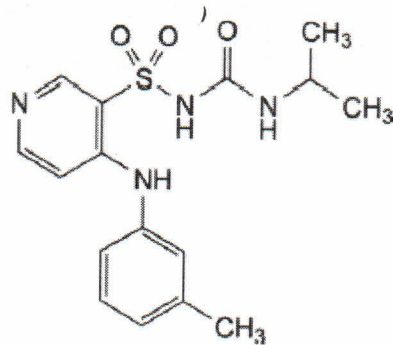


Batch no D5122-24-004
 Mf date Mar 16 2024
 Retest Feb 2028
 Batch size 437.84 kg

Molecular Structure



Molecular Formula C₁₆H₂₀N₄O₃S
 Molecular Weight 348.4
 CAS Registry Number 56211-40-6

Dec 17 2024

<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%	0.1%
Sulfated ash	≤ 0.1%	< 0.1%
Heavy metals	≤ 10 ppm	< 10 ppm
Related substances 1 (HPLC)	Impurity A ≤ 0.15%	< 0.05%
	Impurity B ≤ 0.5%	0.06%
	Impurity C ≤ 0.15%	< 0.01%
	Impurity D ≤ 0.15%	< 0.01%
	Impurity E ≤ 0.15%	< 0.01%
	Unspecified impurities ≤ 0.1%	< 0.01%
Related substances 2 (HPLC)	Total impurities ≤ 0.6%	0.1%
	o-Torasemide ≤ 0.15%	< 0.01%
	p-Torasemide ≤ 0.15%	0.04%
Assay (odb, titration)	99.0% ~ 101.0%	100.1%

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