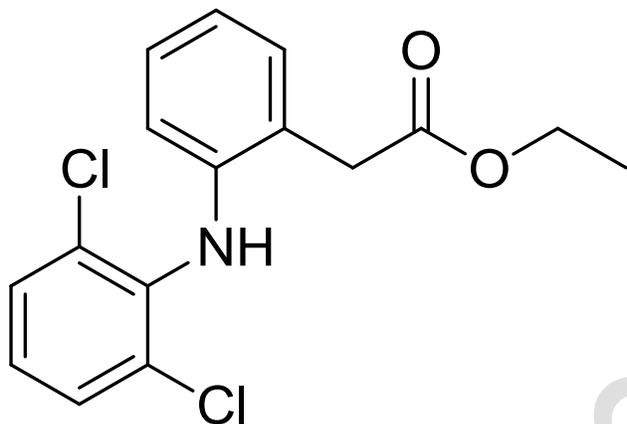


CERTIFICATE OF ANALYSIS

Certified Reference Standard

Aceclofenac Impurity C

Ethyl [2-[(2, 6-dichlorophenyl) amino] phenyl] acetate



Product Number No 11-SA0105.03
CAS Number: 15307-77-4
Lot Number: 010503-17.01.01
Molecular Formula: C₁₆H₁₅Cl₂NO₂
Molecular Weight: 324.20 g/mol

Long-term Storage: 2-8 °C
Appearance: Off White Solid
Melting Point: N.A.
Purity by HPLC: 93.92%

