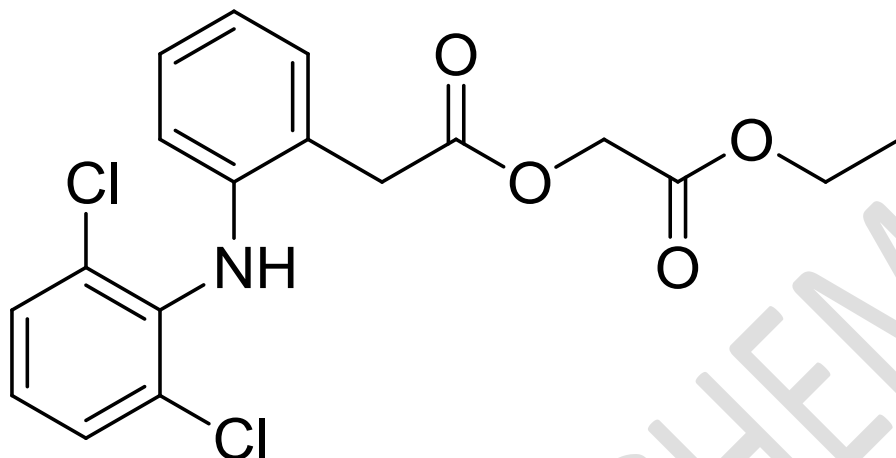


## CERTIFICATE OF ANALYSIS

### Certified Reference Standard

#### **Aceclofenac Impurity E**

#### **Ethyl [[2-[(2, 6-dichlorophenyl) amino] phenyl] acetyl] oxy] acetate**



Product Number No 11-SA0105.05  
CAS Number: 139272-67-6  
Lot Number: 010505-17.01.01  
Molecular Formula: C<sub>18</sub>H<sub>17</sub>Cl<sub>2</sub>NO<sub>4</sub>  
Molecular Weight: 382.24 g/mol

Long-term Storage: 2-8 °C  
Appearance: Off White Solid  
Melting Point: N.A.  
Purity by HPLC: 97.53%

