



BUPROPION HYDROCHLORIDE USP

CAS N. 31677-93-7 CODE 1019 BATCH B220020 MAN. DATE 03/2022 RETEST DATE 03/2028

Description : White powder

| TEST FOR | SPECIFICATIONS | RESULTS |
|--|-----------------------------------|-------------|
| Identification | | |
| · A) IR | positive | Complies |
| · B) HPLC | positive | Complies |
| · C) Chlorides | positive | Complies |
| Water (KF) | ≤ 0.5 % | 0.02 |
| Assay (HPLC, on anhydrous basis) | ≥ 98.0 ≤ 102.0 % | 99.7 |
| Impurities (HPLC) - Limit of m-chlorobenzoic Acid | | |
| · m-chlorobenzoic acid | ≤ 0.10 % (USP spec.: NMT 0.2%) | <0.02 (LOQ) |
| Impurities (HPLC) - Organic Impurities | | |
| · RRT~0.38 (Deschloro bupropion) | ≤ 0.1 % (USP spec.: NMT 0.5%) | <0.05 (LOQ) |
| · RRT~0.58 (Bupropion dione derivative) | ≤ 0.1 % (USP spec.: NMT 0.2%) | <0.05 (LOQ) |
| · RRT~0.71 (o-Bupropion) | ≤ 0.1 % | <0.05 (LOQ) |
| · RRT~0.78 (Chloropropiophenone) | ≤ 0.1 % | <0.05 (LOQ) |
| · RRT~0.92 (USP Rel. Comp. A) | ≤ 0.1 % (USP spec.: NMT 0.2%) | <0.05 (LOQ) |
| · RRT~1.14 (USP Rel. Comp. B) | ≤ 0.1 % (USP spec.: NMT 0.2%) | <0.05 (LOQ) |
| · RRT~2.30 (4-Chlorobupropion) | ≤ 0.1 % (USP spec.: NMT 0.2%) | <0.05 (LOQ) |
| · RRT~2.74 (5-Chlorobupropion) | ≤ 0.1 % (USP spec.: NMT 0.2%) | <0.05 (LOQ) |
| · any other impurity (highest) | ≤ 0.10 % (USP spec.: NMT 0.1%) | <0.05 (LOQ) |
| Total impurities (Limit of m-chlorobenzoic Acid + Organic Impurities) | ≤ 0.5 % (USP spec.: NMT 1.0%) | <0.05 (LOQ) |
| Additional specifications | | |
| 2-Bromo-3'-chloropropiophenone (Bromochloropropiophenone) | NMT 3 ppm | Complies |
| Residual solvents (GC) | | |
| · sec-butyl alcohol | ≤ 300 ppm | <100 (LOQ) |
| · methanol | ≤ 1000 ppm | <60 (LOQ) |
| Particle size (sieving) | | |
| · more than 250 µm | ≤ 10 % | 1.6 |
| Bulk density | ≥ 0.40 ≤ 0.60 g/ml | 0.50 |
| Tapped density (1250 taps) | ≥ 0.60 ≤ 0.86 g/ml | 0.79 |

OBSERVATIONS:

- Other residual solvents are unlikely to be present
- The impurity 2-Bromo-3'-chloropropiophenone (Bromochloropropiophenone) is evaluated with the USP HPLC method slightly modified

Copies of this CoA are not valid**APPROVED**

on May 02, 2022

QUALITY CONTROL

Dr. S.Patroni

May 31, 2022