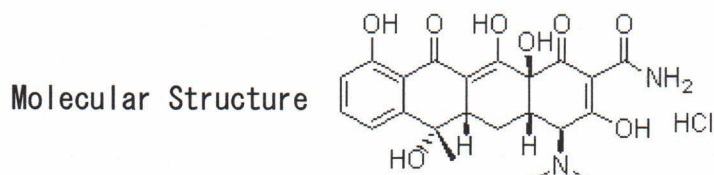


Tetracycline HCl EP9

Batch no 231108-4
 Mf date Nov 10 2023
 Exp date Nov 09 2028
 Batch size 1,162.6 kg



Molecular Formula $C_{22}H_{24}N_2O_8 \cdot HCl$
 Molecular Weight 480.90
 CAS Registry Number 64-75-5

Apr 29 2024

Tests	Specifications	Results
Appearance	Yellow crystalline powder	Conforms
Solubility	Soluble in water, slightly soluble in ethanol (96%), practically insoluble in acetone.	Conforms
Identification	TLC, color reaction, reaction of chloride	Positive
pH	1.8 ~ 2.8	2.3
Specific optical rotation	-240 ~ -255°	-247°
Loss on drying	≤ 2.0%	0.4%
Heavy metals	≤ 50 ppm	Conforms
Sulfated ash	≤ 0.5%	< 0.1%
Related substances	4-Epitetracycline ≤ 3.0%	0.83%
	4-Epianhydrotetracycline ≤ 0.5%	ND
	Anhydrotetracycline ≤ 0.5%	0.13%
	2-Acetyl-2-decarbamoyletetracycline ≤ 1.5%	0.51%
Residual solvents (GC)	Acetone ≤ 100 ppm	5 ppm
	N-Butanol ≤ 3000 ppm	1324 ppm
Assay (odb)	95.0 ~ 102.0% of $C_{22}H_{24}N_2O_8 \cdot HCl$	99.4%

Packaging & storage	Preserve in tight, light-resistant containers
Conclusion	Material complies with EP9.0