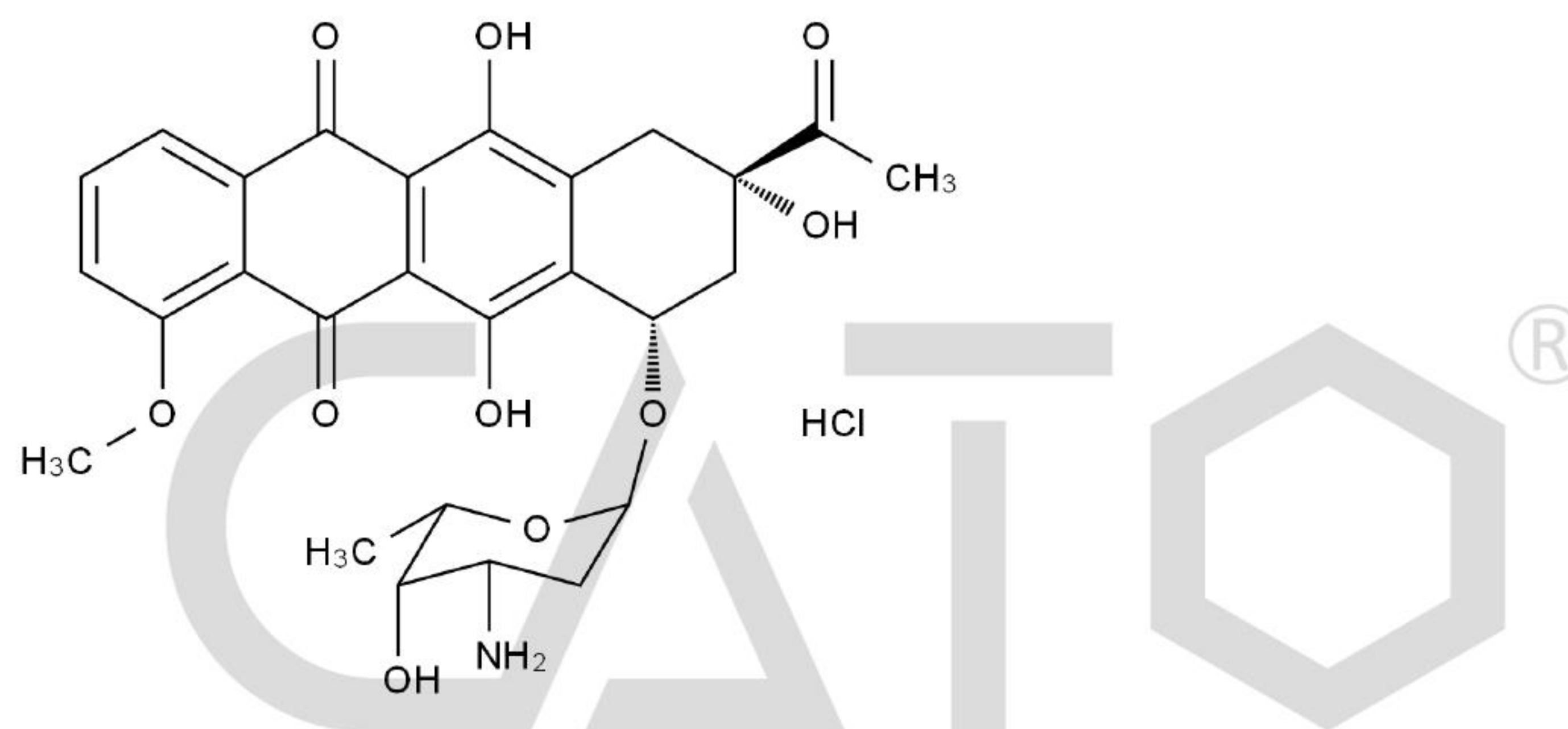


Certificate of Analysis

Reference Material & Standard

Product Name:	Epirubicin EP Impurity D HCl	Catalogue Number:	C4X-19377
Synonyms:	N/A	Lot Number:	0629-RD-0019
CAS Number:	23541-50-6	Expiry Date:	Jun 29, 2025
Molecular Formula:	C ₂₇ H ₂₉ NO ₁₀ HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	527.52 36.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Red Powder
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.838%
Residue on Ignition	TGA	0.8964%
Loss on Drying	TGA	0.8666%
Assay		97.1%

Comment:

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

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

Residue on Ignition and Loss on Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Debia

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Jun 30, 2022

Date: Jul 01, 2022

Date: Jul 01, 2022



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