Letco Medical, LLC.

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October 17, 2024	00	**1** of **2**

CERTIFICATE OF ANALYSIS

Letco Item	691718	691720	691721			
Letco Lot	2407150009	2407150010	2407150011			

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Bupropion Hydrochloride USP	BP-22717	July 2022	June 2027

TEST	SPECIFICATION	RESULT
Description	White powder.	White powder
Solubility	Soluble in 0.1N Hydrochloric acid, in alcohol and in water.	Complies
Identification		
By IR spectroscopy	The Infrared spectrum of test sample should be concordant with similar preparation of that of Bupropion Hydrochloride WS/RS.	Complies
By HPLC	The retention time of the major peak in the chromatogram of the test solution corresponds to that of the standard solution, as obtained in the test of assay.	Complies
Chloride Test	To comply the test	Complies
Water content (by KF)	Not more than 0.5% w/w	0.05%
Residue on ignition	Not more than 0.10%	0.04%
Limit of 3-chlorobenzoic acid	Not more than 0.2%	Not Detected
Organic impurities (By HPLC)		
Deschlorobupropion[a] (DCB)	Not more than 0.5%	0.02%
Bupropion dione derivative[b] (BDD)	Not more than 0.2%	Not Detected
O-Bupropion[c] (OB)	Not more than 0.1%	Below Detection Limit
Chloropropiophenone[d] (CPP)	Not more than 0.1%	Not Detected
Bupropion related compound A (BRC-A)	Not more than 0.2%	Below Quantification Limit
Bupropion related compound B (BRC-B)	Not more than 0.2%	Not Detected
4-chlorobupropion[f] (4CB)	Not more than 0.2%	Below Detection Limit
5-chlorobupropion[g] (5CB)	Not more than 0.2%	Not Detected
Any unspecified impurity	Not more than 0.10%	0.03%
Total impurities[h]	Not more than 1.0%	0.06%
TBA Content (By HPLC)	Not more than 320 ppm	40.06 ppm
Assay (By HPLC)	Not less than 98.0% and Not more than 102.0% on anhydrous basis.	100.25%

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

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CERTIFICATE OF ANALYSIS

Letco Item	691718	691720	691721			
Letco Lot	2407150009	2407150010	2407150011			

Hydrochloride Content (By Potentiometrically)	Not less than 13.0% and not more than 14.0% on anhydrous basis.	13.21%
2-Bromo-3-Chloropropiophenone (By GCMS)	Not more than 4 ppm	Not Detected
Polymorphism (By XRD)	The Pattern should be match with that of Bupropion hydrochloride (Form-I) by XRD.	Complies
Residual solvents (By HSGC)		
Methanol	Not more than 3000 ppm	14 ppm
Acetonitrile	Not more than 410 ppm	Not Detected
Ethyl acetate	Not more than 5000 ppm	26 ppm
Dichloromethane	Not more than 600 ppm	Not Detected

ADDITIONAL INFORMATION

Letco Medical performed identification testing of this material using a validated method.

Manufacturer Remark: The material complies as per USP-43 and above In-house specification.

This product is manufactured by Aarti Pharmalabs Limited, Unit-IV, Plot No: E-50, 50/1, 59/1, M.I.D.C Tarapur, Taluka & District: Palghar, Tarapur, Maharashtra 401506, India (IND)

LETCO QA REVIEW: Essence Martin

Digitally signed by Essence Martin
DN: cn=Essence Martin, o=Letco Medical, ou=Quality Assurance, email=Essence.Martin@fagron.us, c=US
Date: 2024.10.28 11:14:44 -05'00'

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