

## Ganciclovir Sodium

Batch no Mf date

25080701 Aug 07 2025

Expiry

Aug 06 2027

Molecular Structure

Molecular Formula

 $C_9H_{13}N_5NaO_4$ 

Molecular Weight

278.22

CAS Registry Number

107910-75-8

Aug 12 2025

<u>Tests</u>	<u>Specifications</u>	Results
Appearance	White or almost white crystalline	White crystalli
0.1.1.1.1.	powder, odorless, hygroscopic	powder
Solubility	Freely soluble in water, very slightly	Conforms
	soluble in methanol, practically insoluble in chloroform & acetone	
Identification	HPLC, UV	Positive
Clarity & color of solut	ion Meets the requirements	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%	0.1%
	Guanine ≤ 0.5%	0. 1%
	Impurity A ≤ 0.5%	0. 01%
	Total impurities ≤ 1.5%	0. 21%
Water	≤ 6.0%	0. 33%
На	10.8 ~ 11.4	11.0
Organic remain	≤ 0.5% acetone	Conforms
Microbial limit	Total plate count ≤ 1000 cfu/g	Conforms
	Yeasts & Molds ≤ 100 cfu/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	Preserve in well-closed containers. Store	at 25°C,
	excursions permitted between 15 ~ 30°C	
Conclusion	Material complies with in-house standard	***************************************