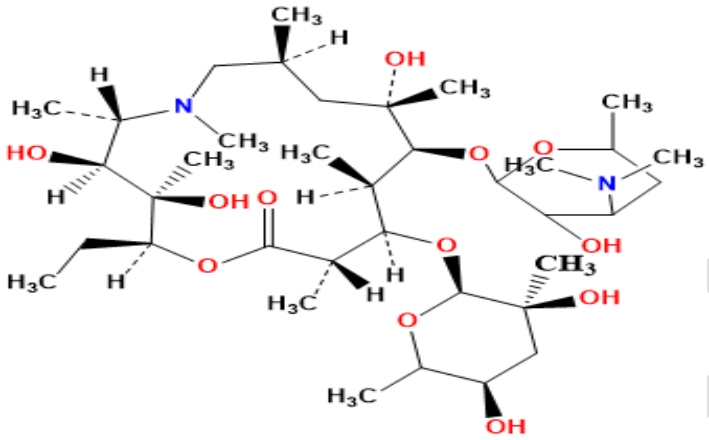
CERTIFICATE OF ANALYSIS

Analytical Reference substance

Azithromycin Impurity C

3′-O-demethylazithromycin



Product Number No 11-OLY0020.03
CAS Number: N.A.
Lot Number: AZI-C-16
Molecular Formula: C37H70N2O12
Molecular Weight: 734.98 g/mol

Long-term Storage: 2-8 ^{0}C
Appearance: Off White Solid
Melting Point: N.A.
Purity by HPLC: 94.01%

Manufacturing date: September-28-2016

Re-Test Date: September-28-2018

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

Additional information:
TLC Condition: (SIO2) plate Ethyl Acetate: Hexane = 6:4, (1 drop Diethyl amine) RF – 0.30
Single Spot, visualization in UV.

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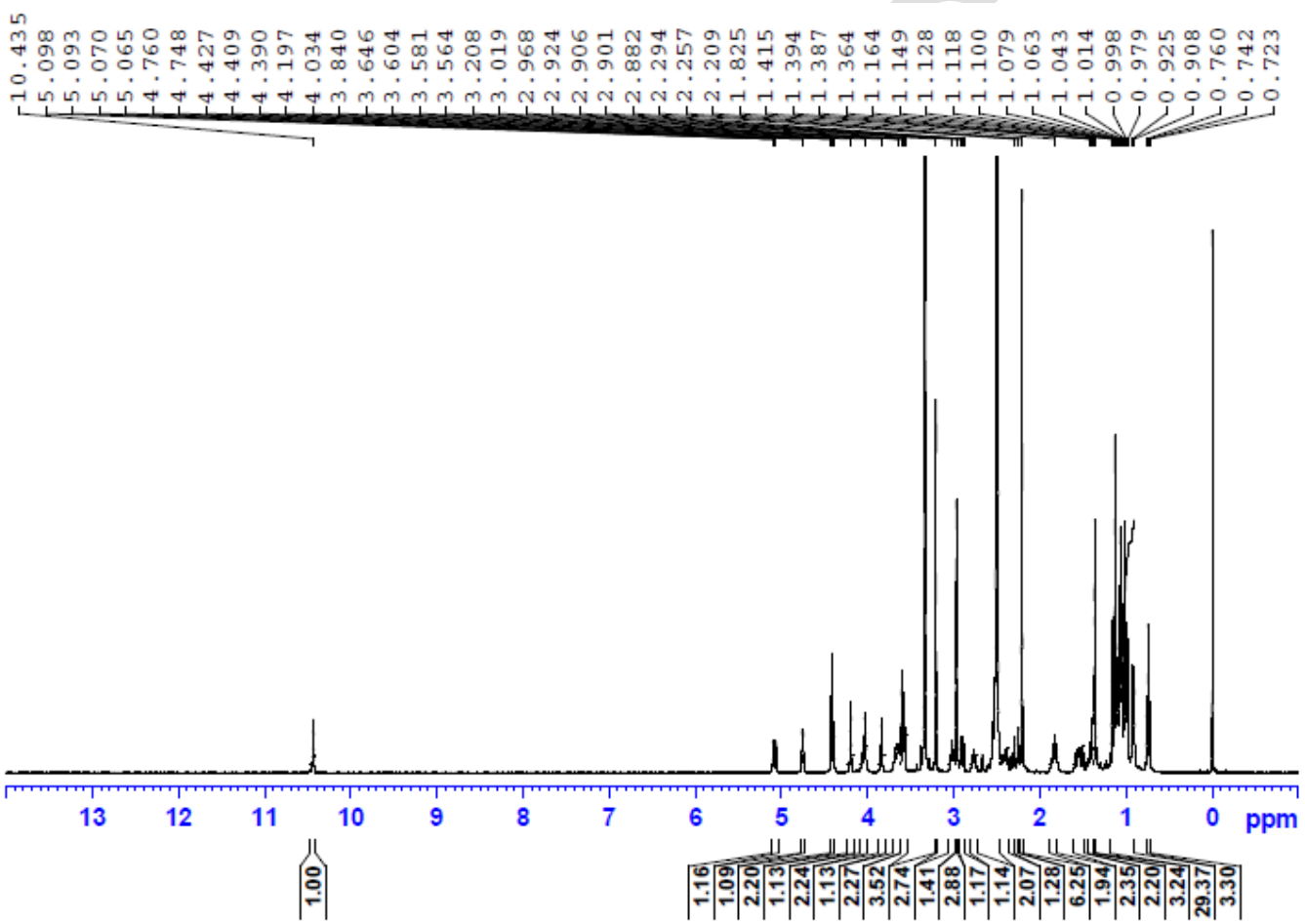
I. Identity
The identity of the reference substance was established by following analyses.

