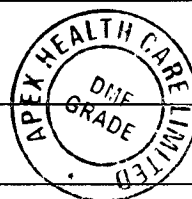


**QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS**

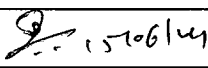
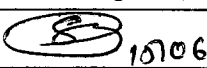
Product	BENZOCAINE	Page No.	01 of 01
Standard for Release	EP	Drug Lic. No.	G/25/1642

Batch No.	BCAH0450524	Batch Quantity	652.700 Kgs.
Mfg. Date	MAY-2024	Date of Sampling	20/05/24
Exp. Date	APR-2029	Date of Approval	29/05/24
A.R. No.	FP/BC/060/24	Dispatched Qty.	NA
C.A.S. No.	94-09-7		

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	Description	White or almost white, crystalline powder or colorless crystals.	White crystalline powder
2.	Solubility	Very slightly soluble in water, freely soluble in ethanol (96 %)	Complies
3.	A. Identification (By IR)	The infrared absorption spectrum of Benzocaine is concordant with the reference spectrum.	Complies
	B. Identification (By Melting Point)	Determination- A: 89° C to 92° C Determination- B: the absolute difference between the melting point of the mixture and the value obtained in determination A is not greater than 2° C.	90 ° C 1 ° C
4.	Related Substances	Unspecified impurities: NMT 0.10 % Total impurities: NMT 0.2 %	BDL BDL
5.	Loss on drying	Not more than 0.5 % w/w	0.15 %
6.	Sulphated Ash	Not more than 0.1 % w/w	0.04 %
7.	Assay	Between 99.0 % and 101.0 %	99.96 %
8.	Residual Solvents (By GC-HS)	Ethanol: NMT 5000 ppm Methanol: NMT 3000 ppm Toluene: NMT 890 ppm	ND 124 ppm ND
9.	Total Aerobic microbial Count Total Yeast & Mould Count	NMT 100 cfu/g NMT 10 cfu/g	35 cfu/g Nil
10.	Escherichia coli	Absent/1 g	Absent



Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per EP'11.3.

Name	Mr. Pankaj Pateliya	Mr. Somnath Kokate	Mr. Chetan Sardhara
Designation-Dept.	Executive -QC	Sr. Executive-QC	Asst. Manager -QC
Sign. /Date	 15/06/24	 15/06/24	 15/06/24
	Prepared by	Reviewed by	Approved by



江苏天和制药有限公司

JIANGSU TIANHE PHARMACEUTICAL CO., LTD

中国 江苏省江都经济开发区三江大道1号 No.1 Sanjiang Road, Economic development zone, Jiangdu, Jiangsu, China
电话 PHONE:0514-86820810 传真 FAX:0514-86820808 邮箱 E-mail:jstianhe3@jstianhezy.com

检验报告单
CERTIFICATE OF ANALYSIS

J.ZL.00.228.1.0

品名 PRODUCT: Sulfacetamide Sodium	报告编号 CERTIFICATE NO: 0002		
批号 BATCH NO: S01-2312039	报告日期 CERTIFICATE DATE: 2024.10.12		
批量 BATCH SIZE: 500kg	生产日期 DATE OF MANUFACTURE: 2023.12.18		
有效日期 EXPIRY DATE: N/A	复测期 RETEST DATE: 2027.12.		
检验项目 Items	标准 Specifications	方法 Method	检验结果 Results
Characters		EP	
Appearance	White or yellowish-white, crystalline powder		White crystalline powder
Solubility	Corresponds		Corresponds
Identification			
B	Conform to the RS spectrum	EP(2.2.24)	Corresponds
F	Gives reaction of sodium	EP(2.3.1)	Corresponds
Test			
Appearance of solution	Clear and $\leq$ GY ₄	EP(2.2.2)	Corresponds
pH	8.0-9.5	EP(2.2.3)	9.0
Related substances		EP(2.2.29)	
Impurity A	$\leq$ 0.2%		0.03%
Single unspecified impurities	$\leq$ 0.10%		0.03%
Total impurities	$\leq$ 0.5%		0.08%
Sulfates	$\leq$ 200ppm	EP(2.4.13)	<200ppm
Water	6.0%-8.0%	EP(2.5.12)	7.1%
Assay(anhydrous)	99.0% ~101.0%	EP(2.5.8)	99.8%
Residual solvent		In house	
Ethanol	$\leq$ 0.5%		0.01%
Microbial clearance		In house	
TAMC	$\leq$ 10 ² cfu/g		1cfu/g
TYMC	$\leq$ 10 ¹ cfu/g		<1cfu/g
Bile tolerant enterobacteria(GN)	None per 1g		N.D
Pseudomonas aeruginosa	None per 1g		N.D
Staphylococcus aureus	None per 1g		N.D
结论 CONCLUSION:	The above mentioned product conforms to purchasing specification		
备注 REMARKS:			
Prepared by/Date(QC) 蔡敏 2024.10.12	Reviewed by/Date(QC) 冯文 2024.10.17	Approved by/Date(QA) 何青 2024.10.14	

