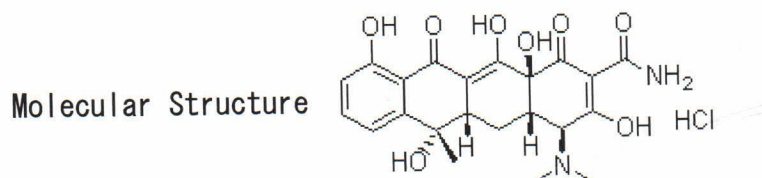


Tetracycline HCl EP9

Batch no 240602-13
 Mf date Jun 04 2024
 Exp date Jun 03 2029
 Batch size 1,080 kg



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

Aug 08 2024

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
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°	-246°
Loss on drying	≤ 2.0%	0.4%
Heavy metals	≤ 50 ppm	Conforms
Sulfated ash	≤ 0.5%	< 0.1%
Related substances	4-Epitetracycline	≤ 3.0% 0.82%
	4-Epianhydrotetracycline	≤ 0.5% ND
	Anhydrotetracycline	≤ 0.5% 0.13%
	2-Acetyl-2-decarbamoyletetracycline	≤ 1.5% 0.51%
	Residual solvents (GC)	Acetone
	N-Butanol	≤ 3000 ppm 1328 ppm
Assay (odb)	95.0 ~ 102.0% of $C_{22}H_{24}N_2O_8 \cdot HCl$	99.2%

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