Manufacturing date: July-11-2017

Re-Test Date: July-11-2019

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

CERTIFICATE OF ANALYSIS

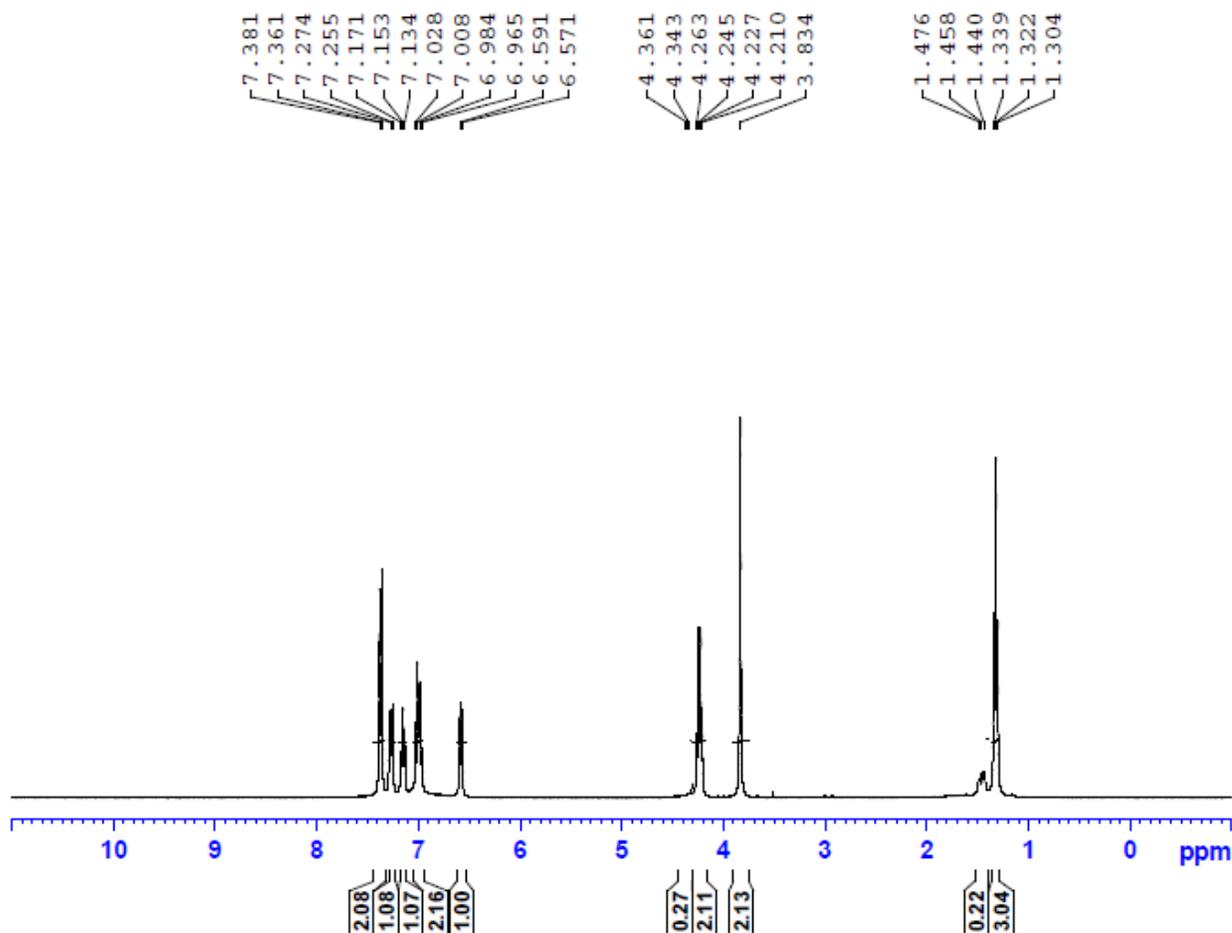
I. Identity

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

Ia. ¹H-NMR Spectrum

Conditions: BRUKER 400 MHz, CDCl₃

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



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Kalyan-Thane-421201

Contact Company: www.Olympusimpuritiestandard.com, Mo – +91-7506256625

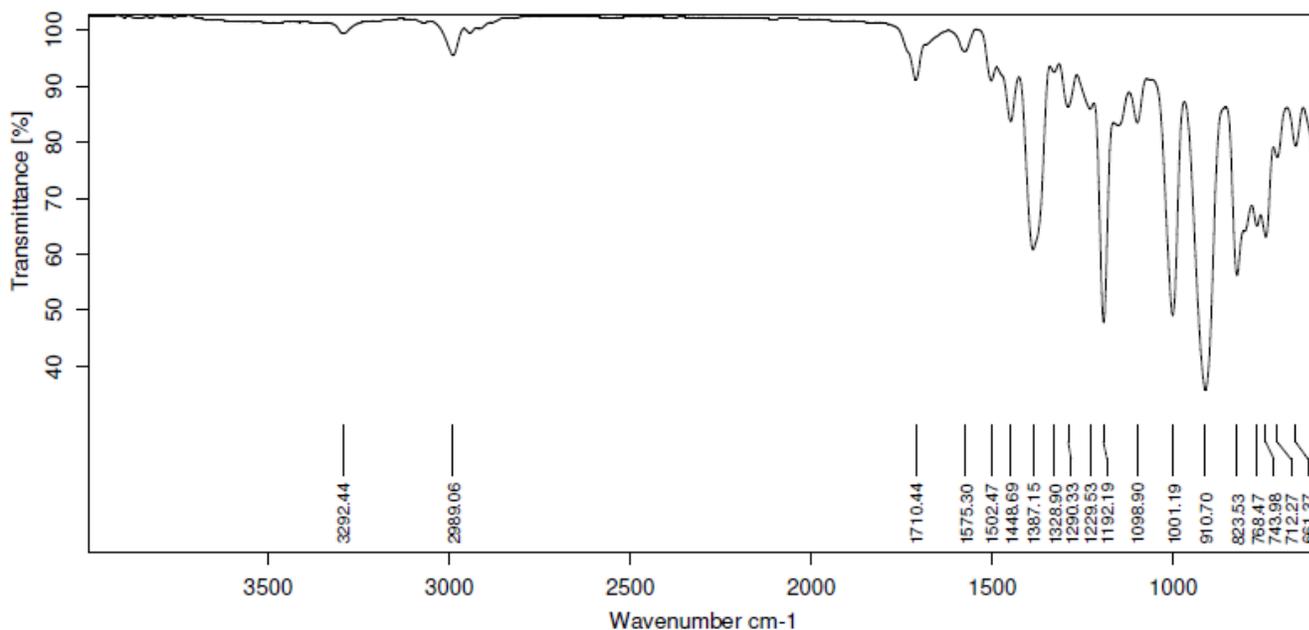
For Further Enquiries: info@Olympusimpuritiestandard.com

