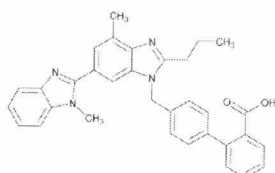


Batch no 231203-1
 Mf date Dec 05 2023
 Expiry Dec 04 2026
 Batch size 281.2 kg

Molecular Structure



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

Apr 10 2024

Tests	Specifications	Results
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	261.5 ~ 262.7°C
Loss on drying	≤ 1.5%	0.07%
Heavy metals	≤ 10 ppm	Conforms
Residue on ignition	≤ 0.1%	0.06%
Related substances	Telmisartan impurity A	≤ 0.1% 0.02%
	Telmisartan impurity B	≤ 0.1% ND
	Telmisartan amide	≤ 0.1% ND
	Telmisartan diacid	≤ 0.1% 0.03%
	Telmisartan tert-butylester	≤ 0.2% 0.02%
	Unknown impurity	≤ 0.2% ND
	Any other impurity	≤ 0.1% ND
	Total impurities	≤ 1.0% 0.23%
	Residual solvents	Ethanol
Ethyl acetate		≤ 5000 ppm 16.8 ppm
Methanol		≤ 3000 ppm 19.6 ppm
N, N-Dimethylformamide		≤ 880 ppm ND
Assay (HPLC) odb	98.0 ~ 102.0%	99.8%
Packaging & storage	Preserve in tight containers, and protect from light. Store at room temperature	
Conclusion	Material complies with USP-NF2023	