



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 226544

Product:	BUPROPION HYDROCHLORIDE
Lot:	226544
Expiry date:	30/09/2027
Reference:	Cumple USP-NF2022-3
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	0,02 %	<= 0,2 %	
Moisture - K.F.	0,03 %	<= 0,5 %	
Assay (HPLC)	100,2 %	98,0-102,0%	
Elemental impurities	Conform		#
Dechloro bupropion	0,01 %	<= 0,5 %	
Bupropion dione derivative	0,01 %	<= 0,2 %	
o-Bupropion	ND	<= 0,1 %	
3-cloropropiophenone	ND	<= 0,1 %	
Bupropion HCl impurity A	ND	<= 0,2 %	
Bupropion HCl impurity B	0,01 %	<= 0,2 %	
4-Clorobupropion	ND	<= 0,2 %	
5-Clorobupropion	ND	<= 0,2 %	
Any impurity	ND	<= 0,1 %	
Total impurities	0,03 %	<= 1,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 02/02/2023

Responsible: M. Mesa

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00430 HIKAL Ltd.

Manufacturer batch: A73400122-090

Product	Name	Capacity	Batch
1115986	BUPROPION CLORHIDRATO	50 g	226544-I-1
1115986	BUPROPION CLORHIDRATO	50 g	226544-I-2
1115989	BUPROPION CLORHIDRATO	500 g	226544-O-1
1115989	BUPROPION CLORHIDRATO	500 g	226544-O-2
1115989	BUPROPION CLORHIDRATO	500 g	226544-O-3
1115990	BUPROPION CLORHIDRATO	1 kg	226544-P-1
1115990	BUPROPION CLORHIDRATO	1 kg	226544-P-2
1115990	BUPROPION CLORHIDRATO	1 kg	226544-P-3
1115996	BUPROPION CLORHIDRATO	25 kg	226544-T-1
1115996	BUPROPION CLORHIDRATO	25 kg	226544-T-2
1115996	BUPROPION CLORHIDRATO	25 kg	226544-T-3

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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C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

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