



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 210829

Product:	BUPROPION HYDROCHLORIDE
Lot:	210829
Expiry date:	01/11/2025
Reference:	Cumple USP43
Synonyms:	Anfebutamona clorhidrato.
Formula:	C ₁₃ H ₁₈ ClNO·HCl
Molecular weight:	276,21 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	NDT	<= 0,2 %	
Moisture - K.F.	0,03 %	<= 0,5 %	
Assay (HPLC)	99,0 %	98,0-102,0%	
Elemental impurities	Conform	Test USP	#
Dechloro bupropion	0,004 %	<= 0,5 %	
Bupropion dione derivative	NDT	<= 0,2 %	
o-Bupropion	NDT	<= 0,1 %	
3-cloropropiophenone	NDT	<= 0,1 %	
Bupropion HCl impurity A	NDT	<= 0,2 %	
Bupropion HCl impurity B	NDT	<= 0,2 %	
Bromochloropropionphenone	NDT	<= 0,1 %	
4-Clorobupropion	NDT	<= 0,2 %	
5-Clorobupropion	NDT	<= 0,2 %	
Any impurity	<= 0,1 %	<= 0,1 %	
Total impurities	0,044 %	<= 1,0 %	
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 24/03/2021

Responsible: M. Mesa

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00064 SUPRIYA LIFESCIENCE

Manufacturer batch: SLL-BPH-1220006

Product	Name	Capacity	Batch
1115986	BUPROPION CLORHIDRATO	50 g	210829-I-1
1115989	BUPROPION CLORHIDRATO	500 g	210829-O-1
1115990	BUPROPION CLORHIDRATO	1 kg	210829-P-1
1115991	BUPROPION CLORHIDRATO	5 kg	210829-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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Date of edition: 28/08/2025