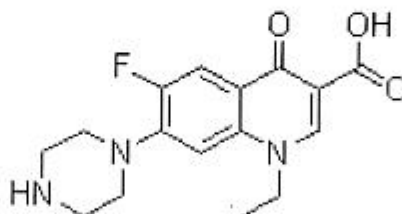




Batch no 211030
Mf date Oct 15 2021
Retest Oct 14 2025
Batch size 775 kg

Molecular Structure



Molecular Formula $C_{16}H_{18}FN_3O_3$
Molecular Weight 319.33
CAS Registry Number 70458-96-7

Nov 22 2021

Tests	Specifications	Results
Appearance	White to pale yellow crystalline powder	Pale yellow powder
Solubility	Slightly soluble in acetone, in water and in alcohol, freely soluble in acetic acid, sparingly soluble in chloroform; very slightly soluble in methanol and in ethyl acetate; insoluble in ether	Conforms
Identification	IR, HPLC	Positive
Related substances	Impurity K $\leq 0.15\%$	0.08%
	Impurity E $\leq 0.15\%$	0.03%
	Impurity A $\leq 0.1\%$	0.04%
	Impurity H $\leq 0.1\%$	ND
	Unidentified impurities $\leq 0.1\%$	0.02%
	Total impurities $\leq 0.5\%$	0.2%
Heavy metals	$\leq 0.0015\%$	Conforms
Loss on drying	$\leq 1.0\%$	0.3%
Residue on ignition	$\leq 0.1\%$	0.02%
Assay	98.0 ~ 102.0% of $C_{16}H_{18}FN_3O_3$	99.7%
Packaging and storage	Preserve in tight, light-resistant containers	
Conclusion	Material complies with USP41	