CERTIFICATE OF ANALYSIS

Ib. IR Spectrum

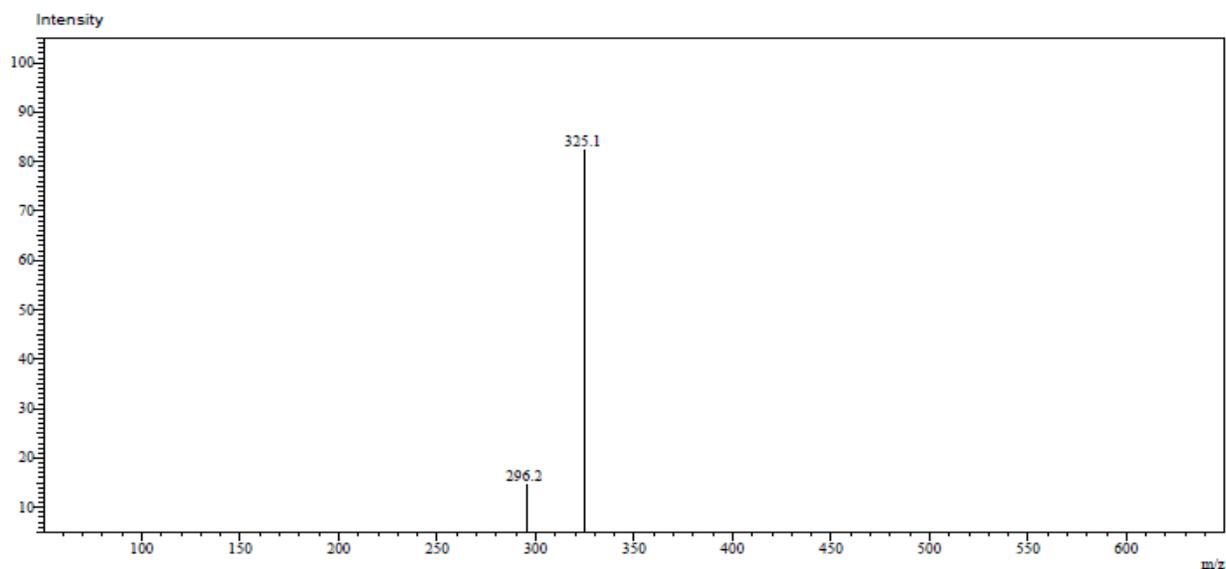
Method: Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy.

Instrument: BRUKER Model ALPHA.



Ic. Mass Spectrum

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



The M+1 (325.1) of the mass spectrum is consistent with the Molecular Weight of the Compound 324.20 Free base g/mol.

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CERTIFICATE OF ANALYSIS

II. Purity

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

HPLC Conditions:

Solution A: Water

Solution B: Acetonitrile

Diluent: Methanol

Column:

Gemini Gold (C18)
5 µm, 150 x 4.6 mm

Conditions:

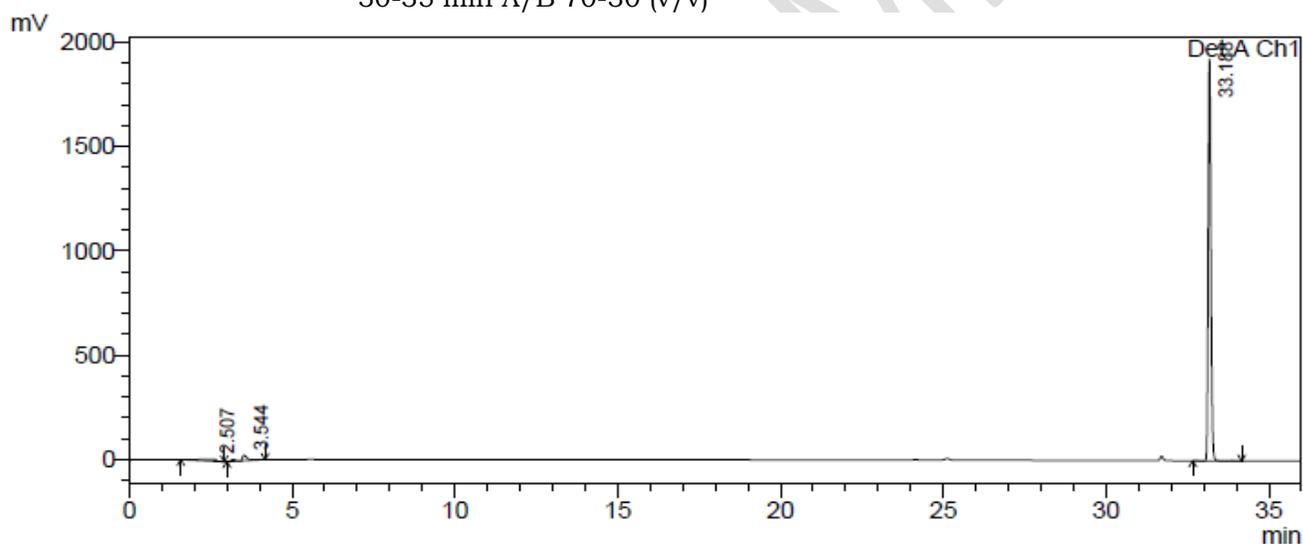
1.0 ml/min,
0-05 min A/B 100-0
05-15 min A/B 70-30
15-25 min A/B 35-65
25-30 min A/B 10-90
30-34 min A/B 10-90
30-35 min A/B 70-30 (v/v)

