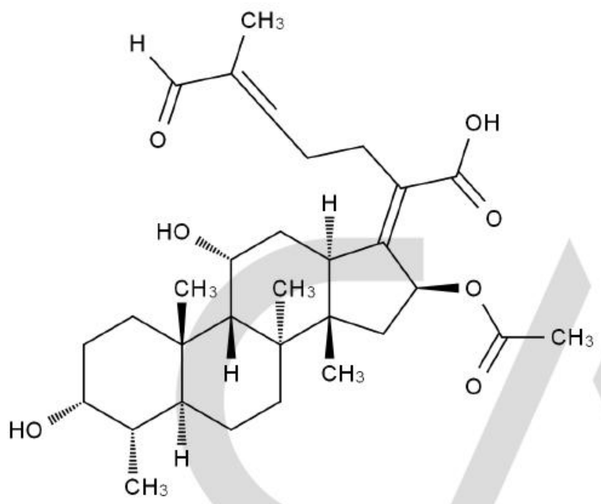
Certificate of Analysis

Reference Material & Standard

Product Name:	Sodium Fusidate EP Impurity F	**Catalogue Number:**	C4X-11976
Synonyms:	(3α,4α,5α,8α,9β,11α,13α,14β,16β,17Z)-16-(Acetyloxy)-3,11-dihydroxy-26-oxo-29-nordammara-17(20),24-dien-21-oic acid	**Lot Number:**	1110-RH-0121
CAS Number:	1415035-94-7	**Expiry Date:**	Nov 16, 2030
Molecular Formula:	$C_{31}H_{46}O_7$	**Storage:**	-20°C±5°C Sealed
Molecular Weight:	530.69	**Shipping Condition:**	Shipping with Ice Packs
Solubility:	Soluble in Acetonitrile and DMSO	**Warning:**	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Light Pink Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	99.280%
Residue on Ignition	TGA	0.6023%
Loss on Drying	TGA	1.6869%
Assay	qNMR	96.0%
Assay (Assigned Value)	Mass Balance	97.0%

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Comment:

1. The retest date of this product is Nov 16, 2029.

2. 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: Koi Date: Nov 17, 2026

Reviewed by: Alice Date: Nov 17, 2026

Approved by General Manager: David Date: Nov 17, 2026

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