METAPHARMACEUTICAL IND SL
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FENOXIBENZAMINA HCL USP

PRODUCT CODE: 010299	CAS Nº: 63-92-3	ANALYSIS Nº: 046/25	
MANUFACTURER BATCH:	PBM241001	CERTIFICATE ID:	45.306
SUPPLIER BATCH:	----	MANUFACTURING DATE:	14/10/2024
METAPH BATCH:	0200225	EXPIRY DATE:	13/10/2027

ATTRIBUTES	SHOULD BE	IS
Description	White or almost white crystalline powder	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Assay	98.0 - 102.0 %	100.1 %
Organic impurities		
Phenoxybenzamine alcohol	=< 0.10 %	Not Detected
Any unspecified impurity	=< 0.10 %	< 0.10 % (#)
Total impurities	=< 0.50 %	0.2 %
Melting point	136 - 141 ºC	140.1 ºC
Loss on drying	=< 0.5 %	0.02 %

COMPLIES WITH

USP 2025

REMARKS

(#) Unspecified impurities detailed underneath:
RT (15.97 min) = 0.06 %
RT (17.29 min) = 0.05 %
RT (19.09 min) = 0.08 %

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

All data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 03/04/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349
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