

告单

Certificate of Analysis

品名 ITEM	盐酸普鲁卡因 PROCAINE HYDROCHLORIDE		
批号 BATCH NO	20220637	数量 QUANTITY	1000KGS
包装 PACKING	25KG 纸鼓桶 25KG/DRUM	报告编号 LOT NO	202206037
生产日期 PRODUCTION DATE	Jun 14, 2022		有效期 EXPIRY DATE
检测标准 STANDARD	EP9.0		
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°C~158°C B. IR C. It gives reaction(s) of chlorides	155.0°C~156.0°C Conform Conform	
酸度 ACIDITY	PH5.0-6.5	PH=5.6	
溶液外观 Appearance of solution	Clear and colourless	Conform	
干燥失重 LOSS ON DRYING	≤0.5%	0.07%	
重金属 HEAVY METALS	≤ 0.0005%	Conform	
有关物质 RELATED SUBSTANCES	Any impurity ≤ 0.05%	Conform	
硫酸灰分 SULPHATED ASH	≤ 0.1%	0.04%	
含量 (烘干) ASSAY (ON DRY BASIS)	99.0-101.0%	100.0%	
结论 CONCLUSION	Conforms to EP9.0		
经理 MANAGER	化验员 ANALYST		



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Contact information: Claudio Bezanilla Salcedo Title: CEO Mail: cbezanilla@limsafo.com.mx Tel: (+52) 55 1941 2141	
ANNEX OF STANDARD OPERATING PROCEDURE FOR CERTIFICATE OF ANALYSIS ELABORATION.	Code: ANX1-PNO-DAC-021
FORMAT FOR CERTIFICATE OF ANALYSIS.	

**Certificate of Analysis.
CoA/S**

Product: Bismuth Tribromophenate .	Internal product code: 410
Sample weight: 500 g	Batch number: PTQ-01410/24
Delivery weight: 1000 Kg	Analysis number: 598/24
Manufacturing date: 18-DIC-23	Internal batch number: 01410/24
Retest date: 18-DIC-29	CAS: 5175-83-7
References: : US Dispensatory 25 ^m , Medicamenta III 1963, BP 1949, USP	

Test	Specification	Method	Result
Description	Bright yellow, amorphous powder with a faint characteristic odor.	MAN-DCC-009	Meets
Identification	Positive for Bi ³⁺	MAN-DCC-009	Positive
% Loss on drying	Not specified	MAN-DCC-009	0.23 %
% Assay (as Bi)	40.00 – 49.00%	MAN-DCC-009	46.09 %
% Bismuth oxide content, in dry basis	50.0 – 55.0 %	MAN-DCC-009	51.5 %
% Substance not precipitate by NH ₄ OH	≤ 0.50 %	MAN-DCC-009	0.01%
% Free 2, 4, 6-Tribromophenol	≤ 3.30 %	MAN-DCC-009	0.28 %
% Arsenic (as As)	≤ 0.00020 %	MAN-DCC-009	<0.00020%
Copper	To pass test	MAN-DCC-009	Pass test
Silver	To pass test	MAN-DCC-009	Pass test
Lead	To pass test	MAN-DCC-009	Pass test
Sulphate	To pass test	MAN-DCC-009	Pass test
Nitrates	To pass test	MAN-DCC-009	Pass test

Analyzed by: J.M Bahena, E. Polanco	Issued by:  Oskar Rivera Balderas Head of Quality Control	Approved by: P.N.  Claudio Bezanilla Martinez. C.P.D.G.P. 187941 Health Responsible No.: ARM-0577-2002
Date: 22-FEB-24	Date: 26-JUN-24	Date: 26-JUN-24

Size Lot sale: 1000 Kg

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MANUFACTURER OF BULK DRUGS AND FINE CHEMICALS

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CERTIFICATE OF ANALYSIS

PRODUCT: IODINE MIN.99.5%

BATCH NO.	MFG. DT.	QUANTITY	ASSAY	NON-VOLATILE MATTER	CHLORINE - BROMINE (AS CL)	SULPHATES	IRON	HEAVY METALS
		KG	%	%	PPM	PPM	PPM	PPM
I-029/23	Nov-2023	900	99.79%	<0.05	<50	<75	<10	<10

REMARK: THE BATCH COMPLIES WITH RESPECT TO THE ABOVE MENTIONED SPECIFICATIONS

For G. AMPHRAY LABORATORIES

AUTHORISED SIGNATORY

