

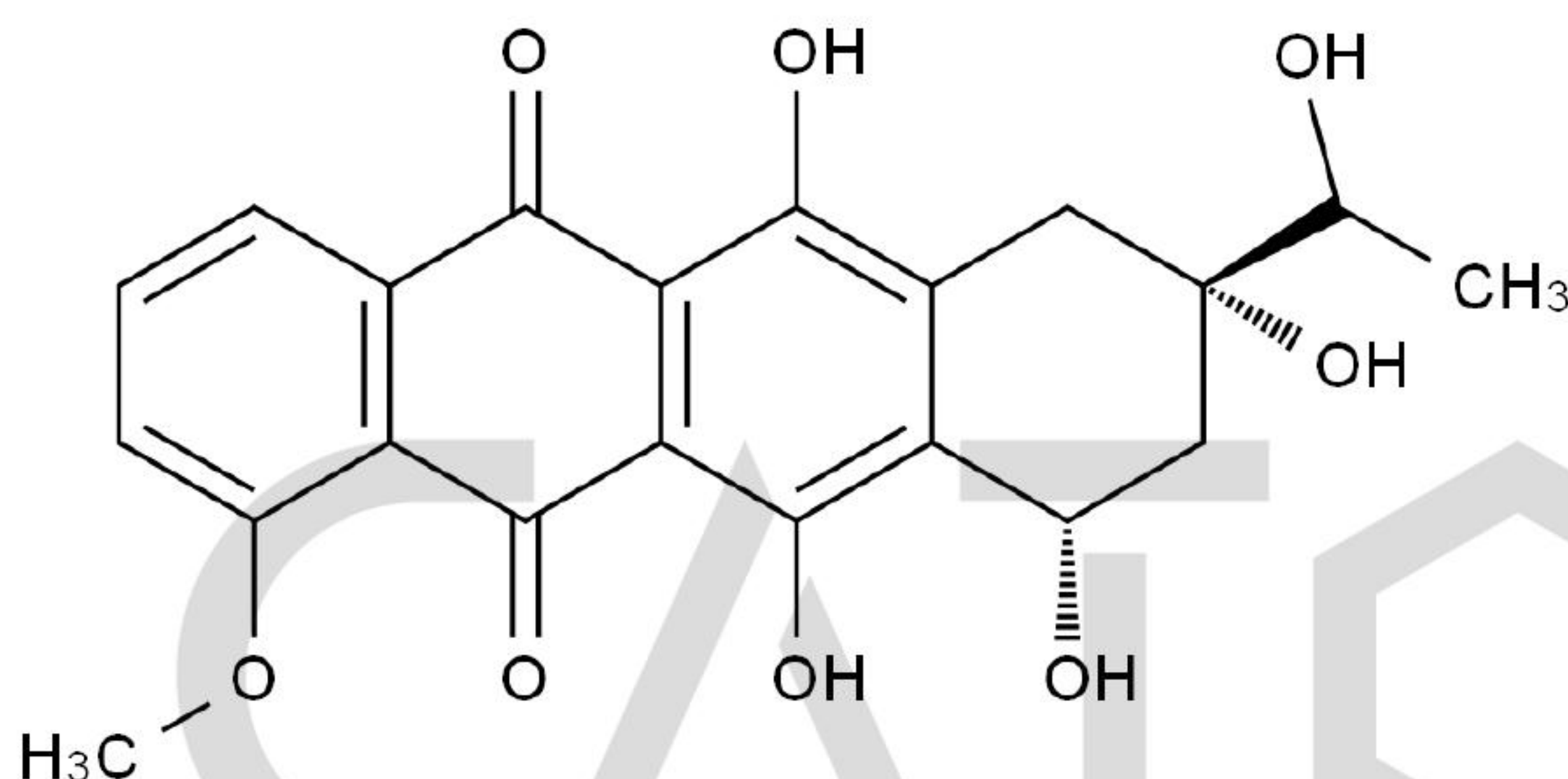
Certificate of Analysis

Reference Material & Standard

Product Name:	Daunorubicin EP Impurity E	Catalogue Number:	C4X-19375
Synonyms:	N/A	Lot Number:	0212-RG-0062
CAS Number:	28008-51-7	Expiry Date:	Feb 17, 2028
Molecular Formula:	C ₂₁ H ₂₀ O ₈	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	400.38	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Red Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	98.7682%
Water Content	Karl Fischer	0.10%
Residual Solvents	NMR	0.6% methanol and 0.4% dichloromethane
Assay		97.7%

Comment:

The calculation of the 100% 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:

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Reviewed by:

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Approved by General Manager:

David

Date: Feb 18, 2025

Date: Feb 19, 2025

Date: Feb 19, 2025

