



TECHNICAL DATA SHEET

010299-TDS-ENG-2022

FENOXIBENZAMINA HCL USP		
DESCRIPTION DCI: PHENOXYBENZAMINE HYDROCHLORIDE		DESCRIPTION DOE: FENOXIBENZAMINA HIDROCLORURO
CAS N°: 63-92-3	EC N°: 200-569-7	AEMPS CODE: 5036CH
MOL. WEIGHT: C18H22ClNO·HCl	MOL. FORMULA: 340.29	ARTICLE CODE: 010299

ATTRIBUTES	SHOULD BE
Description	White or almost white crystalline powder
Identification A	Complies
Identification B	Complies
Assay	98.0 - 102.0 %
Organic impurities	
Phenoxybenzamine alcohol	= < 0.10 %
Any unspecified impurity	= < 0.10 %
Total impurities	= < 0.50 %
Loss on drying	= < 0.5 %

COMPLIES WITH

USP 2022

STORAGE

Store the product in a cool and dry place. Keep away from sources of heat or light.

REMARKS

Phenoxybenzamine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.