: