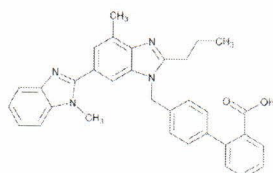


Batch no 241018-6
 Mf date Oct 18 2024
 Expiry Oct 17 2027
 Batch size 350 kg

Molecular Structure



Molecular Formula $C_{33}H_{30}N_4O_2$
 Molecular Weight 514.62
 CAS Registry Number 144701-48-4

Nov 21 2024

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>	
Appearance	White or off-white crystalline powder	Conforms	
Solubility	Practically insoluble in water, slightly soluble in methanol, sparingly soluble in methylene chloride	Conforms	
Identification	IR, HPLC	Positive	
Melting point	261 ~ 263°C	261.4 ~ 262.6°C	
Loss on drying	≤ 1.5%	0.14%	
Heavy metals	≤ 10 ppm	Conforms	
Residue on ignition	≤ 0.1%	0.05%	
Related substances	Telmisartan impurity A	≤ 0.1%	0.03%
	Telmisartan impurity B	≤ 0.1%	ND
	Telmisartan amide	≤ 0.1%	ND
	Telmisartan diacid	≤ 0.1%	0.02%
	Telmisartan tert-butylester	≤ 0.2%	0.015%
	Unknown impurity	≤ 0.2%	ND
	Any other impurity	≤ 0.1%	ND
	Total impurities	≤ 1.0%	0.23%
	Residual solvents	Ethanol	≤ 5000 ppm
Ethyl acetate		≤ 5000 ppm	16.4 ppm
Methanol		≤ 3000 ppm	19.6 ppm
N, N-Dimethylformamide		≤ 880 ppm	ND
Assay (HPLC) odb	98.0 ~ 102.0%	99.72%	
Packaging & storage	Preserve in tight containers, and protect from light. Store at room temperature		
Conclusion	Material complies with USP-NF2023		