

Certificate of Analysis

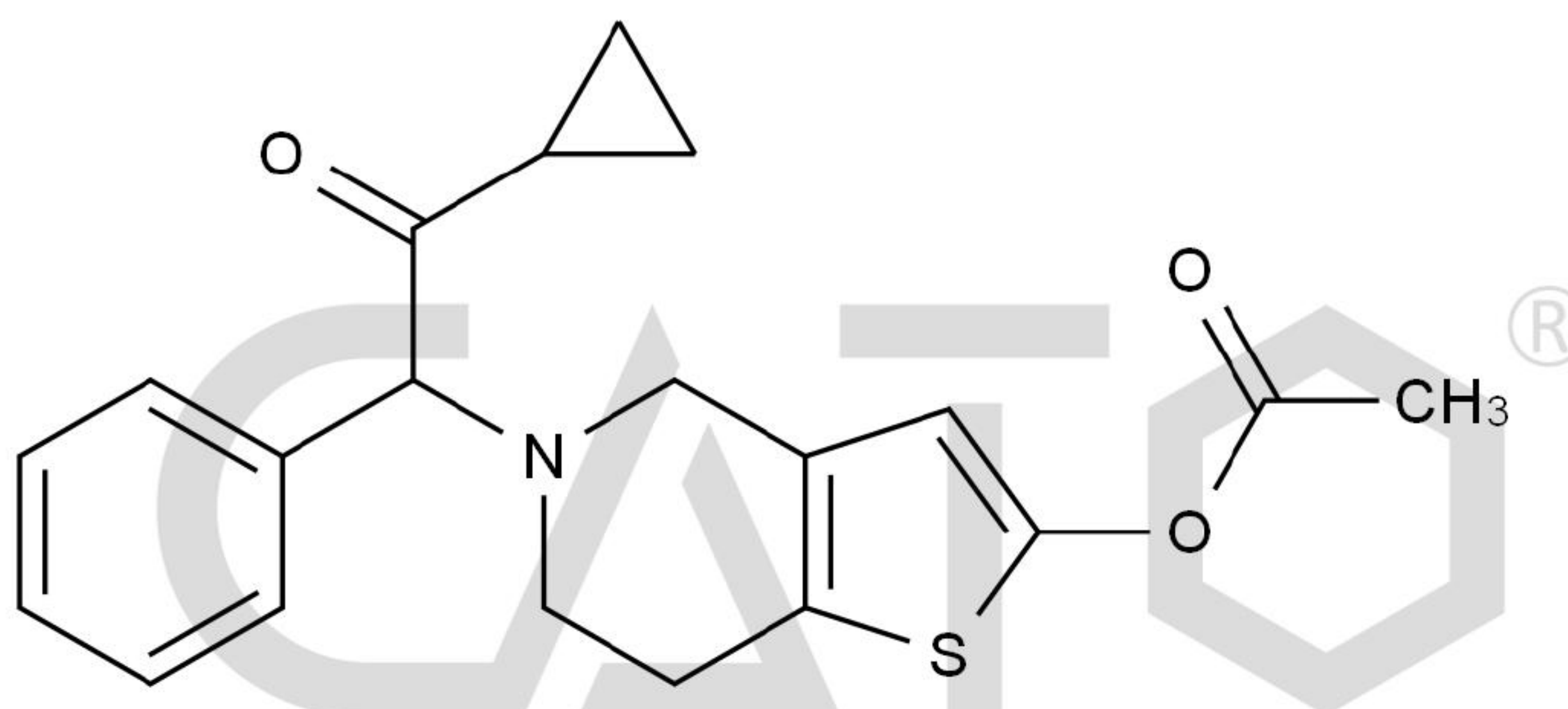
Reference Material & Standard

Product Name:	Prasugrel EP Impurity A	Catalogue Number:	C4X-10862
Synonyms:	N/A	Lot Number:	1223-RF-0118
CAS Number:	1391194-45-8	Expiry Date:	Jan 06, 2028
Molecular Formula:	C ₂₀ H ₂₁ NO ₃ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	355.45		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Orange Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	96.369%
Residual Solvents	NMR	Acetic acid
Loss on Drying	TGA	2.1388%
Assay		94.3%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Residual Solvents - Loss on Drying) * Purity HPLC (%) / 100%

Residual Solvents and Loss on Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Jan 07, 2025

Date: Jan 08, 2025

Date: Jan 08, 2025



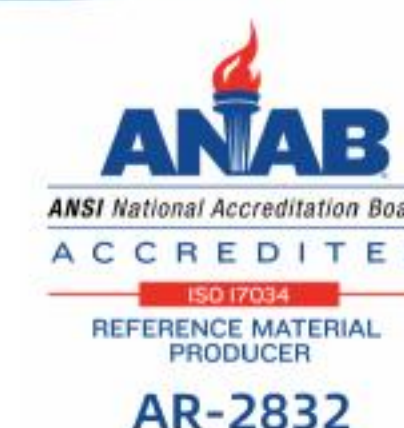
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