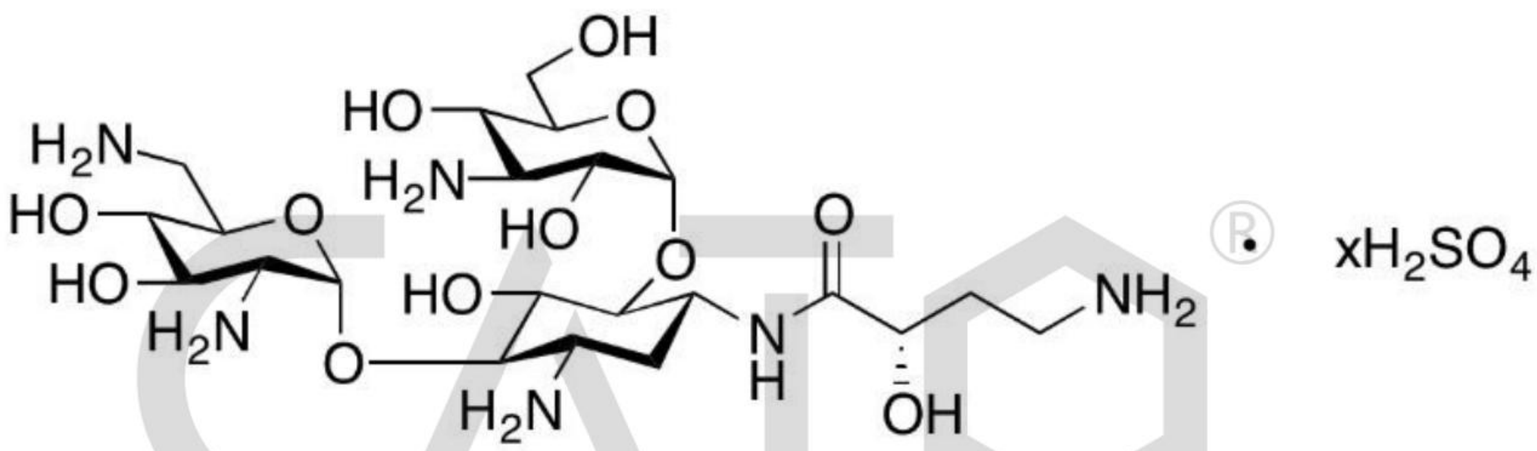
Certificate of Analysis

Reference Material & Standard

Product Name:	Amikacin B Sulfate (Amikacin EP Impurity H Sulfate)	**Catalogue Number:**	C4X-197710
Synonyms:	N/A	**Lot Number:**	0217-RD-0049
CAS Number:	48237-20-3(free base)	**Expiry Date:**	Jan 23, 2026
Molecular Formula:	$C_{22}H_{44}N_6O_{12} \cdot xH_2O_4S$	**Storage:**	-20°C±5°C Protected from light and Sealed
Molecular Weight:	584.62 ? x(98.08)		

Chemical Structure:



$\cdot xH_2SO_4$

Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.10%
Water Content	Elemental Analysis	5.2%
Assay		93.0%

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Comment:

1. Sulfate Content:26.43% by Ion Chromatography
2. The calculation of the mass balance method follows the formula (calculated on the non-dried basis):
*Assay (%) = (100%-Water Content) * Purity HPLC (%) /100%*
Water Content is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by: Hin Lam Date: Feb 25, 2022

Reviewed by: Cady Date: Feb 25, 2022

Approved by General Manager: David Date: Feb 25, 2022

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