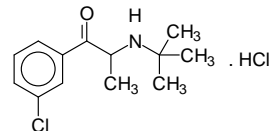


BUPROPION HYDROCHLORIDE

USP



**Globe Reference:
CUSP 5010139**

Formula	C ₁₃ H ₁₈ ClNO.HC Mr= 276,2
Action and use	.Antidepressant
Characteristics	White powder.
Solubility	Conform
IDENTIFICATION	
A. Infrared Spectrum	Conform
B. Liquid chromatograph	Conform
ESSAYS	
. Water	Not more than 0,5 per cent
. Content of chloride	12,6 to 13.1 per cent
Related compounds:	
Test 1	
- m-chlorobenzoic acid	Not more than 0.2 per cent
- Individual impurity	Not more than 0.1 per cent
Test 2	
- 2-(tert-butylamino)propiofenone hydrochloride	Not more than 0.5 per cent
- 1-(3-chlorophenyl)-1,2 propanedione	Not more than 0.2 per cent
- 2-(tert-butylamino)-2-chloropropiofenone hydrochloride	Not more than 0.1 per cent
- 3'- chloropropiofenone	Not more than 0.1 per cent
- Bupropion hydrochloride related compound A	Not more than 0.2 per cent
- Bupropion hydrochloride related compound B	Not more than 0.2 per cent
- 2-bromo-3' chloropropiofenone	Not more than 0.1 per cent
- 2-(tert-butylamino)-3',4'-chloropropiofenone hydrochloride	Not more than 0.2 per cent
- 2-(tert-butylamino)-3',5'-chloropropiofenone hydrochloride	Not more than 0.2 per cent
- Unknown impurity, each	Not more than 0.1 per cent
- Total impurities (test 1 + test 2)	Not more than 1.0 per cent
- Total unidentified impurities	Not more than 0.3 per cent
ASSAY	
. Bupropion Hydrochloride, calculated on the anhydrous basis	98,0 to 102,0 per cent.
Storage	In well-closed containers.
Packaging	25 Kg fiber drum with double polyethylene bags.



GLOBE QUÍMICA
TECHNOLOGICAL EXPERTISE

SYSTEM OF MANAGEMENT QUALITY **ISO-9001/2000**
CERTIFICATE COMPANY IN GOOD MANUFACTURING
PRACTICES – **GMP**

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