



# 东北制药集团股份有限公司

## NORTHEAST PHARMACEUTICAL GROUP CO., LTD

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### CERTIFICATE OF ANALYSIS

#### Sucralfate USP

Analysis Items		Specifications	Analysis Results
BATCH NUMBER	DY0012300058	MANUFACTURE DATE	Mar.28.2023
BATCH SIZE	1000kg	TEST DATE OF APPLICATION	Apr.5.2023
QUANTITY	40Drums	RETEST DATE	Mar.27.2027
1.	Characteristics	White or almost white amorphous powder	white amorphous powder
2.	Identification	A:HPLC:Meets the Requirements B:Positive C:Positive	Meets the Requirements Positive Positive
3.	Acid Neutralization Equivalent	≥12mEq/g	13.1mEq/g
4.	Assay (C <sub>12</sub> H <sub>14</sub> O <sub>35</sub> S <sub>8</sub> )	30.0%~38.0%	33.6%
5.	Assay:Aluminum	15.5%~18.5%	18.0%
6.	Assay: Sulfur	9.5%~12.5%	11.1%
7.	Limit of sucrose heptasulfate	≤0.1	0.01
8.	Free Aluminum	≤0.5%	0.01%
9.	Free Sucrose	≤0.2%	0.01%
10.	Arsenic	≤4ppm	<4ppm
11.	Chloride	≤0.50%	<0.50%
12.	Clarity of Solution	clear	<1# turbidity standard solution
13.	Colour of Solution	practically colorless	<B <sub>9</sub>
14.	α-methylpyridine	≤0.02%	Not detected
15.	Pyridine	≤0.02%	Not detected

We, Northeast Pharmaceutical Group Co., Ltd., certify that this batch of **Sucralfate** meets the requirements of **United States Pharmacopoeia ( Official as of 1-Jan-2018 )** .

Supervisor *[Signature]*  
Final Batch Disposition

**Approved**

By: *[Signature]* 2023.04.13

