

Ipratropium Bromide EP10.0

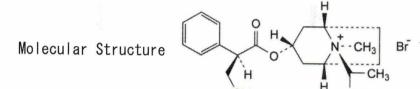
Batch no

240910

Mf date Retest

Sep 10 2024

Aug 2027



Molecular Formula $C_{20}H_{30}BrNO_{3}$, $H_{2}O$

Molecular Weight 430.4

CAS Registry Number 66985-17-9

Dec 02 2024

| Tests | Specifications | Results | |
|--------------------|--|---------------------------------|--|
| Appearance | White or almost white crystalline powder | Almost white crystalline powder | |
| Identification | IR, position, color & size tests, no precipitate is | Positive | |
| Melting point | formed, solution color reaction, reaction of bromides About 230°C 227 ~ 220°C | | |
| Appearance of | 227 223 0 | | |
| Solution | The solution is clear and not more intensely coloured Conforms than reference solution GY7 | | |
| рН | 5.0 ~ 7.5 | 5. 6 | |
| Impurity A | ≤ 0.1% | ND | |
| Related substances | Impurity D ≤ 0.05% | ND | |
| | Impurity B ≤ 0.1% | ND | |
| | Impurity C ≤ 0.1% | ND | |
| | Unspecified impurities for each impurity ≤ 0.1% | ND | |
| | Total impurities ≤ 0.25% | ND | |
| | Disregard limit: 0.03%, disregard the peak due to th | | |
| Water | 3. 9 ~ 4. 4% | 4. 2% | |
| Sulfated ash | ≤ 0.1% | 0. 08% | |
| Residual solvents | Methanol ≤ 0.3% | ND | |
| | Acetone ≤ 0.5% | ND | |
| | Isopropanol ≤ 0.5% | ND | |
| | Dichloromethane ≤ 0.06% | ND | |
| | Chloroform ≤ 0.006% | ND | |
| | Toluene ≤ 0.089% | ND | |
| Assay (oab) | 99.0 ~ 100.5% | 100. 0% | |
| | | w one mails the fit | |

| Packaging & storage | Preserve in well-closed, light-resistant containers |
|---------------------|---|
| Conclusion | Material complies with EP10.0 |

