

IBUPROFENUM 100 g

Lot No.: 24L04-F250062

Authorisation:	1890R05422	Date Of Analysis:	17/10/2024
Analytical Reference:	Ph.Eur. [01/2017 :0721]	Production Number:	180225-G240157
CNK:	3490349	Expiry Date:	02/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder or colourless crystals	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	75°C to 78°C	Complies
Identification C	The spectrum complies with the spectrum obtained with ibuprofen CRS	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and colourless	Complies
Optical rotation	- 0.05° to + 0.05°	- 0.04°
Related substances		
Impurity A	≤ 0.15%	< 0.03%
Impurity J	≤ 0.15%	< 0.03%
Impurity N	≤ 0.15%	< 0.03%
Unspecified impurities	≤ 0.05%	< 0.03%
Total	≤ 0.2%	< 0.03%
Impurity F	≤ 0.1%	< 0.1%
Loss on drying	≤ 0.5%	< 0.5%
Sulfated ash	≤ 0.1%	< 0.1%
ASSAY	SPECIFICATION	RESULT
Titration	98.5% to 101.0% (dried substance)	99.5%

Manufacturer identification code: S/GS/209

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: