

Product **SUCRALFATE MICRONIZED 50**

Batch

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 |
| Identification: | | |
| 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 |
| Additional Tests: | | |
| Vanadium (mg/Kg)*: | n.m.t. 25 | 10 |
| Particle size: | | |
| D100 (µm): | n.m.t. 50 | 16 |

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

28.09.2022