

Product **SUCRALFATE MICRONIZED 50**

Batch IA2201663A

Code 30201

Man. Date 04/08/2022

Exp. Date 03/08/2027

Tests	Limits	Results
Appearance:	White or almost white powder	Complies
Clarity and Colour of Solution:	Clear and practic. Colourless	Complies
<b>Identification:</b>		
Test A (USP):	Positive	Positive
Test A (EP):	Positive	Positive
Test B (USP,EP):	Positive	Positive
Test C (USP,EP):	Positive	Positive
Acid neutralizing capacity (meq):	n.l.t. 12	16
Chloride (%):	n.m.t. 0.50	0.27
Arsenic (ppm):	n.m.t. 4	< 4
Limit of 2-methylPy HPLC (ppm):	n.m.t. 25	< 6,25
Limit of Pyridine HPLC (ppm):	n.m.t. 25	< 6,25
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	
Limit of Sucrose Heptasulphate (Sucrose Heptasulphate/Sucrose Octasulphate ratio):	n.m.t. 0.1	0.04
Total Impurities (% , HPLC, excluding sucrose Heptasulfate):	n.m.t. 1.0	< 0,033
Single Unknown Impurities (% , HPLC):	n.m.t. 0.10	< 0,033
Impurity A HPLC (Sucr. Heptasulphate, %):	n.m.t. 5.0	1.3
Aluminum content (%):	16.5 ÷ 18.5	17.4
Assay HPLC (%):	30.0 ÷ 36.0	33.4
<b>Additional Tests:</b>		
Vanadium (mg/Kg)*:	n.m.t. 25	10
<b>Particle size:</b>		
D100 (µm):	n.m.t. 50	16

\* Analysis performed by an external lab. with ICP-OES on customer request.

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

Batch number of starting material (Sucralfate as is):

30175 - IA2201408A

28.09.2022