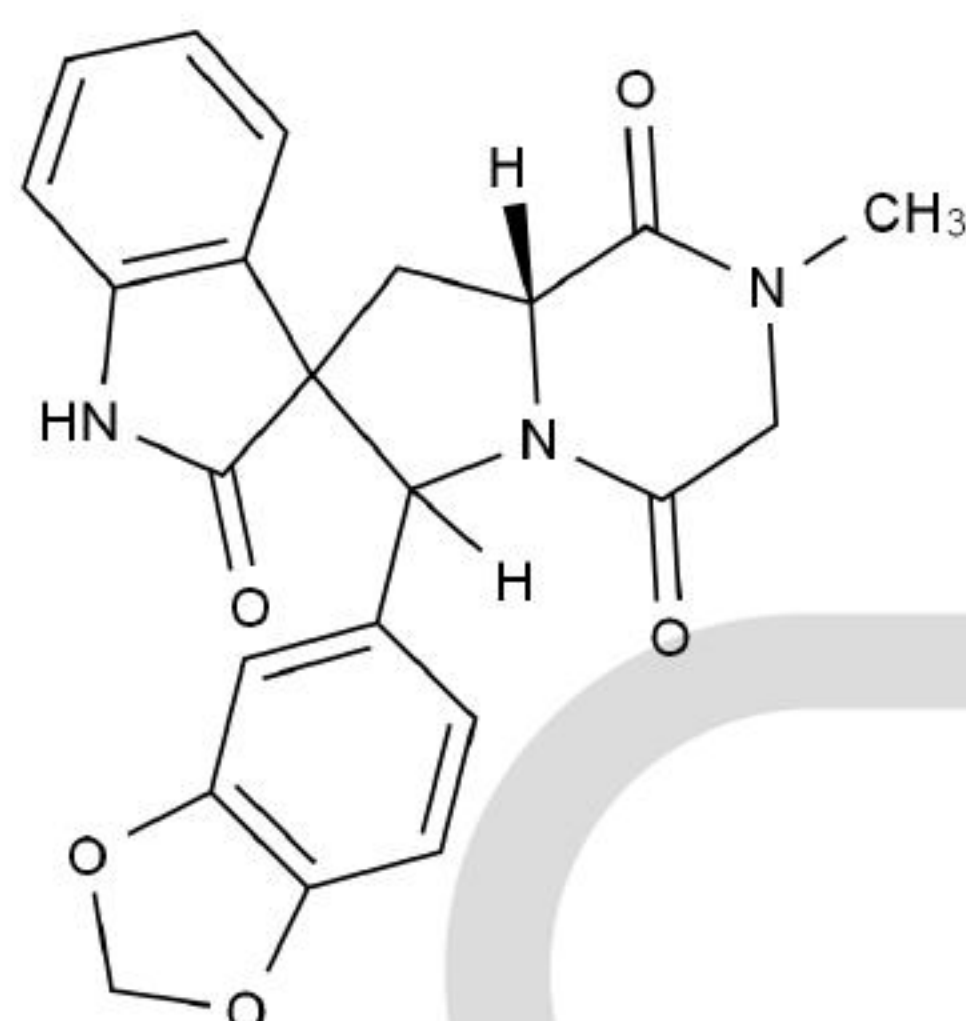


Certificate of Analysis

Reference Material & Standard

Product Name:	Tadalafil EP Impurity I	Catalogue Number:	C4X-10879
Synonyms:	(8a'R)-6'-(1,3-Benzodioxol-5-yl)-2'-methyl-2',3',8',8a'-tetrahydrospiro[indole-3,7'-pyrrolo[1,2-a]pyrazine]-1',2,4'(1H)-trione	Lot Number:	0514-RH-0032
CAS Number:	2378614-29-8	Expiry Date:	May 25, 2030
Molecular Formula:	C ₂₂ H ₁₉ N ₃ O ₅	Storage:	2°C ~ 8°C Sealed
Molecular Weight:	405.40	Shipping Condition:	Shipping at Room Temperature
Solubility:	Soluble in Acetonitrile and DMSO	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	98.968%
Residue on Ignition	TGA	0.3540%
Loss on Drying	TGA	2.9296%
Assay	qNMR	94.7%
Assay	Mass Balance	95.7%

Comment:

- The retest date of this product is May 25, 2029.
- The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Residue on Ignition} - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$$
Residue on Ignition and Loss on Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Alice

Approved by General Manager:

David

Date: May 26, 2026

Date: May 26, 2026

Date: May 26, 2026



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