

Certificate of analysis
Bupropion Hydrochloride

CAS No.	31677-93-7	Code	BIOJBUP001
Batch No	003-210203	Manufacture Date	Feb.02, 2021
Retest Date	Feb.01, 2025	Quantity	20Kg

Testing Items	Specifications	Results	
Appearance	White powder	White powder	
Solubility	Soluble in water, ethanol and 0.1N hydrochloric acid	Complies	
Identification	IR absorption: Matches with standard	Complies	
	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Complies	
	A solution of 1mg/ml in water meets the requirement of the silver nitrate precipitate test for chloride	Complies	
Impurities (HPLC)	3-Chlorobenzoic acid $\leq 0.2\%$	Not detected	
	Organic impurities	Deschloro bupropion $\leq 0.5\%$	0.01%
		Bupropion dione derivative $\leq 0.2\%$	Not detected
		o-Bupropion $\leq 0.1\%$	Not detected
		Chloropropiophenone $\leq 0.1\%$	Not detected
		Bupropion hydrochloride related compound A $\leq 0.2\%$	Not detected
		Bupropion hydrochloride related compound B $\leq 0.2\%$	Not detected
		Bromochloropropionphenone $\leq 0.1\%$	Not detected
		4-Chlorobupropion $\leq 0.2\%$	Not detected
		5-Chlorobupropion $\leq 0.2\%$	Not detected
Any individual impurity $\leq 0.1\%$	Not detected		
	Total impurities $\leq 1.0\%$	0.01%	
Residual solvents (GC)	2-Chloropropane $\leq 3.3\text{ppm}$	Not detected	
	Isopropanol $\leq 3000\text{ppm}$	135ppm	
	Dichloromethane $\leq 300\text{ppm}$	Not detected	
Water (KF)	$\leq 0.5\%$	0.04%	
Assay (HPLC)	98.0%~102.0% (Calculated on the dried basis)	99.0%	
Conclusion	This product conforms to USP43 standard		

***Storage condition: Store below 25°C, Protect from moisture and light.**