

Certificate of Analysis

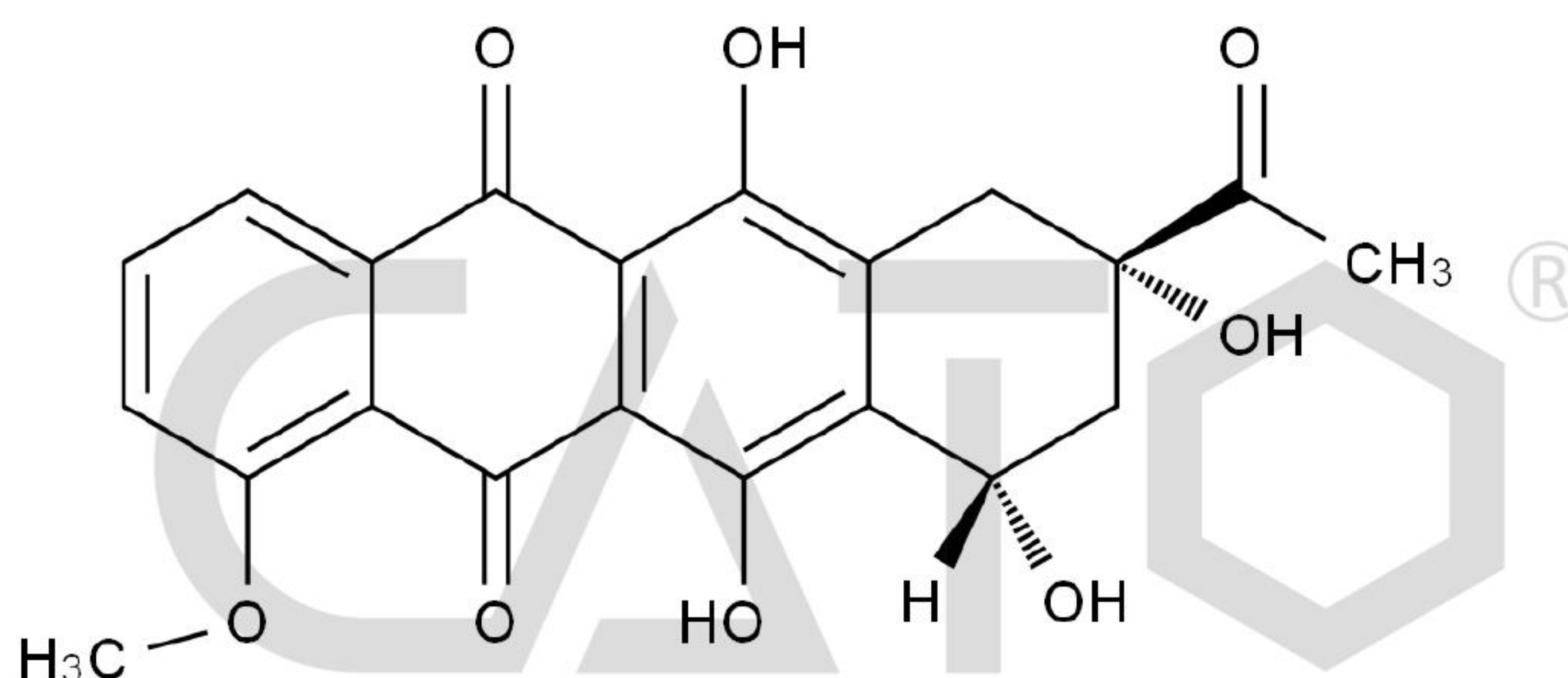
Reference Material & Standard

Product Name:	Epirubicin EP Impurity B	Catalogue Number:	C4X-11162
Synonyms:	Daunorubicinone	Lot Number:	0618-RH-0112
CAS Number:	21794-55-8	Expiry Date:	Jun 24, 2029
Molecular Formula:	C ₂₁ H ₁₈ O ₈	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	398.36	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Red Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	98.427%
Water Content	Karl Fischer	2.35%
Residual Solvents	NMR	Not detected in NMR
Assay		96.1%

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:

Hin Lam

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Jun 22, 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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