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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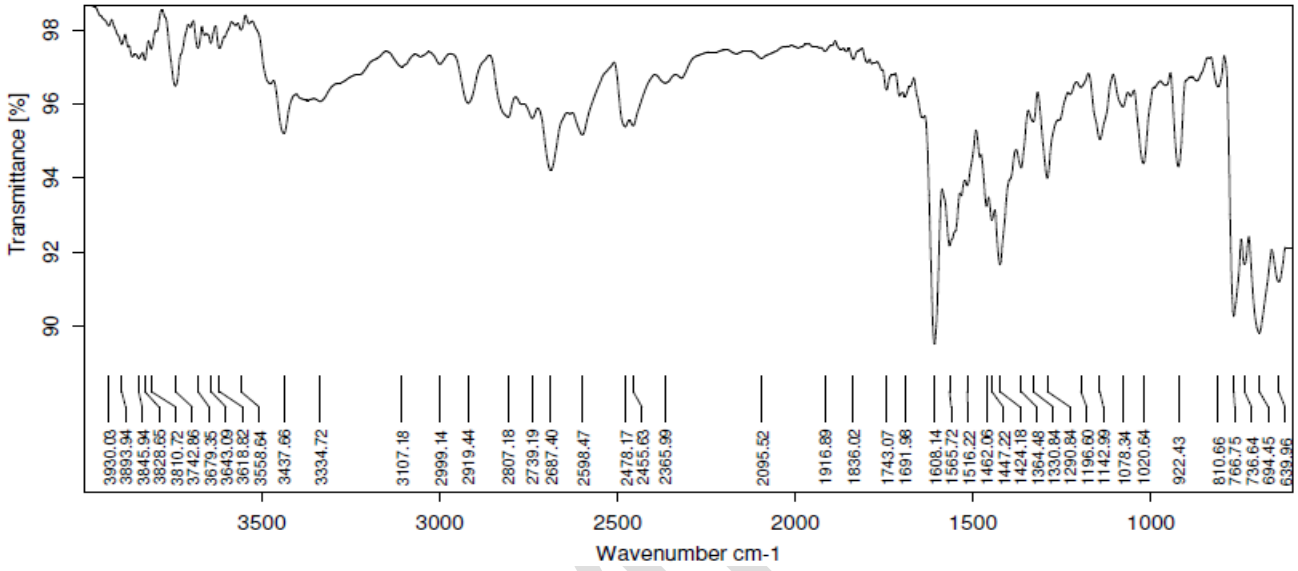
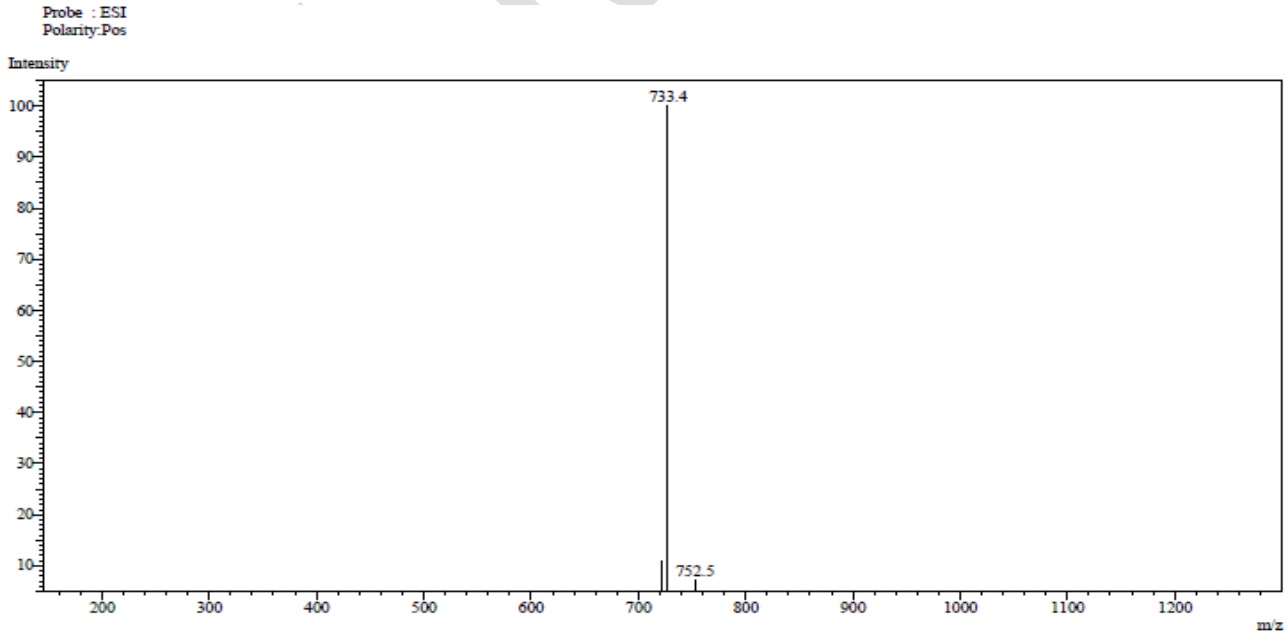
Ic. IR Spectrum

