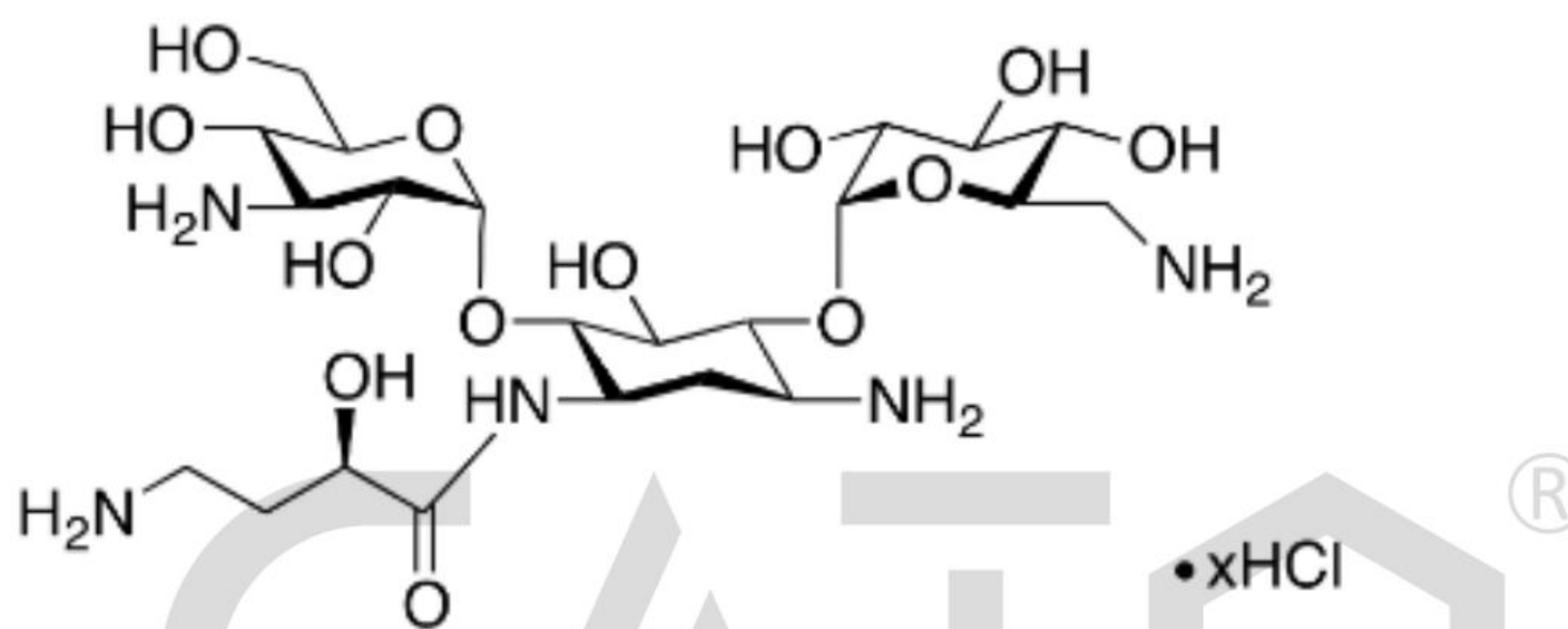


Certificate of Analysis

Reference Material

Product Name:	Amikacin EP Impurity G · x HCl	Catalogue Number:	C4X-197711
Chemical Name:	N/A	Lot Number:	0913-RD-0018
CAS Number:	50896-99-6(Free Base)	Expiry Date:	May 09, 2026
Molecular Formula:	C ₂₂ H ₄₃ N ₅ O ₁₃ x(HCl)	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	585.60 + x(36.46)		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	95.85%
Water Content	Elemental Analysis	4.9%
Assay		91.2%

Comment:

1. Chloride Content:18.8%
2. The calculation of the 100% 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:

Hinlam

Reviewed by:

Xenia

Aporoved by General manager:

David

Date: May 06, 2022

Date: Sep 13, 2022

Date: Sep 13, 2022