**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

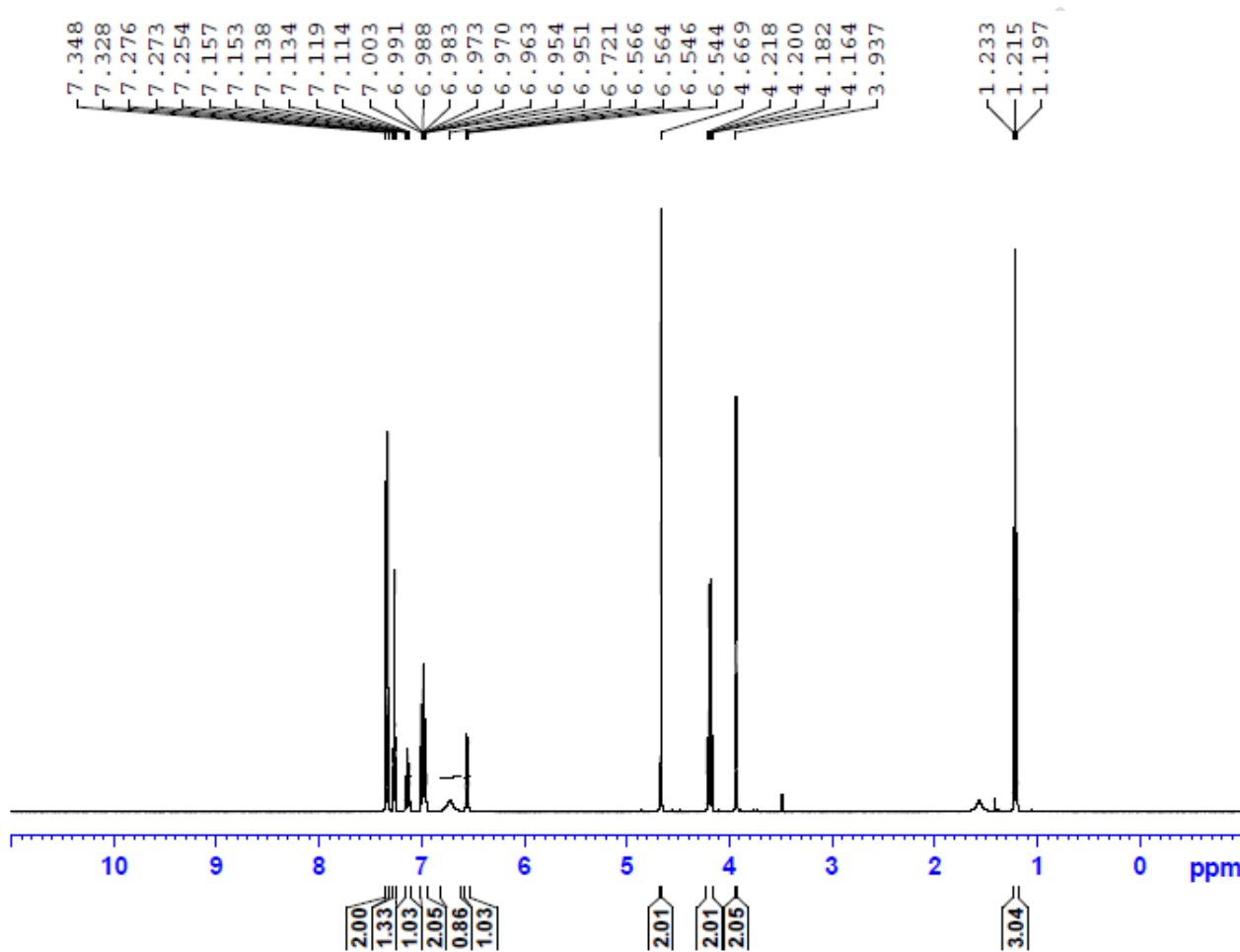
## I. Identity

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

### Ia. <sup>1</sup>H-NMR Spectrum

Conditions: BRUKER 400 MHz, DMSO-d<sub>6</sub>

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



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

Contact Company: [www.Olympusimpuritiestandard.com](http://www.Olympusimpuritiestandard.com), Mo - +91-7506256625

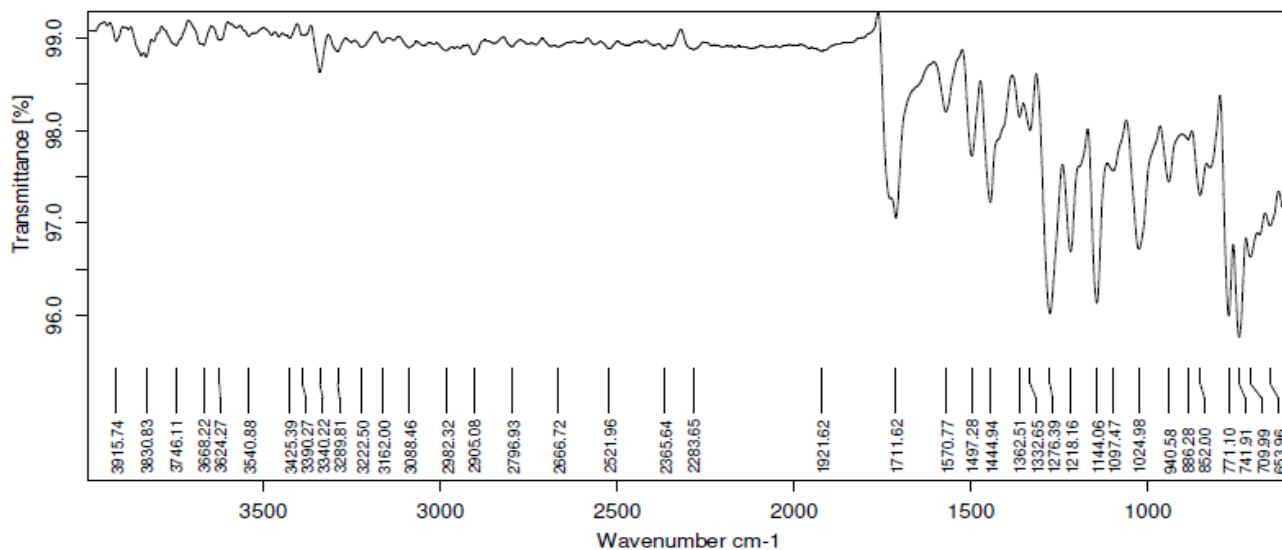
For Further Enquiries: [info@Olympusimpuritiestandard.com](mailto:info@Olympusimpuritiestandard.com)

