

HENANLIHUAPHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20250366EP11

PRODUCT		HYDROCORTISONE	DATE OF SAMPLING	MAR.15,2025
BATCH NUMBER		K05M20250319	DATE OF REPORT	MAR.19,2025
BATCH SIZE		167.06Kg	MANUFACTURING DATE: MAR.08,2025 RETEST DATE:FEB.2030	
CRITERIA: EP11				
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULTS	
APPEARANCE		WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:IR	CONFORM	CONFORM	
	B:HPLC	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION		+162° ~+168°	+166°	
RELATED SUBSTANCES		IMPURITY C:≤0.5% IMPURITY D:≤0.5% IMPURITY E:≤0.5% IMPURITY I:≤0.5% IMPURITY F:≤0.3% IMPURITY A:≤0.2% IMPURITY B:≤0.2% IMPURITY G:≤0.4% IMPURITY H:≤0.15% IMPURITY N:≤0.15% UNSPECIFIED IMPURITY≤0.10% TOTAL:≤2.0%	IMPURITY C : <0.05% IMPURITY D : <0.05% IMPURITY E : <0.05% IMPURITY I : <0.05% IMPURITY F : <0.05% IMPURITY A : <0.05% IMPURITY B : <0.05% IMPURITY G : 0.14% IMPURITY H : <0.05 % IMPURITY N : <0.05% UNSPECIFIED IMPURITY: RRT(2.05)0.06% TOTAL: 0.20%	
LOSS ON DRYING		≤0.5%	0.1%	
ASSAY		97.0~103.0% (ON DRIED SUBSTANCE)	100.5%	
CONCLUSION: CONFORMS TO EP11				
RESIDUAL SOLVENTS		METHANOL≤1500PPM ACETONE≤3000PPM DICHLOROMETHANE≤100PPM	23 PPM 1124 PPM NOT DETECTED	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 杨文 2025.03.19

QC DIRECTOR 梁张 2025.03.19

ADDRESS: MIDDLE OF HUANGHE STREET, ANYANG HI-TECH INDUSTRY DEVELOPMENT ZONE,
HENAN, CHINA

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METAPHARMACEUTICAL

N DE LOTE:

0170525

Alcandro
9.3/05/2025

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COA NO.:20250098EP11.0

PRODUCT		HYDROCORTISONE ACETATE	DATE OF SAMPLING	JAN.21,2025
BATCH NUMBER		K06M20250117	DATE OF REPORT	APR.08,2025
BATCH SIZE		102.16 Kg	MANUFACTURING DATE:JAN.17,2025 RETEST DATE: DEC.2029	
CRITERIA : EP11.0				
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULTS	
APPEARANCE		WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A: IR	CONFORM	CONFORM	
	B:HPLC	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION		+158° ~+167°	+166°	
RELATED SUBSTANCES		IMPURITY A ≤ 0.5% IMPURITY B ≤ 0.3% IMPURITY C ≤ 0.6% IMPURITY D ≤ 0.3% IMPURITY E ≤ 0.3% IMPURITY G ≤ 0.15% UNSPECIFIED IMPURITY ≤ 0.10% TOTAL ≤ 1.5%	IMPURITY A: <0.05% IMPURITY B: <0.05% IMPURITY C: 0.06% IMPURITY D: <0.05% IMPURITY E: 0.06% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.12%	
LOSS ON DRYING		≤0.5%	0.1%	
ASSAY		97.0%~102.0% (ON DRIED SUBSTANCE)	99.8%	
CONCLUSION: CONFORMS TO EP11.0				
RESIDUAL SOLVENTS		METHANOL ≤3000PPM ACETONE ≤5000PPM METHYLENE CHLORIDE ≤600PPM	13 PPM 348 PPM NOT DETECTED	
MICRONIZED				
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT				

