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CERTIFICATE OF ANALYSIS

Analysis Date: Oct 2024

Re-test Date: Sep 2027

Product Name: N-Nitroso N-Desmethyl Erythromycin EP Impurity A

Identification:

Chemical Name: N-((2S,3R,4S,6R)-2-(((3R,4S,5S,6R,7R,9R,11R,12R,13S,14R)-14-ethyl-7,12,13-trihydroxy-4-(((2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyltetrahydro-2H-pyran-2-yl)oxy)-3,5,7,9,11,13-hexamethyl-2,10-dioxoxacyclotetradecan-6-yl)oxy)-3-hydroxy-6-methyltetrahydro-2H-pyran-4-yl)-N-methylnitrous amide

Synonyms : N-Nitroso Erythromycin EP
Impurity B ; N-Nitroso N-Desmethyl Erythromycin

CAS Number : NA

CAT Number : CP-E18018

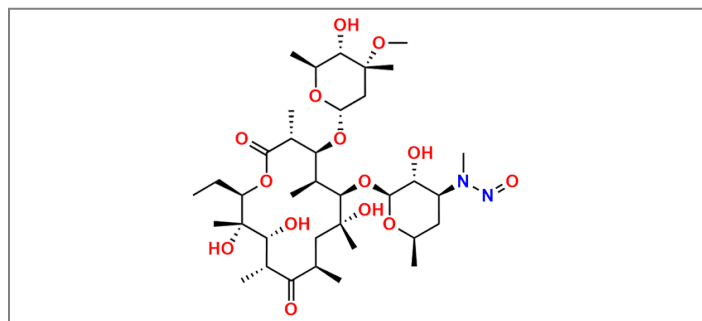
Molecular Formula : C₃₆H₆₄N₂O₁₄

Molecular Weight : 748.9

Batch Number : CP-ERY-DMN-0225

Storage Condition : Tightly closed, Inert atmosphere at 2 to 8° C

Shipping condition : All Products are stable to be shipped at room temperature, if specific condition required it is mention in the COA



Analytical Information:

Sr. No.	Test	Result
1)	Description	White to Off White Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to structure
4)	Purity By HPLC	Isomer 1=84.70 % Isomer 2=10.80 % Total Purity= 95.50%
5)	H1NMR	Confirm to structure
6)	IR	Confirm to structure
7)	Weight loss by TGA	-
8)	Potency by TGA	-



Prepared and Reviewed By

A handwritten signature in blue ink, appearing to read "Priyanka Salunkhe".

Ms Priyanka Salunkhe
(Manager QC Analytical)

Approved By

A handwritten signature in blue ink, appearing to read "Rohini Gagare".

Ms Rohini Gagare
(QA Head)

Note: Product supplied by Chemicea are for R&D purpose only and not for human consumptions.