



ISO 9001:2015 CERTIFIED CERTIFICATE OF ANALYSIS

Product Name	Abemaciclib Metabolite M18 Dihydrochloride		
Molecular Formula	C ₂₅ H ₃₀ Cl ₂ F ₂ N ₈ O(HCl Salt):C ₂₅ H ₂₈ F ₂ N ₈ O(Free Base)	The chemical structure shows a central benzimidazole core. The benzimidazole ring has a 1-isopropyl group and a 2-hydroxymethyl group. The benzimidazole ring is substituted with a 4-fluoro group and a 6-(5-fluoro-2-((5-(piperazin-1-ylmethyl)pyridin-2-yl)amino)pyrimidin-4-yl) group. The piperazine ring is substituted with a 1-(2-(4-(2-(2-hydroxymethyl)-1-isopropyl-1H-benzimidazol-5-yl)-5-fluoropyrimidin-2-yl)pyridin-2-yl)methyl group. The structure is shown as a dihydrochloride salt (2HCl).	
Molecular Weight	567.47(HCl Salt):494.55(Free base)		
Batch Number	XX-XXXX		
Batch Quantity	XXX		
Date of Manufacturing	DD-MM-YYYY		
Date of Analysis	DD-MM-YYYY		
Next Retest Date	DD-MM-YYYY		
Catalogue Number	XX		
CAS Number	NA		
COA Number	PA-XXXX		
IUPAC Name	(4-fluoro-6-(5-fluoro-2-((5-(piperazin-1-ylmethyl)pyridin-2-yl)amino)pyrimidin-4-yl)-1-isopropyl-1H-benzo[d]imidazol-2-yl)methanol dihydrochloride		
Storage and Handling	2°C to 8°C		

Sl. No	* Test	Result
	Description	
1.	Identification i) By IR ii) By NMR iii) By MS	--
2.	Chromatographic Purity (% by HPLC)	--

Remarks: *Test or tests as mentioned above may vary as per the product nature or customer's requirement

Function	Compiled by	Reviewed by	Reviewed by	Approved by
Name	xxx	xxx	xxx	xxx
Department	Pharma Standards QC	Pharma Standards QC	Quality Assurance	Quality Assurance
Sign and Date				

Attachments	IR, NMR, MS spectra, HPLC Chromatogram.
Date of Shipment	DD-MMM-YYYY

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