四川武胜春瑞医药化工有限公司
Sichuan Wusheng Chunrui Medicine Chemical Co., Ltd.

检验报告单

Certificate of Analysis

品名 ITEM	盐酸普鲁卡因 PROCAINE HYDROCHLORIDE		
批号 BATCH NO	20250313	数量 QUANTITY	150KGS
包装 PACKING	25KG/桶 25KG/ Bucket	报告编号 LOT NO	20250313
生产日期 PRODUCTION DATE	Mar.13, 2025	有效期 EXPIRY DATE	Mar.12, 2029
检验标准 STANDARD	EP10.0		
指标 INDEX	标准 STANDARD	结果 RESULTS	
外观 APPEARANCE	白色结晶性粉末或无色晶体。 White crystalline powder or colorless crystal	Conform	
鉴别 IDENTIFICATION	A. Melting point: 154℃~158℃ B. IR E. It gives reaction(a) of chlorides	155.0℃~155.5℃ Conform Conform	
酸度 ACIDITY	PH5.0-6.5	PH=5.8	
溶液外观 Appearance of solution	Clear and colourless	Conform	
干燥失重 LOSS ON DRYING	≤0.5%	0.05%	
重金属 HEAVY METALS	≤0.0005%	Conform	
有关物质 RELATED SUBSTANCES	Any impurity ≤0.05%	Conform	
硫酸盐灰份 SULPHATED ASH	≤0.1%	0.05%	
含量(折干) ASSAY (ON DRY BASIS)	99.0-101.0%	99.8%	
微生物限度 Microbial limit	TAMC ≤100CFU/g TYMC ≤100CFU/g	Conform Conform	
细菌内毒素 BACTERIAL ENDOTOXINS	≤0.6Eu/mg	<0.3Eu/mg	
结论 CONCLUSION	Conforms to EP10.0		
主管 MANAGER	报告人 REPORTER		
2025.04.10		2025.04.10	



CERTIFICATE OF ANALYSIS

Product Name :	PAPAVERINE HYDROCHLORIDE Ph.Eur	Report Date :	17.04.2025
Batch / Lot No. :	64020125	Mfg. Date :	Jan-2025
Quantity :	50.00 Kg	Expiry/Retest Date :	Nov-2029
Test Parameter	Specification		Result
CHARACTERS			
Appearance	White or almost white, crystalline powder or white or almost white crystals.		White Crystalline Powder, Complies
Solubility			
In water	Sparingly soluble in water.		Complies
In Ethanol (96%)	Slightly soluble in Ethanol (96%).		Complies
IDENTIFICATION			
A. Infrared absorption Spectrophotometry	Sample spectrum should be concordant with the spectrum of Papaverine HCl Working Standard.		Complies
B. Thin-layer chromatography	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.		Complies
C. Melting point (⁰ C)	Between 146°C and 149°C		148.5°C, Complies
D. Reaction of chlorides	A curdled, white precipitate is formed.		Complies
TESTS			
Appearance of solution	Solution S is clear and not more intensely colored than reference solution BY ₆ .		Complies
pH	Between 3.0 and 4.0.		3.20, Complies
Related substances by Liquid chromatography (% w/w)	Impurity-A	Not more than 0.1 %.	*ND, Complies
	Impurity-B	Not more than 0.1 %.	*ND, Complies
	Impurity-C	Not more than 0.1 %.	*ND, Complies
	Impurity-D	Not more than 0.1 %.	*ND, Complies
	Impurity-E	Not more than 0.1 %.	*ND, Complies
	Impurity-F	Not more than 0.1 %.	*ND, Complies
	Any unknown impurity	Not more than 0.1 %.	*BDL, Complies
	Total Impurities	Not more than 0.5 %.	*BDL, Complies
Loss on drying (% w/w)	Maximum 0.5 %.		0.12%, Complies
Sulphated ash (% w/w)	Maximum 0.1 %.		0.02%, Complies
Assay (% w/w)	Between 99.0 % and 101.0 % (dried substance).		100.2%, Complies



