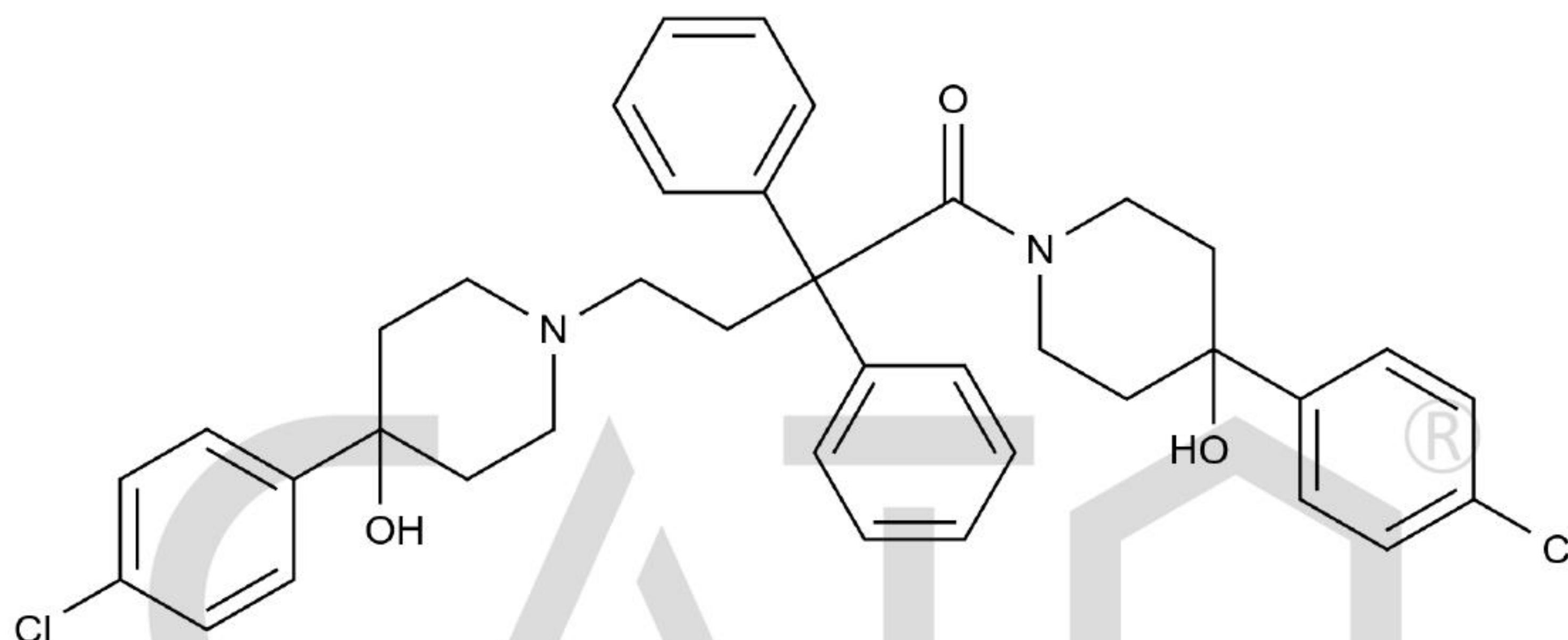


Certificate of Analysis

Reference Material & Standard

Product Name:	Loperamide EP Impurity E	Catalogue Number:	C4X-17885
Synonyms:	N/A	Lot Number:	0824-RE-0066
CAS Number:	1426322-82-8	Expiry Date:	Jul 30, 2029
Molecular Formula:	C ₃₈ H ₄₀ Cl ₂ N ₂ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	643.64		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	95.1058%
Loss On Drying	TGA	2.554%
Assay		92.7%

Comment:

The calculation of the 100% 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: Jul 31, 2025

Date: Jul 31, 2025

Date: Jul 31, 2025

