

SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Bupropion HCl (Cas 31677-93-7)		
Batch No.	20200403	Mfg. date	2020.04.23
Rep. Date	2020.04.29	Exp. date	2022.04.22
Packaging	25kg/Drum	Batch Size	1008.4kg
Test Items	Standards: USP40		Results
Solubility	Soluble in water, ethanol and 0.1N HCl		Conforms
Identification	IR/HPLC		Conforms
Water(KF)	≤0.5%		0.06%
Solvent residue (GC)	Ethanol ≤ 0.5%		0.004%
	Tert-butylamine ≤ 0.2%		<0.2%
Related substances (HPLC)	3-chlorobenzoic ≤ 0.2%		ND
	Deschloro bupropion ≤ 0.5%		0.009%
	Bupropion dione derivative ≤ 0.2%		ND
	O-bupropion ≤ 0.1%		ND
	Chloropropiophenone ≤ 0.1%		ND
	Bupropion hydrochloride related compound A ≤ 0.2%		0.01%
	Bupropion hydrochloride related compound B ≤ 0.2%		ND
	Bromochloropropionphenone ≤ 0.1%		ND
	4-chlorobupropion ≤ 0.2%		ND
	5-chlorobupropion ≤ 0.2%		ND
	Any individual impurity ≤ 0.10%		ND
Total impurities ≤ 1.0%		0.019%	
Assay(HPLC)	98.0%-102.0%(anhydrous basis)		99.6%
Conclusion	It meets the requirements of USP40 Standards		
Storage	Store in a well-closed container at ambient temperature		
Prepared by: LI Reviewed by: WEI Released by: Zhang			