## CERTIFICATE OF ANALYSIS

### Ib. IR Spectrum

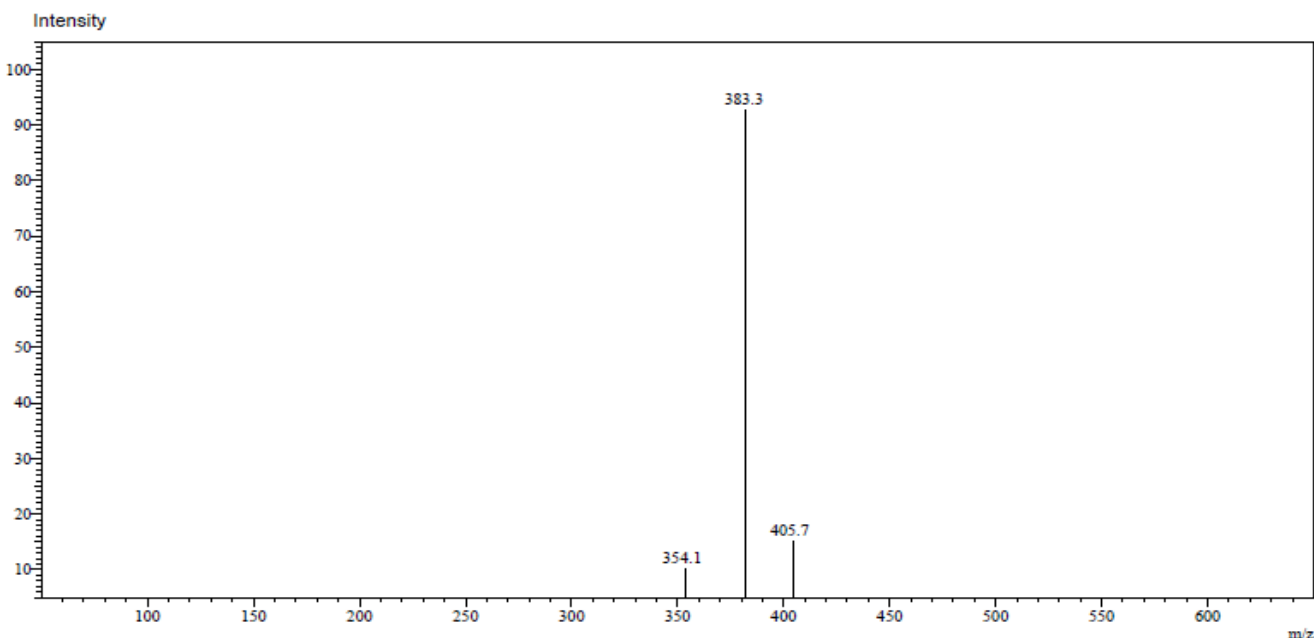
**Method:** Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy.

**Instrument:** BRUKER Model ALPHA.



### Ic. Mass Spectrum

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



The M+1 (383.3) of the mass spectrum is consistent with the Molecular Weight of the Compound 382.24 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:

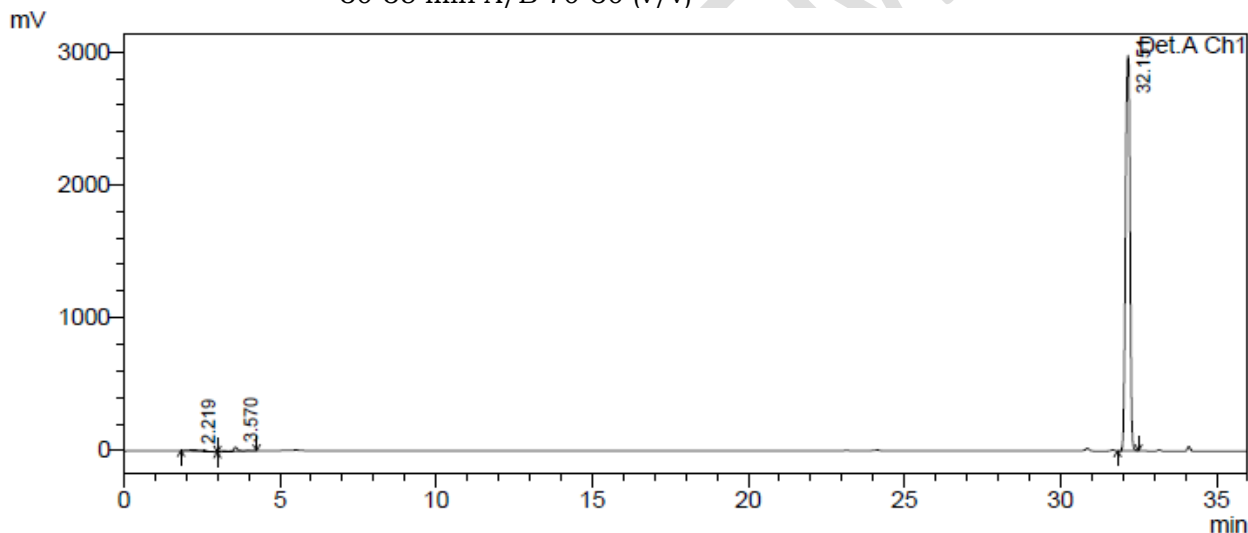
1.0 ml/min,  
0-05 min A/B 100-0  
05-15 min A/B 70-30  
15-25 min A/B 35-65  
25-30 min A/B 10-90  
30-34 min A/B 10-90  
30-35 min A/B 70-30 (v/v)

