

Ganciclovir Sodium

Batch no Mf date

24072801 Jul 28 2024

Expiry

Jul 27 2026

Molecular Structure

Molecular Formula C₉H₁₃N₅NaO₄

Molecular Weight 278.22

CAS Registry Number

107910-75-8

Sep 24 2024

	<u>Tests</u>	<u>Specifications</u>		Results
	Appearance	White or almost white crysta powder, odorless, hygroscop		White crystalline powder
	Solubility	Freely soluble in water, ver soluble in methanol, praction in chloroform & acetone	y slightly	Conforms
	Identification	HPLC, UV		Positive
	Clarity & color of solution			Conforms
	Absorption coefficient	470 ~ 500		Conforms
	Heavy metals	≤ 20 ppm		Conforms
	Residue on ignition	≤ 0.1%		0. 03%
	Related substances	Ganciclovir related compound	≤ 0.5%	0. 16%
		Guanine	≤ 0.5%	0. 2%
		Impurity A	≤ 0.5%	0. 03%
		Total impurities	≤ 1.5%	0.4%
	Water	≤ 3.0%		0.63%
	pH .	10.8 ~ 11.4		11.0
	Organic remain	≤ 0.5% acetone		Conforms
	Microbial limit	Total plate count ≤ 1000 cfu,	/g	Conforms
		Yeasts & Molds \leq 100 cfu/s	g	Conforms
		E. coli Negative		Negative
	Bacterial endotoxins	≤ 0.84 EU/mg		< 0.25 EU/mg
	Residual solvent	Ethanol ≤ 5000 ppm		Conforms
	Assay (HPLC) oab	98.0 $^{\sim}$ 102.0% of $C_9H_{13}N_5O_4$		99.4%
	Packaging & Storage	reserve in well-closed cont		t 25°C,

Packaging & storage	Preserve in well-closed containers. Store at 25°C, excursions permitted between 15 ~ 30°C	
Conclusion	Material complies with in-house standard	

