APEX HEALTHCARE LIMITED

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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

APEX HEALTH CARE LIMITED DMF GRADE

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**

Mfg. Site Address: Plot no. 4710, 4711, 4707-A/8, 4707-A/9, GIDC Industrial Estate Ankleshwar, Dist.-Bharuch-393002, Gujarat, India. Phone no.: +91 2646 222525/223525/227289.

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
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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	≤0.2%		0.03%
Single unspecified impurities	≤0.10%		0.03%
Total impurities	≤0.5%		0.08%
Sulfates	≤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	≤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)	Reviewed by/Date(QC)	Approved by/Date(QA)
2024. 10. 12	2024.10.13	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	2025.04.10	报告人 REPORTER	2025.04.10

SYNNAT PHARMA PRIVATE LIMITED
Plot No.60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District-531019,
Andhra Pradesh, India.
Website: www.synnatpharma.com

Format No. : QC/GEN/34/FT-03
Effective date: 16.10.2023

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

SYNNAT PHARMA PRIVATE LIMITED
Plot No.60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District-531019,
Andhra Pradesh, India.
Website: www.synnatpharma.com

Format No. : QC/GEN/34/FT-03
Effective date: 16.10.2023

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	10 cfu/gm, Complies
	Total yeast/ Mould count		Not more than 10 cfu/gm	<10 cfu/gm, Complies
	Pathogens			
	Escherichia Coli		Should be absent	Absent, Complies
	Salmonellae		Should be absent	Absent, Complies
	Pseudomonas aeruginosa		Should be absent	Absent, Complies
	Staphylococcus aureus		Should be absent	Absent, Complies
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

SYNNAT PHARMA PVT. LTD. Anakapalli

Prepared by : Soury Date : 20/05/25

Reviewed by : Date : 20/05/25

Approved by: Rao Date : 20/05/2025

Laboratorios Imperiales, S.A. de C.V.
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LIMSA

ANNEX OF STANDARD OPERATING PROCEDURE FOR CERTIFICATE OF ANALYSIS ELABORATION.

FORMAT FOR CERTIFICATE OF ANALYSIS.

Code: ANX1-PNO-DAC-021

CoA/S

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

Test	Specification	Result
Description	Light yellow, amorphous powder with a faint characteristic odor.	Meets
Identification Bismuth ion (Bi^{+3}) Tribromophenol	 Positive for Bi^{+3} Positive for tribromophenol	 Positive Positive
Substance not precipitated by NH_4OH	≤ 0.50%	0.03%
Free 2, 4, 6-Tribromophenol	≤ 3.3%	1.09%
Arsenic	0.0002	< 0.0002
Cooper	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)	40.0-49.0	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	p.a. 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