

Ipratropium Bromide EP10.0

Batch no

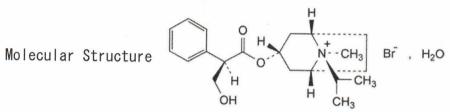
240910

Mf date

Sep 10 2024

Retest

Aug 2027



Molecular Formula $C_{20}H_{30}BrNO_3$, H_2O

Molecular Weight 430.4

CAS Registry Number 66985-17-9

Mar 27 2025

Tests	Specifications	<u>Results</u>
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Identification	IR, position, color & size tests, no precipitate is formed, solution color reaction, reaction of bromides	Positive
Melting point	About 230°C	227 ~ 229°C
Appearance of Solution	The solution is clear and not more intensely coloured than reference solution ${\sf GY}_7$	
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 $\leq 0.25\%$	ND
	Disregard limit: 0.03%, disregard the peak due to the	
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%
		100.0/0

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

