Art.-Nr.: 5059
Charge: 23003608

VEN PETROCHEM & PHARMA (INDIA) PVT LTD.

F&A PHARMA

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CERTIFICATE OF ANALYSIS

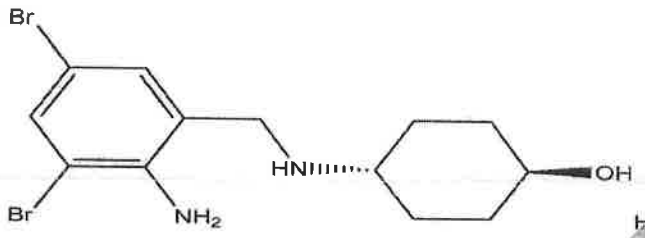
ISSUED FOR : **M/S. F. & A. PHARMA-Handels-GmbH, GERMANY.**

RE : INVOICE NO. : **FOR APPROVAL** DATED : **03 / 02 / 2023** QUANTITY SUPPLIED : **400 KG**

PURCHASE ORDER NO : **047 / 2023** DATED : **03 / 02 / 2023**

PRODUCT NAME : **AMBROXOL HYDROCHLORIDE** BATCH NO : **AXL 0763202301**

COPY QA APPROVED Date 16/02/23 Signature F&A PHARMA-Handels-GmbH



MOLECULAR FORMULAE	:	$C_{13}H_{18}Br_2N_2O$ HCl	MOL. WEIGHT	:	414.6
CAS NO	:	23828-92-4 MERCK INDEX NO : 401	EINECS NO	:	245-899-2
CHEMICAL NAME	:	trans-4-(2-amino-3,5-dibromobenzylamino)cyclohexanol hydrochloride			

DATE OF MANUFACTURE	:	04 / 01 / 2023	DATE OF EXPIRY	:	03 / 01 / 2028
RELEASE DATE	:	29 / 01 / 2023	BATCH QUANTITY	:	500 KG
ANALYSIS REPORT NO	:	582023509E	MANUFACTURING L/C NO	:	G / 25 / 836

MONOGRAPH : **BRITISH PHARMACOPOEIA 2022 / EUROPEAN PHARMACOPOEIA 11.0**

PARAMETERS		UNIT	LIMITS	RESULTS
CHARACTERISTICS		-	A white or yellowish crystalline powder	**A white crystalline powder**
MELTING POINT		°C	234.0 to 240.0	**235.3 to 236.2**
SOLUBILITY	Methanol	parts	10 to 30	**15**
	Water	parts	30 to 100	**70**
	Methylene Chloride	parts	more than 10000	**Insoluble**
IDENTIFICATION	Test A : UV Absorption Ratio	-	3.2 to 3.4	**3.3**
	Test B : IR Test	-	Complies with standard	**Conforms**
	Test C : Thin Layer Chromatography	-	Complies with standard	**Conforms**
	Test D : Chloride Test	-	Complies with chloride test	**Conforms**

CORPORATE OFFICE : # 409/410, "KESHAVA", PLOT NO C-5, 'E' BLOCK BANDRA KURLA COMPLEX, BANDRA (EAST), MUMBAI - 400051 - INDIA
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CERTIFICATE OF ANALYSIS

