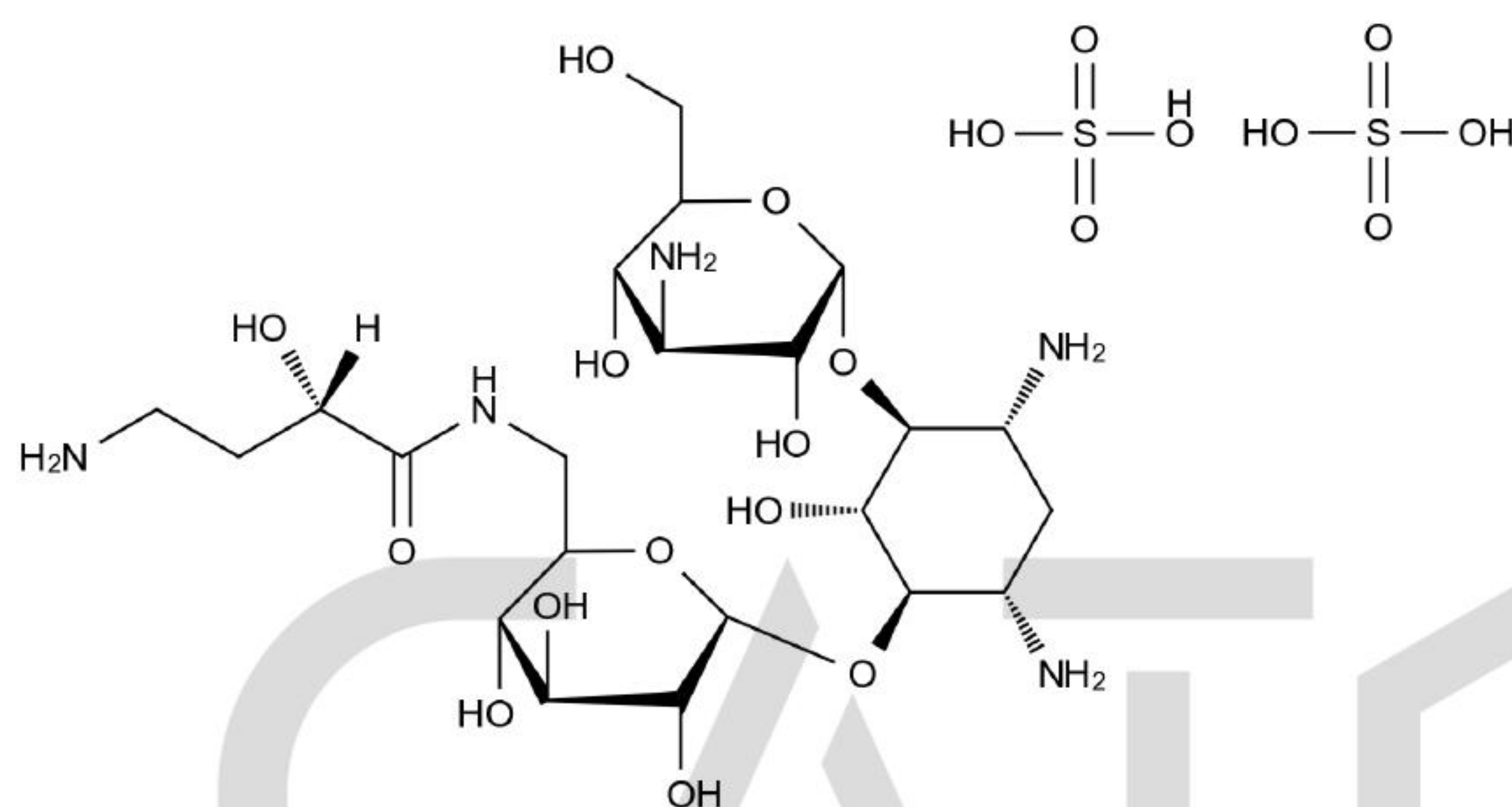


Certificate of Analysis

Reference Material

Product Name:	BB-K 6 Disulfate Salt (Amikacin EP Impurity E Disulfate)	Catalogue Number:	C4X-19776
Chemical Name:	N/A	Lot Number:	1128-RD-0010
CAS Number:	50866-72-3(Free Base)	Expiry Date:	Aug 07, 2026
Molecular Formula:	C ₂₂ H ₄₃ N ₅ O ₁₃ 2*H ₂ O ₄ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	585.60 2*98.08		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	ELSD	95.20%
Water Content	Elemental Analysis	7.9%
Assay(Free base)		65.7%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (%) = (100%-Water Content) * Purity ELSD (%) / 100%

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

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Aporoved by General manager:

David

Date: Aug 08, 2022

Date: Aug 31, 2023

Date: Aug 31, 2023

