

Certificate of Analysis

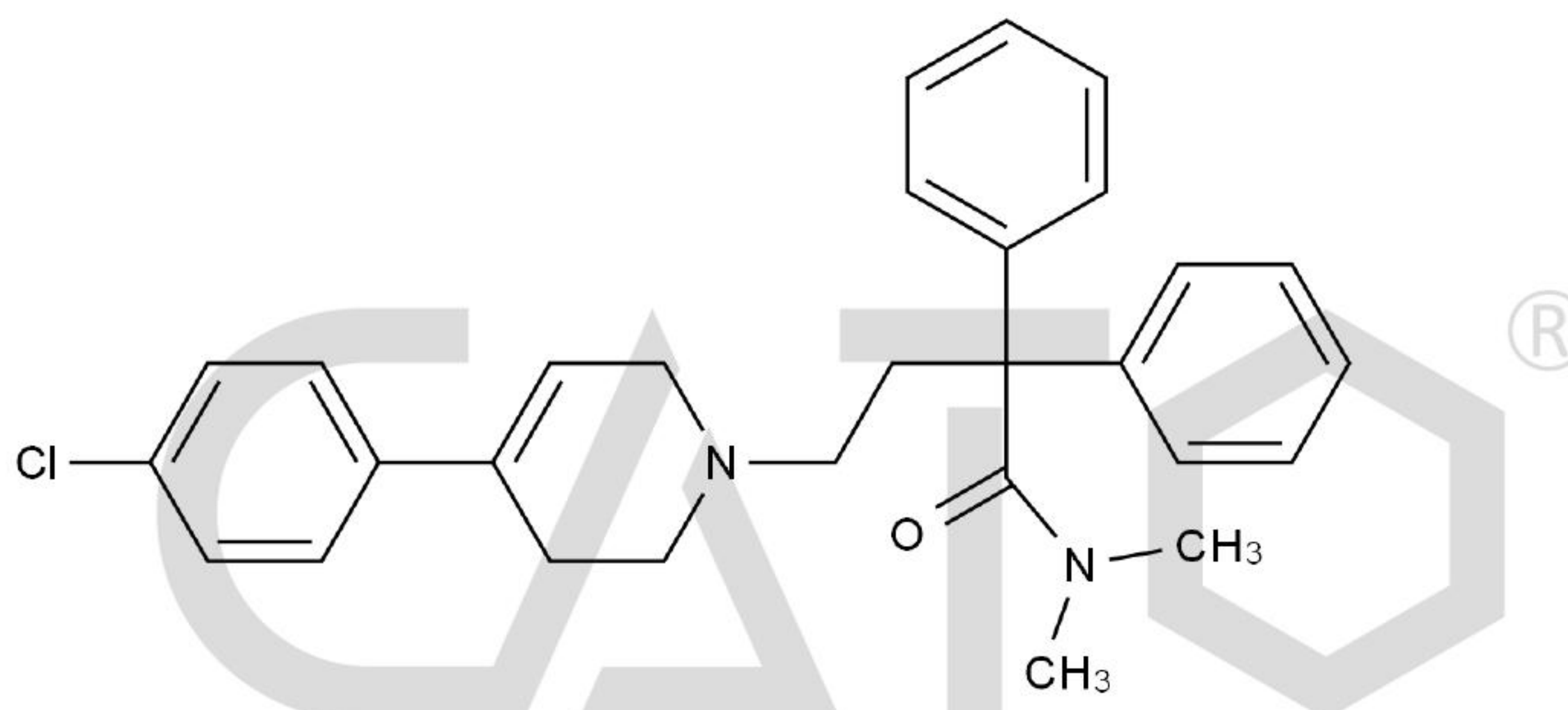
Reference Material & Standard

Product Name:	Loperamide EP Impurity H	Catalogue Number:	CP142174
Synonyms:	N/A	Lot Number:	0824-RE-0065
CAS Number:	61299-42-1	Expiry Date:	Sep 08, 2030
Molecular Formula:	C ₂₉ H ₃₁ ClN ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	459.03	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.9318%
Loss on Drying	TGA	0.053%
Assay		98.9%

Comment:

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

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

Loss on Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Sep 09, 2026

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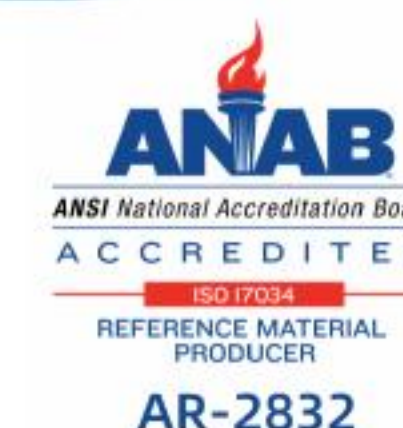
Add: 3rd Floor, Building B, No.179, Guangpu Rd East, Huangpu District, Guangzhou, China

Tel: +86-20-81960175

Email: supports@cato-chem.com

Web: <https://www.cato-chem.com>

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