

Certificate of Analysis

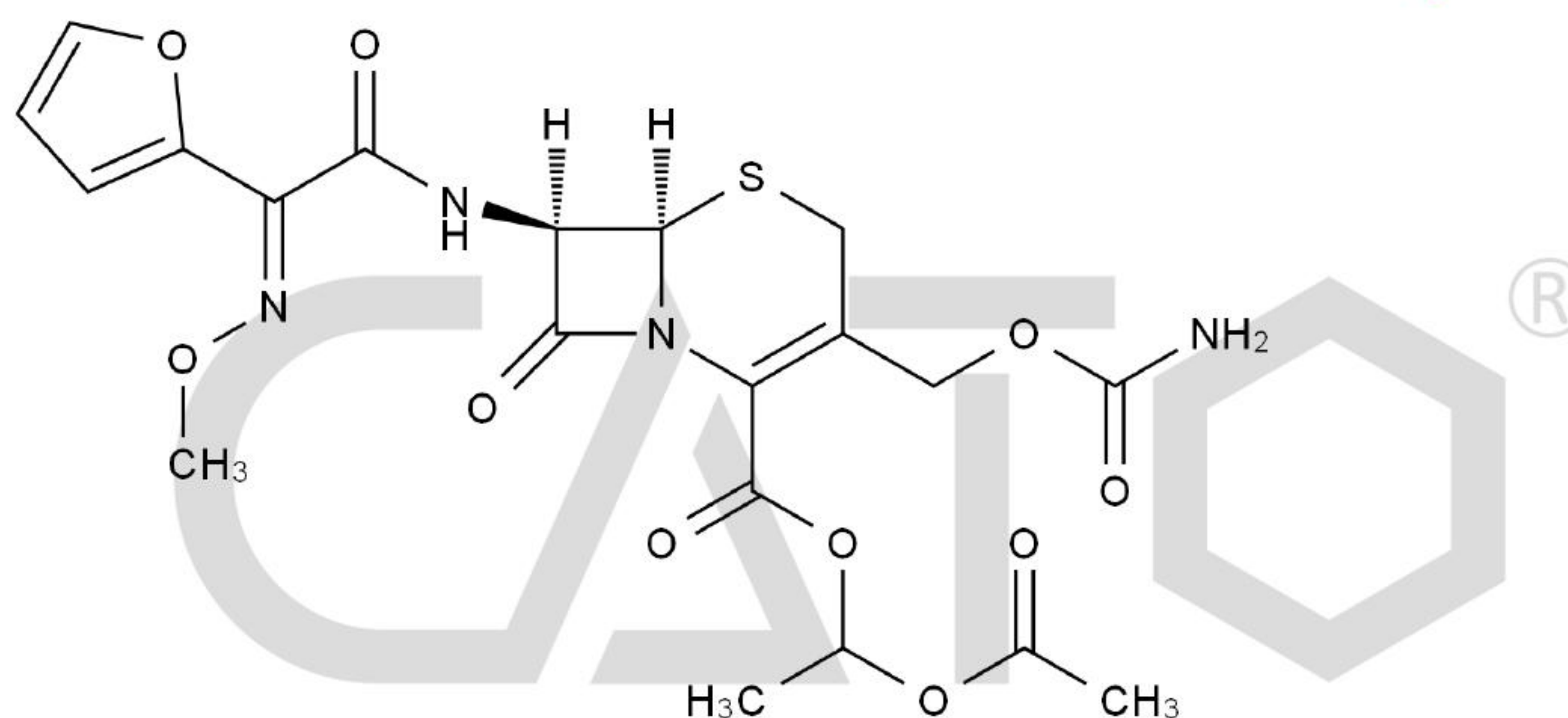
Reference Material & Standard

Product Name:	Cefuroxime Axetil EP Impurity B	Catalogue Number:	C4X-14362
Synonyms:	N/A	Lot Number:	0601-RH-0083
CAS Number:	97232-96-7	Expiry Date:	Dec 04, 2029
Molecular Formula:	C ₂₀ H ₂₂ N ₄ O ₁₀ S	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	510.47	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	98.913%
Water Content	Karl Fischer	0.18%
Residual Solvents	NMR	3.97% acetonitrile
Assay		94.8%

Comment:

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

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Jun 02, 2026

Date: Jun 03, 2026

Date: Jun 03, 2026



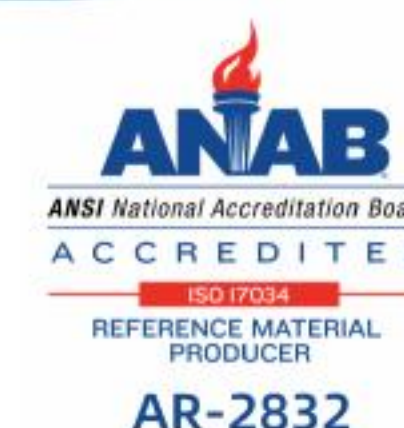
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