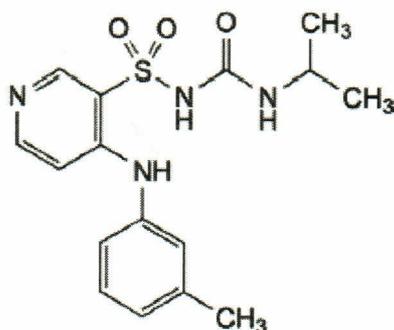


Batch no D5122-25-012
Mf date Dec 12 2025
Retest Nov 2029
Batch size 185 kg

Molecular Structure



Molecular Formula $C_{16}H_{20}N_4O_3S$
Molecular Weight 348.4
CAS Registry Number 56211-40-6

Jan 07 2026

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White or almost white powder	Almost white powder
Solubility	Practically insoluble in water, slightly soluble in ethanol (96%). It is sparingly soluble in dilute solutions of alkali hydroxides and slightly soluble in dilute acids	Conforms
Identification	IR, X-ray	Positive
Loss on drying	≤ 0.5%	0.09%
Sulfated ash	≤ 0.1%	0.04%
Heavy metals	≤ 10 ppm	< 10 ppm
Related substances 1 (HPLC)	Impurity A	≤ 0.15% ND
	Impurity B	≤ 0.5% 0.02%
	Impurity C	≤ 0.15% ND
	Impurity D	≤ 0.15% ND
	Impurity E	≤ 0.15% ND
	Unspecified impurities	≤ 0.1% 0.08%
Related substances 2 (HPLC)	o-Torasemide	≤ 0.15% Conforms
	p-Torasemide	≤ 0.15% Conforms
	Total impurities	≤ 0.6% 0.15%
Assay (odb, titration)	99.0% ~ 101.0%	100.2%

Packaging & storage	Preserved in a well-closed container, protected from light.
Conclusion	Material complies with EP