

CERTIFICATE OF ANALYSIS

Corporate Office: Unit No F/10, 1st Floor Shubha Parvti Industrial Premises, Dombivali (East)
Kalyan-Thane-421201.

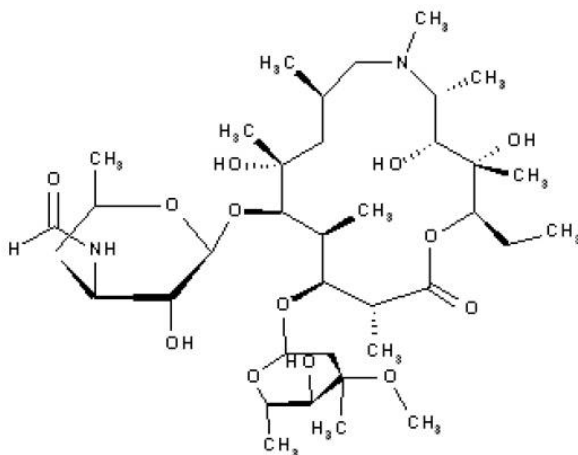
URL: www.olympusimpuritiesstandard.com / Email: info@olympusimpuritiesstandard.com

CERTIFICATION: ISO 9001:2015 / WHO-GMP

ANALYTICAL REFERENCE SUBSTANCE

AZITHROMYCIN IMPURITY N

3'-N,N-didesmethyl-3-oxo Azithromycin



Product Number No OLYAZ.015
CAS Number: 612069-25-7
Lot Number: OLYAZ0010.0N
Molecular Formula: C₃₆H₆₅NO₁₃
Molecular Weight: 719.90 g/mol

Long-term Storage: 2-8 °C
Appearance: Off White Solid
Melting Point: N.A.
Purity by HPLC: 96.30%

Manufacturing date: September 31, 2016

Re-Test Date: September 31, 2018

This certificate is valid for two years from the date of Manufacturing
Provided the substance is stored under the recommended conditions.

Additional information:

TLC Condition: (SiO₂) plate Dichloromethane: Ethyl Acetate / Hexane= 2:8, RF – 0.4 Single Spot, visualization in H₂SO₄.

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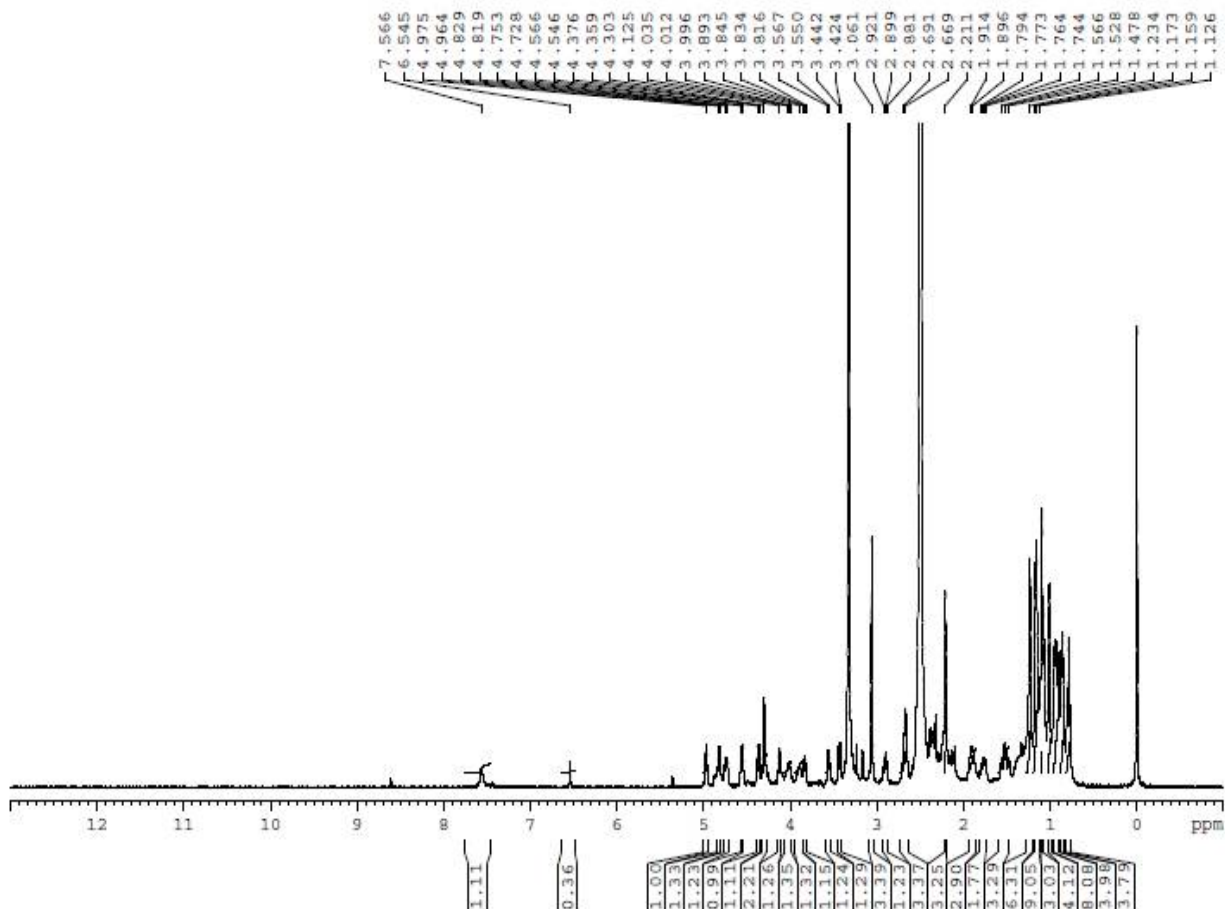
I. Identity

The identity of the reference substance was established by following analyses.

Ia. ¹H-NMR Spectrum

Conditions: BRUKER 400 MHz, DMSO-d₆

The structure is confirmed with the signals of the spectrum and their interpretation



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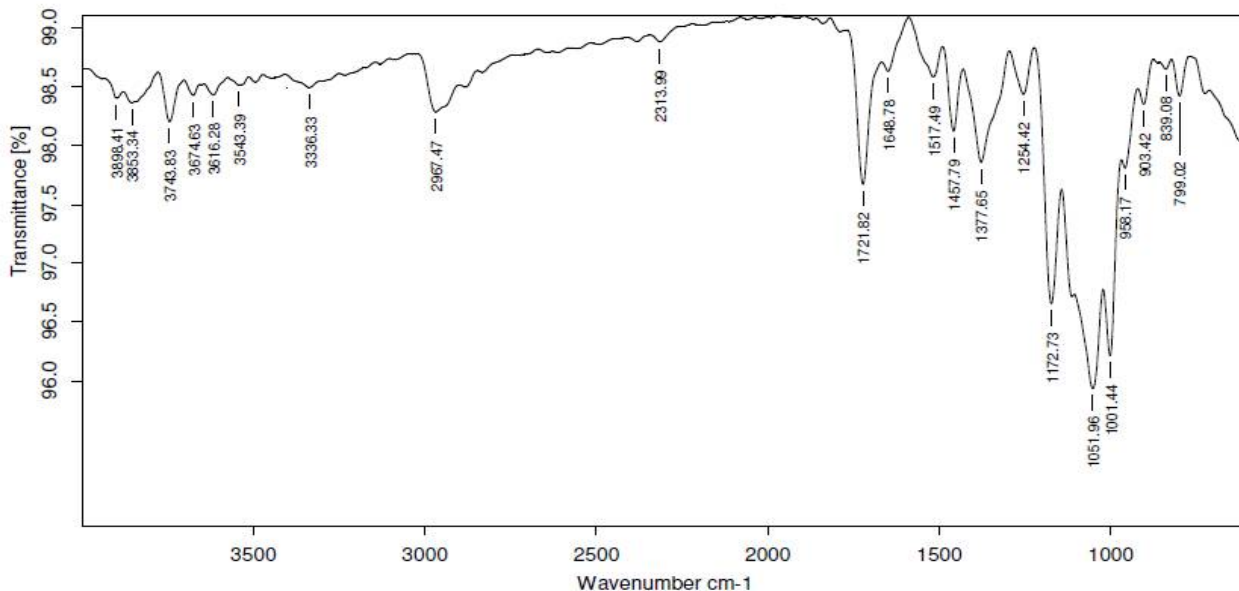
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Ic. IR Spectrum

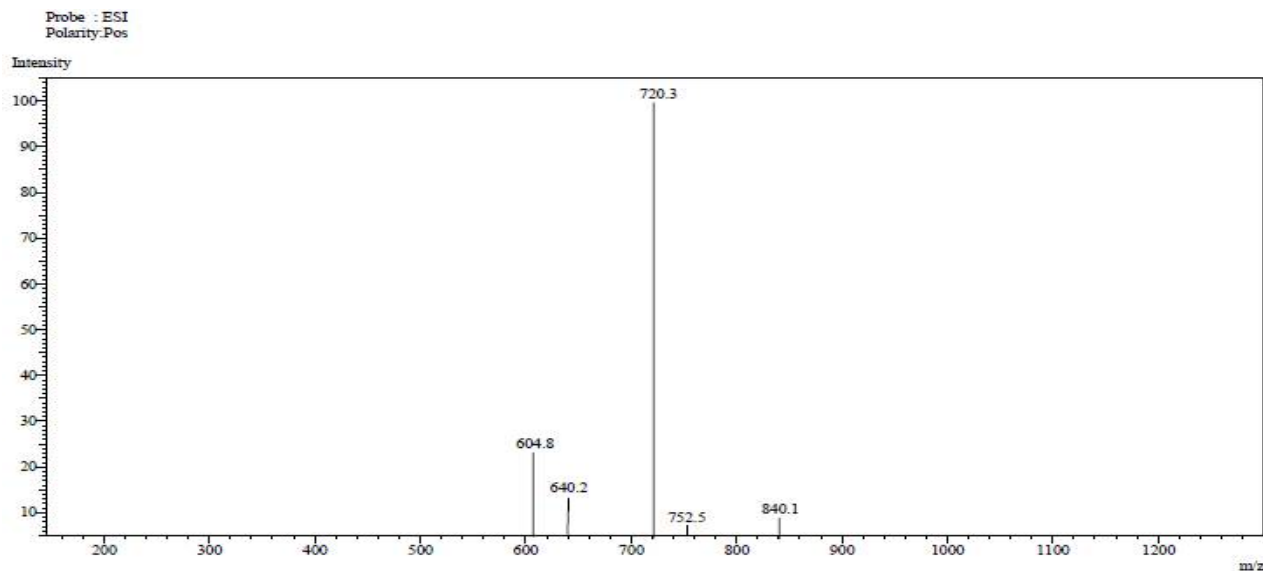
Method: Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy.

Instrument: BRUKER Model ALPHA.



Ib. Mass Spectrum

Method: Agilent LC-, Model 1200 Infinity Series: Agilent MS, Model 6120



The M+1 (720.3) of the mass spectrum is consistent with the Molecular Weight of the Compound 719.90 g/mol.

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II. Purity

The purity of the reference substance was analyzed by SHIMADZU SCL-10AVP high performance liquid chromatography (HPLC).

HPLC Conditions:

Solution A: 1.80 g/l solution of disodium hydrogen phosphate, pH adjusted to 8.9 using dilute phosphoric acid or dilute sodium hydroxide.

Solution B: Methanol: Acetonitrile (250:750 V/V)

Diluent: 1.73g/l solution of ammonium dihydrogen phosphate adjusted pH 10.0 using ammonia, Transfer 350ml of this solution to suitable container. Add 300 ml of acetonitrile and 350 ml methanol. Mix well and sonicate.

Column:

Gemini NX (C18)
5 µm, 250 x 4.6 mm

Conditions:

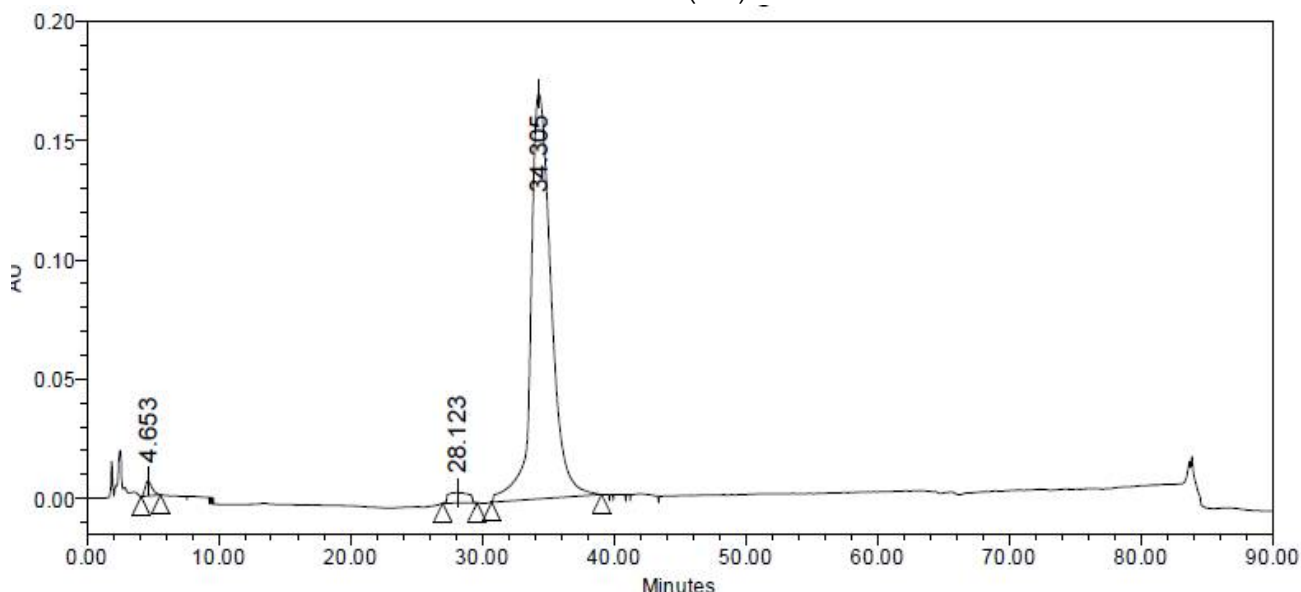
1.0 ml/min,
0-25 min A/B 50-55
25-30 min A/B 55-60
30-80 min A/B 60-75
80-92 min A/B 75-50 (v/v)

Detector:

210nm/UV

Injector:

Manual
50µl



	Retention Time (min)	Area	% Area	Height
1	4.653	224606	1.19	6216
2	28.123	474498	2.51	4375
3	34.305	18178999	96.30	169926

Relative Retention Time (RRT) Calculation – Retention Time of Impurity (RT)/Retention (RT) Time of API. (34.305/48.519 = 0.70)

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Results:

