

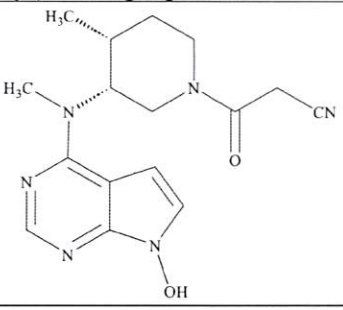


## Certificate of Analysis



Certificate No.: 20240819007

Date: August 19, 2024

Retest date: August 15, 2027

<b>Compound Name:</b>	<b>Tofacitinib Impurity 45</b>	
<b>Synonyms:</b>	3-((3R,4R)-3-((7-hydroxy-7H-pyrrolo[2,3-d]pyrimidin-4-yl)(methyl)amino)-4-methylpiperidin-1-yl)-3-oxopropanenitrile	
<b>TLC Catalogue Number:</b>	T-117117	
<b>CAS Number:</b>	2407039-29-4	
<b>Molecular Weight:</b>	328.38	
<b>Molecular Formula:</b>	C <sub>16</sub> H <sub>20</sub> N <sub>6</sub> O <sub>2</sub>	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	6423-065A5	
<b>Storage Conditions:</b>	Store at 2-8 °C	
<b>Solubility:</b>	Methanol, DMSO, DMF	

Test Description	Specifications	Results
<b>Visual Description</b>	Off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>99.2%</b>
<b>Impurity (HPLC)</b>	RT 10.28, 0.83%	
<b>Water Content (KF)</b>	N/A	<b>0.8%</b>
<b>Optical Rotation</b>	N/A	$[\alpha]_D^{25.0}(c=0.35, \text{CHCl}_3): +19.8^\circ$
<b>Residual Solvents (NMR)</b>	0.3% methanol and 2.4% isopropyl ether	
<b>Assay (%)</b>	Not less than 90.0%	<b>95.7%</b>
<b>Recommendation:</b>	<b>Release.</b> The compound contains 0.8% Tofacitinib (RT 10.28, free form of TLC No. T-117001) according to its HPLC.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		08/20/2024
Approved by:	Quality Assurance		08/20/2024

Attachments: HPLC, IR, MS and NMR spectra.