PRODUCT NAME : **AMBROXOL HYDROCHLORIDE** BATCH NO. **AXL 0763202301**

PARAMETERS			UNIT	LIMITS	RESULTS
TESTS	Appearance of solution		-	Complies with test	**Conforms**
	pH		-	4.5 to 6.0	**5.0**
	Foreign Particles *		/ gm	Not Detected	**Not Detected**
	Loss on Drying		%	NMT 0.5	**0.1**
	Sulphated Ash		%	NMT 0.1	**0.01**
	Particle Size (< 50 microns)		%	90	**Conforms**
RELATED SUBSTANCE (BY LIQUID CHROMATOGRAPHY)	Identified Impurity	Impurity A	%	NMT 0.15	**Not Detected**
		Impurity B	%	NMT 0.15	**0.01**
		Impurity C	%	NMT 0.15	**Not Detected**
		Impurity D	%	NMT 0.15	**Not Detected**
		Impurity E	%	NMT 0.15	**Not Detected**
	Unknown Impurity	Impurity 1	%	NMT 0.10	**0.01**
		Impurity 2	%	NMT 0.10	**Not Detected**
	Total Impurities		%	NMT 0.30	**0.01**
RESIDUAL SOLVENTS ©	n-Butanol		ppm	NMT 5000	**221**
	Toluene		ppm	NMT 890	**094**
ASSAY (on dried basis, by potentiometric titration)			%	99.0 to 101.0	**99.8**

SUMMARY : **WE CERTIFY THAT THE PRODUCT WAS TESTED ACCORDING TO THE PROCEDURES, AS PER BRITISH PHARMACOPOEIA 2022, Page No. I-135 AND AS PER EUROPEAN PHARMACOPEIA 11.0, PAGE NO. 1930, AND ALL RESULTS MEET THE SPECIFICATIONS. THE PRODUCT COMPLIES WITH THE REQUIRED QUALITY.**

TESTS MARKED (©) ARE AS SPECIFIED IN CERTIFICATE OF SUITABILITY BEARING REGISTRATION NUMBER R1-CEP 2004-240-Rev 00, AS ISSUED BY EURPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES

TESTS MARKED (*) ARE IN HOUSE SPECIFICATION TESTS

REMARKS : **WE CERTIFY THAT AMBROXOL HYDROCHLORIDE IS FREE OF TSE (TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES) AND BSE (BOVINE SPONGIFORM ENCEPHALOPATHY) I.E. TSE / BSE IS ABSENT IN THE PRODUCT. WE FURTHER CERTIFY THAT RESIDUAL SOLVENTS OF CLASS 1 AS PER CPMP/ICH/283/95 GUIDELINES ARE NOT USED IN THE MANUFACTURING PROCESS NOR COULD THEY BE INTRODUCED DURING STORAGE AND HANDLING OF MATERIAL. CLASS 2 & 3 SOLVENTS WHICH ARE LIKELY TO BE PRESENT ARE WITHIN THE LIMITS SPECIFIED.**

WE, AS MANUFACTURER, HEREBY CERTIFY THAT THIS BATCH HAS BEEN MANUFACTURED BY US IN FULL COMPLIANCE WITH GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY. (GMP CERTIFICATE NUMBER S-GMP/21062639 VALID TILL THE 27th OF JUNE 2023, ISSUED BY THE COMMISSIONER, FOOD & DRUGS CONTROL ADMINISTRATION, AS PER GMP GUIDELINES UNDER THE REVISED SCHEDULE 'M' OF THE DRUGS & COSMETICS ACT.).
WE FURTHER CERTIFY THAT THIS BATCH HAS BEEN MANUFACTURED BY US IN COMPLIANCE WITH EU GUIDELINES ON GOOD MANUFACTURING PRACTICE FOR ACTIVE SUBSTANCES USED AS STARTING MATERIALS, AS PUBLISHED IN THE RULES GOVERNING MEDICINAL PRODUCTS IN THE EUROPEAN UNION, VOLUME 4, PART II.

WE HEREWITH CONFIRM THAT THE MANUFACTURING PROTOCOL (BATCH RECORD) AND THE ANALYSIS PROTOCOL OF THE BATCH ARE DULY SIGNED AND RELEASED BY THE RESPONSIBLE QUALIFIED PERSON.

STORAGE : **STORE IN A WELL CLOSED CONTAINER, PROTECTED FROM LIGHT.**

PACKING : **DONE IN FIBRE DRUMS, EACH CONTAINING 25 KG NETT**

ANALYST-IN-CHARGE