

SACCHARINUM NATRICUM 25 g

Lot No.: 24E07-AP24117

Autorisation :	1890IR05395	Date Of Analysis :	07/05/2024
Analytical Reference :	Ph.Eur. (04/2019:0787)	Production Number :	160524-0170424
CNK :	3462-876	Expiry Date :	10/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder or colourless crystals, efflorescent in dry air	White crystalline powder
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with saccharin sodium CRS	Complies
Identification E	Reaction (a) of sodium	Complies
TESTS	SPECIFICATION	RESULT
Solubility	Freely soluble in water, sparingly soluble in ethanol (96%)	Complies
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	Colour reaction complies	Complies
o- and p-Toluenesulfonamide		
o-toluenesulfonamide	≤ 10ppm	Not Detected
p-toluenesulfonamide	≤ 10ppm	Not Detected
Readily carbonisable substances	Colour reaction complies	Complies
Water	≤ 15.0%	14.7%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% - 101.0% (anhydrous substance)	100.7%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: