

EUTICALS SPA - Quality Control
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CERTIFICATE OF ANALYSIS: 040000136300 Date of Analysis: 07/06/2018

Product: SUCRALFATE

Code: 30175

Batch: IA1800610A

Manufacturing date: 12/05/2018

Expiring date: 11/05/2023

Tests	Limits	Results
Appearance:	White or almost white powder	Complies
Clarity and color of solution:	Clear and practic. colourless	Complies
Identification:	Test A (USP): Positive Test A (EP): Positive Test B (USP,EP): Positive Test C (USP,EP): Positive	Positive Positive Positive Positive
Acid neutralizing capacity (meq):	n.l.t. 12	16
Chloride (%):	n.m.t. 0.50	0,28
Arsenic (ppm):	n.m.t. 4	Complies
Heavy metals (ppm):	n.m.t. 10	Complies
Limit of 2-methylPy (ppm, HPLC):	n.m.t. 25	Complies
Limit of Pyridine (ppm, HPLC):	n.m.t. 25	Complies
Limit of Sucrose Heptasulphate (Sucrose Heptasulphate/Sucrose Octasulphate ratio):	n.m.t. 0.05	0,05
Total Impurities (% , HPLC): (Excluding Sucrose Heptasulphate)	n.m.t. 1,0	0,01
Single Unknown Impurities (% , HPLC):	n.m.t. 0,10	0,01
Impurity A (Sucr. Heptasulf., %, HPLC):	n.m.t. 5,0	4,7
Aluminum content (%):	16.5 ÷ 18.5	17,5
Residual solvents USP<467>:	No class 1 solvents are used Class 2 solvents are used: Pyridine n.m.t. 200 ppm (internal limit 25 ppm) No class 3 solvents are used	
Assay (HPLC, %):	30.0 ÷ 36.0	33,5

The product's quality meets the specifications set forth in USP and EP current editions

0022-SPC-22

Quality Control Manager

Date of Issue

14.06.2018