



ISO 9001:2015 CERTIFIED CERTIFICATE OF ANALYSIS

Product Name	(S,S)-Dolutegravir Isomer (Dolutegravir Impurity-16)		
Molecular Formula	C ₂₀ H ₁₉ F ₂ N ₃ O ₅	The chemical structure of (S,S)-Dolutegravir Isomer (Dolutegravir Impurity-16) is shown. It features a central pyridine ring substituted with a 7-hydroxy-4-methyl-6,8-dioxo-3,4,6,8,12,12a-hexahydro-2H-pyrido[1',2':4,5]pyrazino[2,1-b][1,3]oxazine-9-carboxamide group and a (2,4-difluorobenzyl) group. The pyrazine ring is fused to the pyridine ring, and the oxazine ring is fused to the pyrazine ring. The structure is labeled with 'A' and 'E' in the background.	
Molecular Weight	419.38		
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	DCTI-C-000688		
CAS Number	DCTI-C-001401		
COA Number	PA-XXXX		
IUPAC Name	(4S,12aS)-N-(2,4-difluorobenzyl)-7-hydroxy-4-methyl-6,8-dioxo-3,4,6,8,12,12a-hexahydro-2H-pyrido[1',2':4,5]pyrazino[2,1-b][1,3]oxazine-9-carboxamide		
Storage and Handling	2-8°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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