CERTIFICATE OF ANALYSIS

Product Name :	PAPAVERINE HYDROCHLORIDE Ph.Eur	Report Date :	17.04.2025
Batch / Lot No. :	64020125	Mfg. Date :	Jan-2025
Quantity :	50.00 Kg	Expiry/Retest Date :	Nov-2029

Test Parameter	Specification		Result
ADDITIONAL TESTS			
Residual solvents (by GC-HS)	Chloroform	Not more than 60 ppm.	*ND, Complies
	Toluene	Not more than 100 ppm.	11 ppm, Complies
	Mesitylene	Not more than 70 ppm.	*BQL, Complies
Microbial analysis	Total bacterial count		Not more than 100 cfu/gm
	Total yeast/ Mould count		Not more than 10 cfu/gm
	Pathogens		
	Escherichia Coli		Should be absent
	Salmonellae		Should be absent
	Pseudomonas aeruginosa		Should be absent
	Staphylococcus aureus		Should be absent
Bacterial Endotoxin	Not more than 2.5 EU/mg		Less than 2.5 EU/mg, Complies

STORAGE: Preserve Papaverine Hydrochloride in a well-closed containers and protected from light.

REMARKS: The above batch complies/~~does not comply~~ with the prescribed standards of quality as described above.

For HSGC:

*LOQ: Limit of Quantification

*BQL: Below Quantification Limit

For HPLC:

*BQL: Below Quantification limit: 0.05 %

*ND: Not Detected

*BDL: Below detection limit

Name of the Solvent LOQ Value

Mesitylene : 2 ppm

Chloroform : 7 ppm

Toluene : 3 ppm



Prepared by : Samp
Date : 20/05/25

Reviewed by : [Signature]
Date : 20/05/25

Approved by: Ran
Date : 20/05/2025

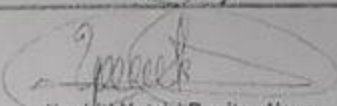
Laboratorios Imperiales, S.A. de C.V. Calle 13-Este, No. 606, CIVAC Jiutepec Morelos, CP: 62578 Tel: (+52) 777 3191410, 777 321 66 71		 LIMSA
Contact information: Claudio Bezanilla Salcedo Title: CEO Mail: cbezanilla@limsa.com.mx Tel: (+52) 55 1941 2141		
ANNEX OF STANDARD OPERATING PROCEDURE FOR CERTIFICATE OF ANALYSIS ELABORATION. FORMAT FOR CERTIFICATE OF ANALYSIS.		Code: ANX1-PNO-DAC-021

Product: Bismuth Tribromophenate.		CoA/S
Sample weight: 400 g		Internal product code: 412
Delivery weight: 200.00 Kg		Batch number: PTQ-3551/23
Manufacturing date: 28-JUN-22		Analysis number: 3551/23
Retest date: 28-JUN-28		Internal batch number: H-72/23
Reference: US Dispensatory 25 th , Medicamenta III 1963, BP 1949, USP		CAS No: 5175-83-7

Test	Specification	Result
Description	Light yellow, amorphous powder with a faint characteristic odor.	Meets
Identification		
Bismuth ion (Bi ³⁺)	Positive for Bi ³⁺	Positive
Tribromophenol	Positive for tribromophenol	Positive
Substance not precipitated by NH ₄ OH	≤ 0.50%	0.03%
Free 2, 4, 6-Tribromophenol	≤ 3.3%	1.09%
Arsenic	0.0002	< 0.0002
Copper	To pass test	Pass test
Silver	To pass test	Pass test
Lead	To pass test	Pass test
Sulphate	To pass test	Pass test
Nitrates	To pass test	Pass test
Loss on drying	Not specified	0.3%
Assay of Bismuth(as Bi)	400-490	46.92%

Storage and packaging conditions.

Package	Double polyethylene plastic bag, packed in cardboard fiber drum.	Storage	Less than 25°C protect from direct sunlight exposure.
Marks	According to ND	Shelf life	6 years.

Analyzed by:	Issued by:	Approved by:
J. Martinez, JM. Bahena, B. Treviño	 Xochitl Yutziri Benitez Nava C.P. D.G.P. - 4719879 Head of Quality Control	 Claudio Bezanilla Martinez. C.P.D.G.P. 187941 Sanitary Responsible N o. ARM-0577-2002
Date: 16-NOV-23	Date: 17-NOV-23	Date: 17-NOV-23