

Specification

Technical Data Sheet

CAS 171596-29-5	STORAGE Ambient	MOLECULAR WEIGHT 389.40
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PRODUCT**Tadalafil USP**

Product number	90035367
CAS number	171596-29-5
Molecular formula	C ₂₂ H ₁₉ N ₃ O ₄
Molecular weight	389.40 g/mol

PARAMETER	SPECIFICATION
Appearance	White or almost white powder
Assay	97.5 - 102.5%
Conclusion	Conforms to USP43 spec
Loss on Drying	≤0.5%
Enantiomeric	6R,12aS diastereomer not more than 0.1%. 6S,12aS enantiomer not more than 0.1%. 6S,12aR diastereomer not more than 0.1%
HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Identification solution, as obtained in the test for Enantiomeric and Diastereomeric Purity.
Infrared Absorption	The infrared absorption spectrum of the sample shall be consistent with that of the reference substance.
Organic impurities	Individual impurities not more than 0.1%. Total impurities not more than 0.15%
Residual Solvents	Methylamine ≤0.163% Methanol ≤0.3% Acetonitrile ≤0.041% Isopropanol ≤0.5% Ethyl acetate ≤0.5% DMF ≤0.088%
Residue on Ignition	≤0.1%
Solubility	Freely soluble in dimethyl sulfoxide, slightly soluble in dichloromethane, practically insoluble in water
Specific optical rotation	+78.0° to +84.0°

SPECIFICATION STATEMENT	The values stated above represent the standard specification for this product, issued under Molekula Ltd 's quality management system. Batch-specific results are provided on the Certificate of Analysis.
STORAGE	Store as indicated on the product label, away from light, moisture and incompatible materials.

Molekula Ltd would like to thank you for your support of our products and service.

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