

Tetracycline hydrochloride

Item	Standard
Characteristics	A white or yellowish white powder .Odorless or almost bygroscopic
Identification	A:B:C The positive reaction.
Solubility	Very soluble in water, insoluble in acetone , chloroform, ether.
Specific optical rotation	+53.5°~ +59.0°
Acidity of alkalinity	5.0~7.5
Impurity A	2%max
Impurity C	3% ~15%
Any other impurity	not more than the area of the principal peak in the chromatogram obtained with RS(B)5%
Total other impurity	not more than 3times the area of the principal peak in the chromatogram obtained with RS(B)15%
Disregard limit	ae of the principal peak in the chromatogram obtained with RS(C)1%
Loss on drying (pct)	max8.0
Sulphate	27.0-31.0%
Sulphated ash	1% max
Microcount limit test	NMT 500 col/g
Microcount-yeast and molds	NMT 10 col/g
Microcount-Escherichia coli	Absent
Microcount-Staphylococcus aureus	Absent
Microcount-Pseudomonas	Absent
Assay	≥680I.U./mg (DRY)