Certificate Of Analysis

Analysis Date: 26-07-2024 **Re-test Date:** 26-06-2027

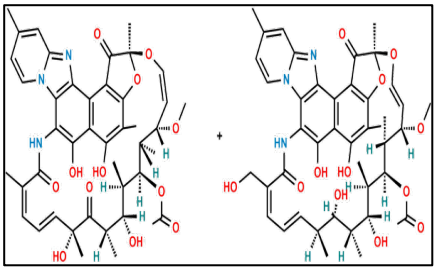
RIFAXIMIN EP IMPURITY D & H

Identification

Chemical Name : (2S,16Z,18E,20R,21S,22R,23R,24R,25S,26R,27S,28E)-5,6,20, 21,23-Pentahydroxy-27-methoxy-2,4,11,16,20,22,24,26-octamethyl-1,15-dioxo-1,2-dihydro-2,7-(epoxypentadeca[1,11,13]-trienoimino)[1]benzofuro[4,5-e] pyrido[1,2-a]ben + (2S,16Z,18E,20S,21S,22R,23R,24R,25S,26R,27S,28E)-5,6,21,23-Tetrahydroxy-16-(hydroxymethyl)-27-methoxy-2,4,11,20,22,24,26-heptamethyl-1,15-dioxo-1,2-dihydro-2,7-(epoxypentadeca[1,11,13] trienoimino)[1]benzofuro-[4,5-e]pyri

CAT No : ALL-R07090

CAS No : NA



Molecular Formula : C43H49N3O12 + C43H51N3O12

Molecular Weight : 799.86 + 801.88

Analytical Information

Batch Code	: ALL-R07090	**HPLC Purity**	: 95.40 %
Solubility	: MeOH: ACN	**Potency**	: 93.52 %
Appearance of Product	: Red Solid	**Mass**	: Confirm
Long Term Storage	: 2-8 0C	**IR Analysis**	: Confirm
Weight Loss By TGA	: 0.111 %	**1HNMR**	: Confirm
Residue Of Ignition	: 1.858 %		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =

[100 – (0.111 +1.858) × 95.40]/100 = 93.52 %

Recommendation : Released

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

Attachment : HPLC, Mass, 1H NMR, IR, TGA

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

Corporate Office

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