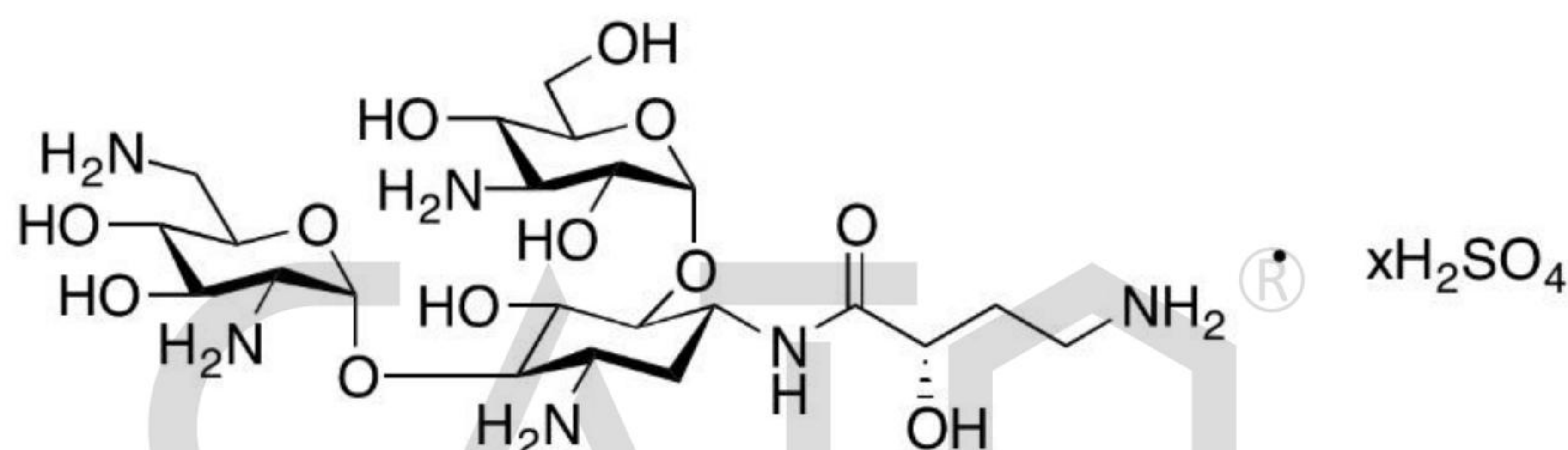


Certificate of Analysis

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:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	584.62 ? x(98.08)		

Chemical Structure:



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%

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):

$$\text{Assay (\%)} = (100\% - \text{Water Content}) * \text{Purity HPLC (\%)} / 100\%$$

Water Content is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Hin Lam

Reviewed by:

Cady

Approved by General Manager:

David

Date: Feb 25, 2022

Date: Feb 25, 2022

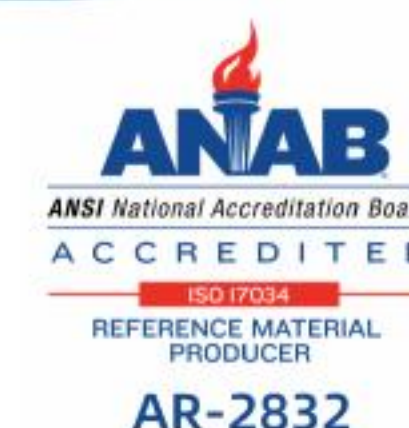
Date: Feb 25, 2022

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