

TROMETAMOLUM 100 g

Lot No.: 24D02-APR24066

Autorisation :	1890R05440	Date Of Analysis :	08/01/2024
Analytical Reference :	Ph. Eur. 10.7 [01/2017 :1053]	Production Number :	020424-GS24001
CNK :	3490-968	Expiry Date :	07/2026

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	A white or almost white, crystalline powder, or colourless crystals	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	168 °C to 174 °C	Complies
Identification C	The spectrum complies with the spectrum obtained with trometamol CRS	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and colourless	Complies
pH	10.0 to 11.5	10.8
Related substances	Any impurity $\leq$ 1.0%	Complies
Chlorides	$\leq$ 100 ppm	Complies
Iron	$\leq$ 10 ppm	Complies
Loss on drying	$\leq$ 0.5%	0.04%
Sulfated ash	$\leq$ 0.1%	0.1%
ASSAY	SPECIFICATION	RESULT
Titration	99.0% to 100.5% (dried substance)	99.3%

Manufacturer identification code: S/GS/001

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: