

Analysis Date: 29-12-2025

Re-test Date: 29-12-2028

## ABIRATERONE IMPURITY 16

### Identification

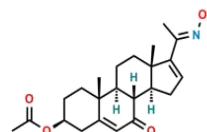
**Chemical Name** : (3S,8R,9S,10R,13S,14S)-17-(1-(Hydroxyimino)ethyl)-10,13-dimethyl-7-oxo-2,3,4,7,8,9,10,11,12,13,14,15-dodecahydro-1H-cyclopenta[a]phenanthren-3-yl acetate

**CAT No** : ALL-ABI-8983

**CAS No** : N.A.

**Molecular Formula** : C<sub>23</sub>H<sub>31</sub>NO<sub>4</sub>

**Molecular Weight** : 385.5



### Analytical Information

<b>Batch No</b>	: ALL-ABI-8983	<b>HPLC Purity</b>	: 98.00 %
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 97.53%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 0.105%	<b><sup>1</sup>H NMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 0.366%		

### Additional Information

**%Potency** = [100 -( Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
[100 – (0.105+0.366) × 98.00]/100 = 97.53%

**Recommendation** : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul Khadase QA Officer	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

**Attachment** : HPLC, Mass, <sup>1</sup>H NMR, IR

**Shipping Condition** : All Product are stable to be shipped at room temperature, unless otherwise specified

### Corporate Office

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