Detector:

254nm/UV

Injector:

Manual
50µl



1 Det.A Ch1/254nm

PeakTable

Detector A Ch1 254nm

Peak#	Ret. Time	Area	Height	Area %	Height %
1	2.507	345026	9506	2.880	0.731
2	3.544	382263	23860	3.191	1.834
3	33.188	11251327	1267741	93.928	97.436
Total		11978616	1301107	100.000	100.000

Results:

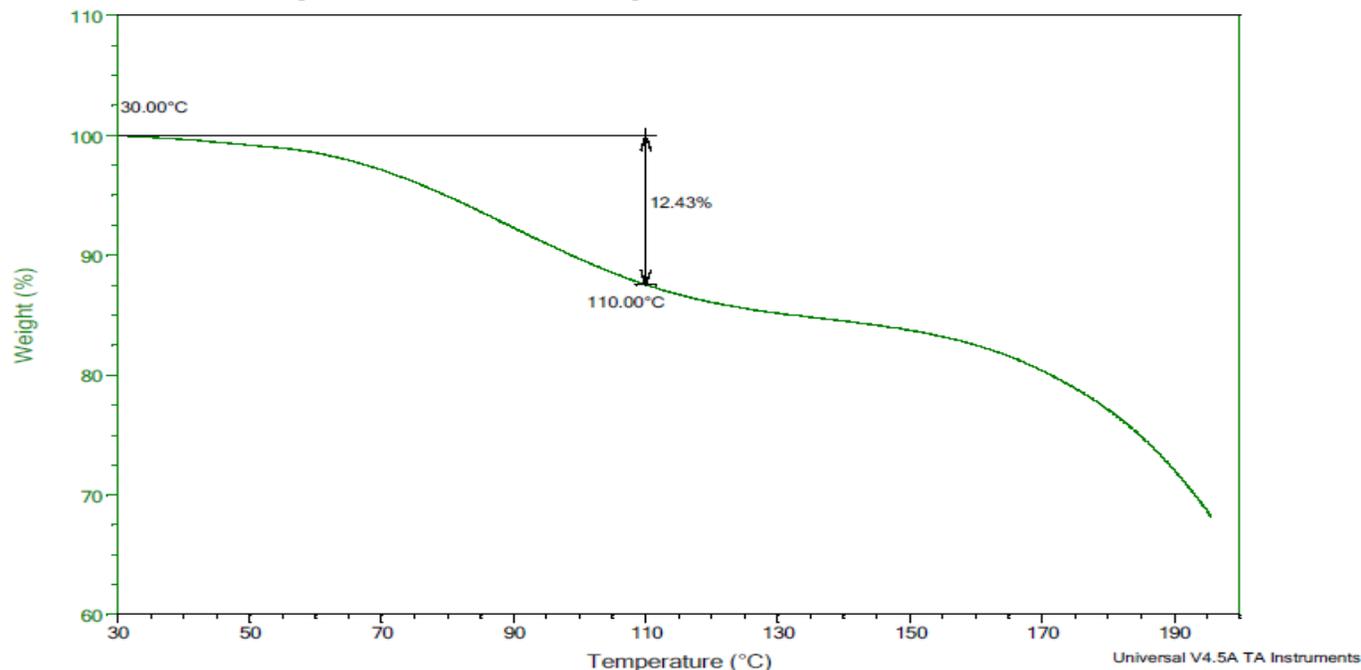
Purity: 93.92 %

Method: General

CERTIFICATE OF ANALYSIS

III. Water Content

Method: TGA Thermograms, The Percent of weight loss at 30-120°C is 0.5832%



IV. Residual Solvents

Method: 1H-NMR

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

V. Potency

%Potency = (Chromatographic purity – TGA Value) = (93.92-12.43) = 81.49%

VI. Final Result

Total impurities (HPLC): 6.08%

Water Content: 12.43%

Purity by HPLC: 93.92%

Residual solvents: < 0.05 %

Potency: 81.49%

Release Date:

Reviewed By

Dr. Ashish Keche
Director of QA

Approved By

Ashish Keche
Managing Director