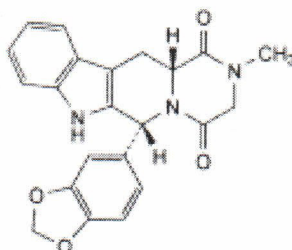


## Tadalafil EP11.0

Batch no 021241002  
 Mf date Oct 27 2024  
 Retest Oct 26 2026  
 Batch size 517.42 kg

### Molecular Structure



Molecular Formula  $C_{22}H_{19}N_3O_4$   
 Molecular Weight 389.40  
 CAS Registry Number 171596-29-5

Dec 06 2024

Tests	Specifications	Results
Appearance	White or almost white powder	Conforms
Solubility	Freely soluble in dimethyl sulfoxide, sparingly soluble in dichloromethane and practically insoluble in water	Conforms
Identification	IR, RRT	Positive
Specific optical rotation	+78.0 ~ +84.0°	+80.5°
Impurities A, B, C	Impurity A	≤ 0.15%
	Unspecified impurities	≤ 0.1%
Loss on drying	≤ 0.5%	0.16%
Sulfated ash	≤ 0.1%	0.025%
Related substances	Unspecified impurities	≤ 0.1%
	Total impurity	≤ 0.3%
Residual solvents	Methylamine	≤ 0.163%
	Methanol	≤ 0.3%
	Ethanol	≤ 0.5%
	Acetonitrile	≤ 0.041%
	Acetone	≤ 0.5%
	Dichloromethane	≤ 0.06%
	Ethyl acetate	≤ 0.5%
	Triethylamine	≤ 0.032%
	N,N-Dimethylformamide	≤ 0.088%
Assay (oab)	97.5 ~ 102.0% of $C_{22}H_{19}N_3O_4$	99.6%

Packaging & storage	Well-closed, light-resistant container, store at controlled room temperature
Conclusion	Material complies with EP11.0