### Detector:

254nm/UV

### Injector:

Manual  
50µl



1 Det.A Ch1/254nm

PeakTable

Detector A Ch1 254nm

Peak#	Ret. Time	Area	Height	Area %	Height %
1	2.219	291092	7253	0.955	0.270
2	3.570	460460	22960	1.511	0.854
3	32.151	29721356	2657850	97.534	98.876
Total		30472908	2688063	100.000	100.000

## Results:

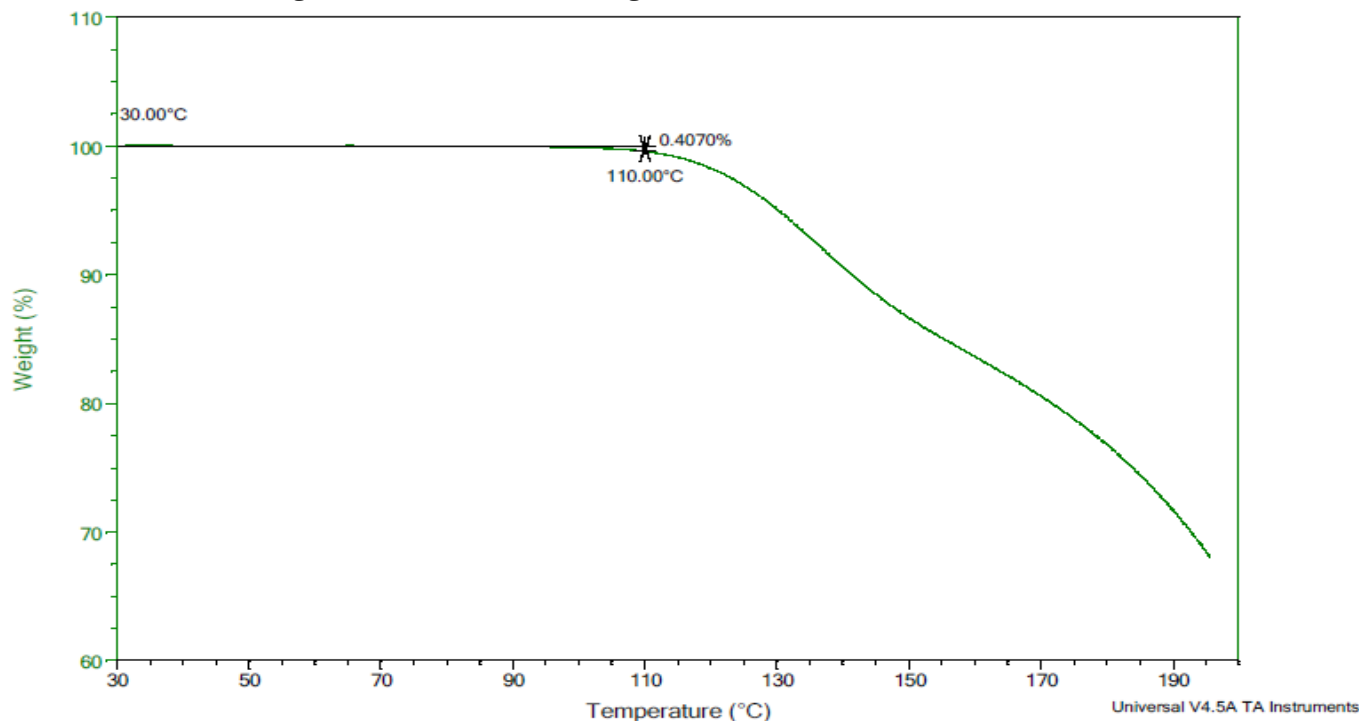
**Purity:** 97.53 %

**Method:** General

## CERTIFICATE OF ANALYSIS

### III. Water Content

**Method:** TGA Thermograms, The Percent of weight loss at 30-120°C is 0.4070%



### IV. Residual Solvents

**Method:** 1H-NMR

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

### V. Potency

%Potency = (Chromatographic purity – TGA Value) = (97.53-0.4070) = 97.12%

### VI. Final Result

Total impurities (HPLC): 0.33%

Water Content: 0.4070%

Purity by HPLC: 97.53%

Residual solvents: < 0.05 %

Potency: 97.12%

**Release Date:**

**Reviewed By**

**Dr. Ashish Keche**  
Director of QA

**Approved By**

**Ashish Keche**  
Managing Director