Purity: 96.30 %

Method: Azithromycin USP

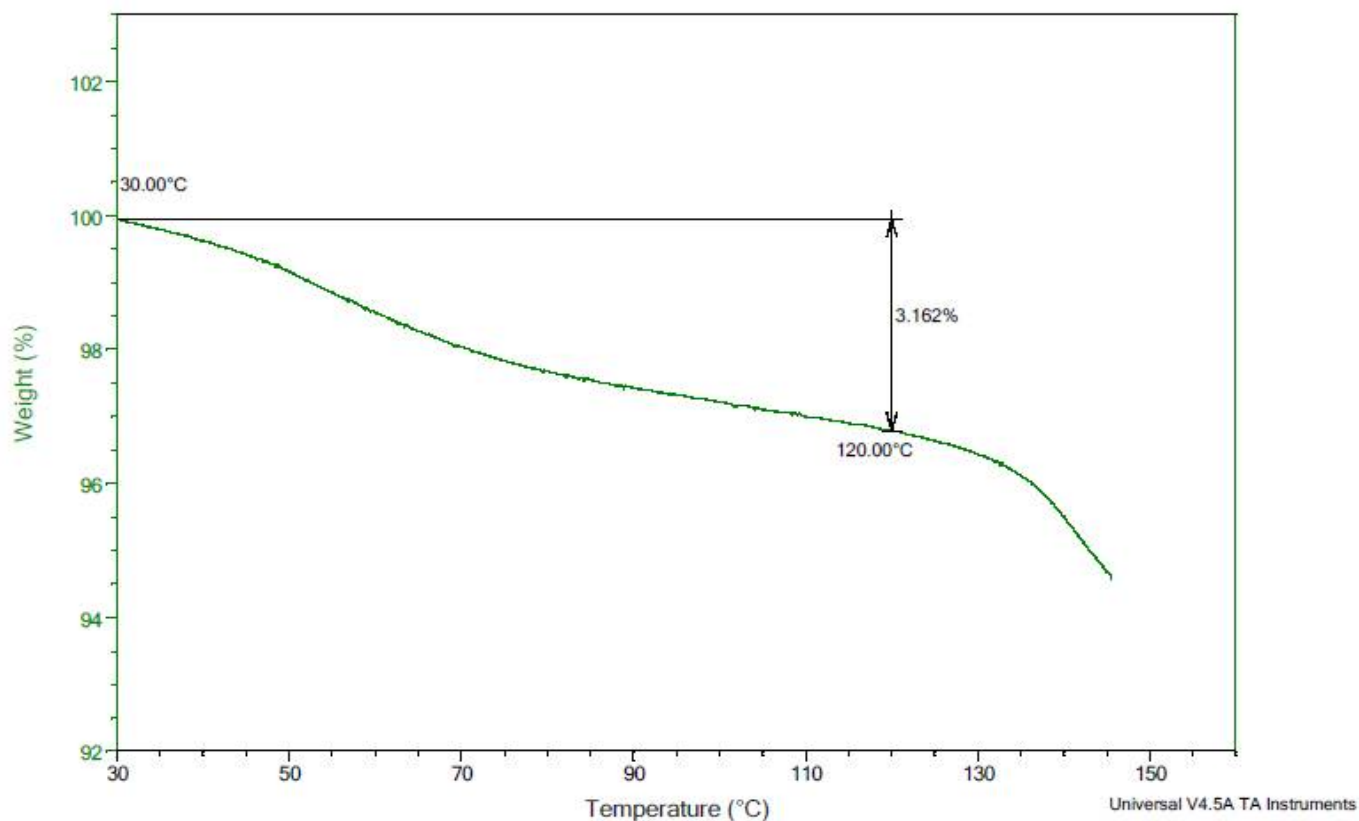
API RT: 48.519

Observed RRT: 0.70

Reported RRT: 0.76

III. Water Content

Method: TGA Thermograms, The Percent of weight loss at 30-150°C is 3.162%



IV. Residual Solvents

Method: 1H-NMR

No significant amounts of residual solvents were detected (< 0.05 %).

V. Potency

%Potency = (Chromatographic purity – TGA Value) = (96.30-3.162) = 93.13%

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VI. Final Result

Total impurities (HPLC) 3.7 %

Water Content: 3.162%

Purity by HPLC: 96.30

Residual solvents: < 0.05 %

Potency: 93.13%

Release Date: 2016-10-02

Reviewed By

Dr. Ashish Keche
Director of QA

Approved By

Dr. Atish Rodge
Managing Director