



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251246

Product:	BUPROPION HYDROCHLORIDE
Lot:	251246
Expiry date:	30/04/2030
Reference:	Cumple USP-NF2025-1
Synonyms:	Anfebutamona clorhidrato.
Formula:	C ₁₃ H ₁₈ ClNO·HCl
Molecular weight:	276,20 g/mol

Assay	Result	Specification	
Identification	Conform (A,B,C)	Test USP (A,B,C)	
Organoleptic properties	Conform		
Organic impurities	Conform	Test USP	
Content of 3-chlorobenzoic acid	< 0,2 %	<= 0,2 %	
Moisture - K.F.	0,04 %	<= 0,5 %	
Assay (HPLC)	100,0 %	98,0-102,0%	
Elemental impurities	Conform		#
Dechloro bupropion	< 0,05 %	<= 0,5 %	
Bupropion dione derivative	ND	<= 0,2 %	
o-Bupropion	< 0,05 %	<= 0,1 %	
3-cloropropiophenone	ND	<= 0,1 %	
Bupropion Impurity A	0,05 %	<= 0,2 %	
Bupropion Impurity B	ND	<= 0,2 %	
4-Clorobupropion	ND	<= 0,2 %	
5-Clorobupropion	ND	<= 0,2 %	
Total impurities	< 0,05 %	<= 1,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Hexane	< 290 ppm	<= 290 ppm	#
Nitrosamine impurities	Conform		#
Unspecified Impurities	< 0,05 %	<= 0,1 %	

Organoleptic characteristics: Fine, white powder. Soluble in water and in ethanol.

Conservation: In tightly closed containers. Protect from light.

Judgement:

Date of analysis: 10/07/2025

APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01047 KARUNESH REMEDIES

Manufacturer batch: BPR-008-25-26

Product	Name	Capacity	Batch
1115989	BUPROPION CLORHIDRATO	500 g	251246-O-1
1115990	BUPROPION CLORHIDRATO	1 kg	251246-P-1
1115991	BUPROPION CLORHIDRATO	5 kg	251246-Q-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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