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



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The M-1 (733.4) of the mass spectrum is consistent with the Molecular Weight of the Compound 734.98 g/mol.

II. Purity

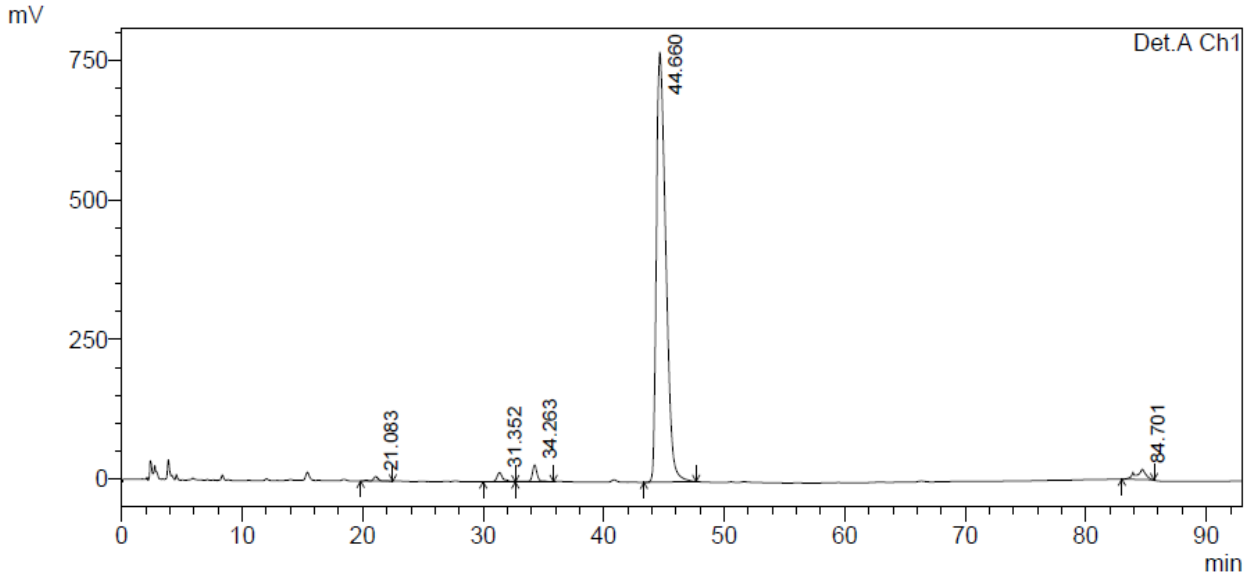
The purity of the reference substance was analyzed by SHIMADZU SCL-10AVP high performance liquid chromatography (HPLC).

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:	**Conditions:**	**Detector:**	**Injector:**
Gemini Gold (C18) 5 µm, 150 x 4.6 mm	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)	210nm/UV	Manual 50µl



1 Det.A Ch1/210nm

PeakTable

Detector A Ch1 210nm

Peak#	Ret. Time	Area	Height	Area %	Height %
1	21.083	249947	7628	0.564	0.938
2	31.352	555201	14933	1.252	1.836
3	34.263	853118	28617	1.924	3.519
4	44.660	41678089	745371	94.017	91.643
5	84.701	993924	16791	2.242	2.065
Total		44330278	813341	100.000	100.000

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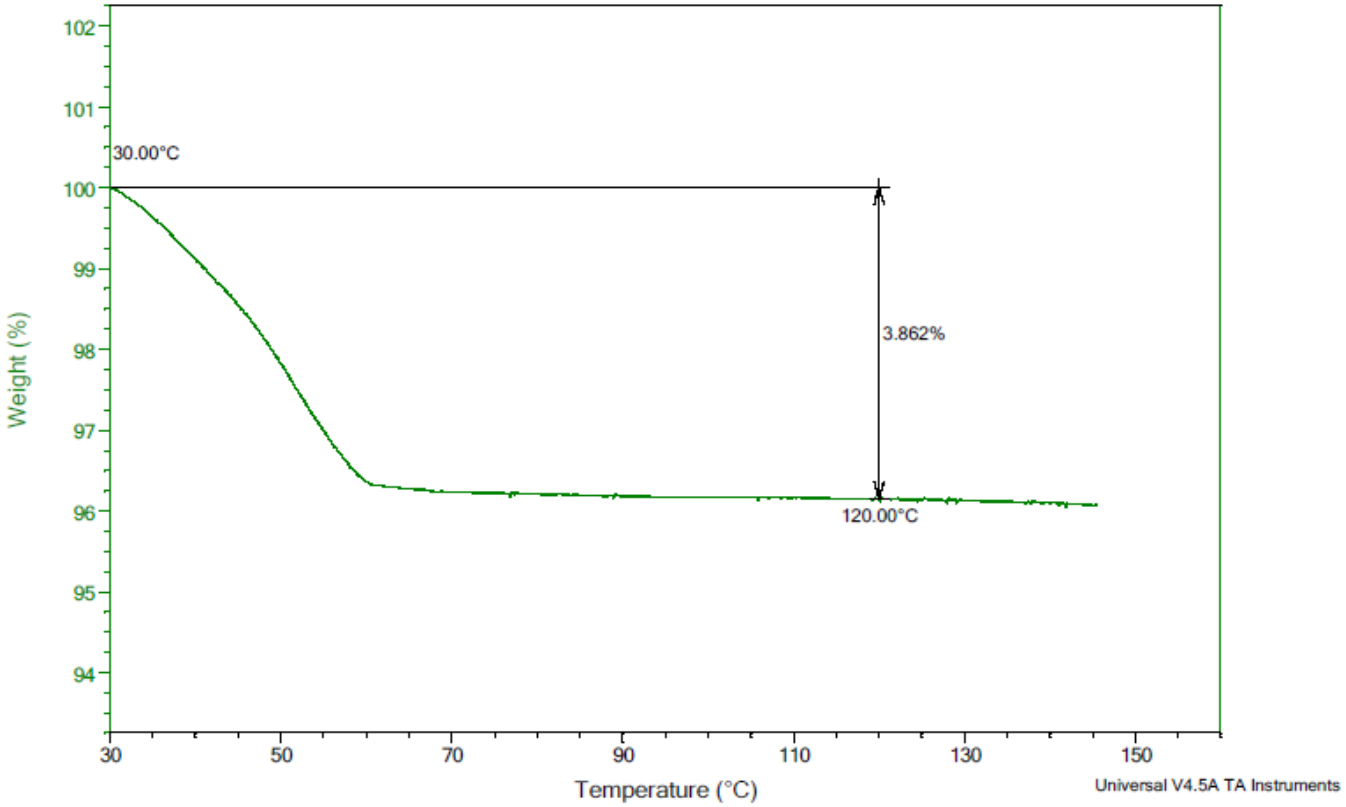
Relative Retention Time (RRT) Calculation – Retention Time of Impurity (RT)/Retention (RT) Time of API. (44.660/60.378 = 0.73)

Results:
Purity: 94.01 %
Method: Azithromycin USP
API RT: 60.378
Observed RRT: 0.73
Reported RRT: 0.73

III. Water Content
Method: TGA Thermograms, The Percent of weight loss at 30-120^{0}C is 3.862%



IV. Residual Solvents
Method: 1H-NMR
No significant amounts of residual solvents were detected (< 0.05 %).

V. Potency
%Potency = (Chromatographic purity – TGA Value) = (94.01-3.862) = 90.14%

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VI. Final Result
Total impurities (HPLC) 5.983 %
Water Content: 3.862%
Purity by HPLC: 94.01
Residual solvents: < 0.05 %
Potency: 90.14%
Release Date: 2016-10-10

Reviewed By **Approved By**

Director of QA **Managing Director**

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