CHECKER 李敏 2025.04.08

QC DIRECTOR 梁敏 2025.04.08

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METAPHARMACEUTICAL

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Aljandra

13/05/2025



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 EP

BATCH NUMBER	DY02012500006	MANUFACTURE DATE	Mar.18.2025
BATCH SIZE	25kg	TEST DATE OF APPLICATION	Mar.25.2025
QUANTITY	1Drums	RETEST DATE	Mar.17.2028
Analysis Items		Specifications	Analysis Results
1.	Characteristics	White or almost white, amorphous powder	white, amorphous powder
2.	Identification	A:IR:Complies B:Positive C:Positive	Complies Positive Positive
3.	Acid Neutralization Equivalent	Meets the Requirements	Meets the Requirements
4.	Assay: (C ₁₂ H ₁₄ O ₃ S ₆)	30.0%~38.0%	33.9%
5.	Assay:Aluminum	15.5%~18.5%	17.9%
6.	Related Substances	Impurity A≤5.0%	0.04%
7.	Chloride	≤0.50%	<0.50%
8.	Particle-Size	100% pass though 50μ m	100%

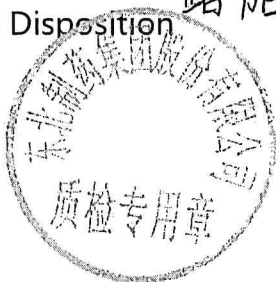
We, **Northeast Pharmaceutical Group Co., Ltd.**, certify that this batch of **Sucralfate** meets the requirements of **EP11.0**

Supervisor

Final Batch Disposition

路阳 2025.04.01

Approved



By: 马红芳 2025.04.01

METAPHARMACEUTICAL

N DE LOTE:

0150525

Mjandao
13/05/2025



大邦（湖南）生物制药有限公司
ARGUS PHARMACEUTICALS, LTD.

N DE LOTE:

0140525

Alfonso
13/05/2025

Certificate of Analysis

Orlistat (Bulk Material)

Batch No:	202504002	Quantity:	181.05kg
M.F. Date:	Apr. 02, 2025	Test Date:	Apr.04, 2025
Expiry Date:	Apr. 01, 2028	Standard	USP-42
Storage: Preserve in well-closed containers between 2°C and 8°C			
Item	Results	Specifications	
Description	White crystalline powder	White to off-white crystalline powder	
Solubility	Conforms	Very soluble in methanol and ethanol, freely soluble in chloroform, practically insoluble in water.	
Identification HPLC IR	HPLC retention time Conforms with the reference Conforms	HPLC retention time Conforms with the reference Conforms	
Specific Optical Rotation	-50.3°	-48.0° to -51.0°	
Water content	0.03%	NMT 0.2%	
Related substances I a. Orlistat related compound A	Not detected	NMT 0.2%	
Related substances II a. Orlistat related compound B	0.005%	NMT 0.05%	
Related substances III a. Formylleucine b. Orlistat related compound C c. Orlistat open ring epimer d. D-Leucine orlistat e. Individual unidentified Impurity	0.006% 0.01% 0.05% Not detected 0.06%	NMT 0.2% NMT 0.05% NMT 0.2% NMT 0.2% NMT 0.1%	
Related substances IV a. Orlistat related compound D b. Orlistat open ring amide	0.03% 0.01%	NMT 0.2% NMT 0.1%	
Related substances V a. Orlistat related compound E	0.10%	NMT 0.2%	
Total impurities(I to V)	0.27%	NMT 1.0%	
Residual solvents	Methanol: Not detected EtOAc: Not detected n-Heptane: 200ppm	Methanol: NMT 3000PPM EtOAc: NMT 5000ppm n-Heptane: NMT 5000ppm	
Residue on Ignition	0.02%	NMT 0.1%	
Heavy Metals as Pb	Less than 20ppm	NMT 20ppm	
Assay by HPLC (Orlistat)	99.9%	NLT 98.0% to 101.5% (on anhydrous, solvent-free basis)	
Microbial Limit Bacteria Mould Escherichia coli	<10cfu/g <10cfu/g Not detected	NMT1000cfu/g NMT 100cfu/g Not detected	
Conclusion:	The results conform with the USP-42 specification		
QC Chemist	Zhu Dai Xia		
QA Chemist	Bong Liang		

This document is approved and is electronically released without personal signature.

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