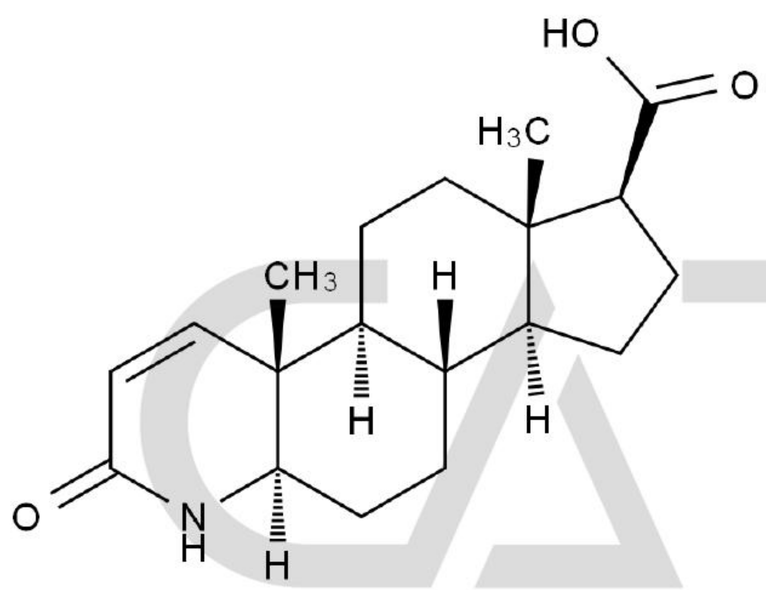
Certificate of Analysis

Reference Material & Standard

Product Name:	Dutasteride EP Impurity A	**Catalogue Number:**	C4X-11033
Synonyms:	N/A	**Lot Number:**	1016-RH-0120
CAS Number:	104239-97-6	**Expiry Date:**	Oct 19, 2030
Molecular Formula:	$C_{19}H_{27}NO_3$	**Storage:**	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	317.42	**Shipping Condition:**	Shipping at Room Temperature
		Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Loss on Drying	TGA	0.2151%
Assay	Mass Balance	99.8%

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Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):
*Assay (%) = (100%-Loss on Drying) * Purity HPLC (%) /100%*
Loss on Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by: Alice Date: Oct 20, 2026

Reviewed by: Koi Date: Oct 20, 2026

Approved by General Manager: David Date: Oct 20, 2026

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