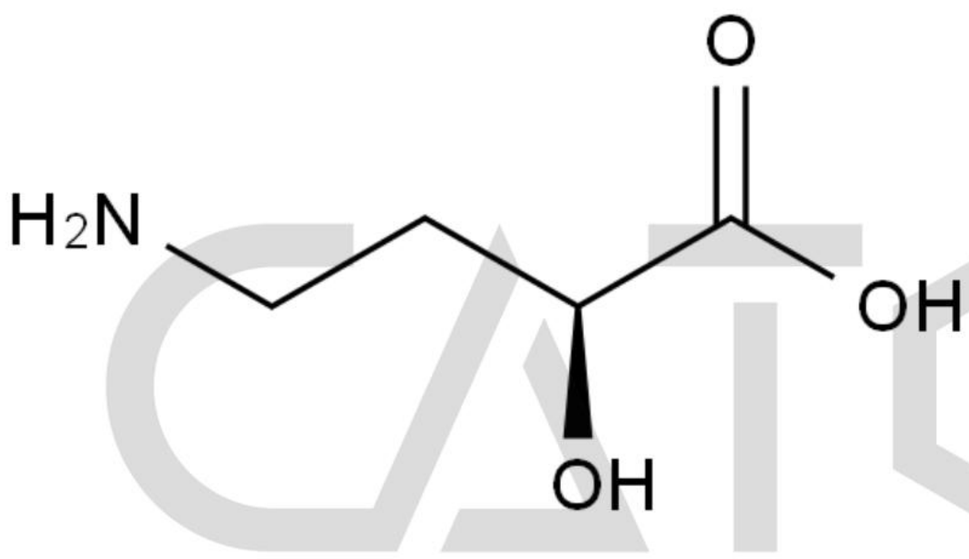
Certificate of Analysis

Reference Material & Standard

Product Name:	Amikacin EP Impurity I	**Catalogue Number:**	C4X-197716
Synonyms:	(S)-(-)-4-Amino-2-hydroxybutyric Acid	**Lot Number:**	0917-RH-0131
CAS Number:	40371-51-5	**Expiry Date:**	Sep 16, 2030
Molecular Formula:	$C_4H_9NO_3$	**Storage:**	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	119.12	**Shipping Condition:**	Shipping at Room Temperature
		Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Light Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	ELSD	100.000%
Water Content	Karl Fischer	0.5282%
Assay		99.5%

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Comment:

The calculation of the mass balance 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: Koi Date: Sep 17, 2026

Reviewed by: Lisa Date: Sep 17, 2026

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

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