

CLOBETASONI BUTYRAS 500 mg

Lot No.: 22E23-APR22159

Authorisation:	1890R05727	Date Of Analysis:	21/03/2022
Analytical Reference:	Ph. Eur. 10.6 [01/2010:1090] Corr. 8.4	Production Number:	020622-GS22055
CNK:	3968-773	Expiry Date:	05/2026

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification	The spectrum complies with the spectrum obtained with clobetasone butyrate CRS	Complies
TESTS	SPECIFICATION	RESULT
Specific optical rotation	+ 131 to + 138 (dried substance)	+131
Related substances		
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Loss on drying	≤ 0.5%	0.1%
ASSAY	SPECIFICATION	RESULT
UV	97.0% to 102.0% (dried substance)	99.9%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: