

## International Journal of PharmTech Research

CODEN (USA): IJPRIF, ISSN: 0974-4304, ISSN(Online): 2455-9563 Vol.10, No.4, pp 225-236, 2017

PharmTech

## Method Development, Validation and Impurity Profiling of Ticagrelor by Acid Degradation Method

Rajendra B. Kakde<sup>1</sup>\*, Dinesh D Satone<sup>2</sup>, Geyata Dongare<sup>1</sup>, Rahul Chilbule<sup>1</sup>, Yogesh Malkhede<sup>1</sup>

<sup>1</sup>Department of Pharmaceutical Sciences Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur-33, Maharashtra, India.

<sup>2</sup>Analytical Development Division, Orbicular Pharmaceutical Technologies Pvt Ltd, Hyderabad-500072, India

**Abstract :** A simple method is developed for impurity profiling of Ticagrelor by High Performance liquid Chromatography. Forced degradation under acidic condition were carried out. Only one degradant has been found. Cosmocil  $C_{18}$  (250 x 4.6 mm i.d., 5  $\mu$ ) column with mobile phase composed of 0.1% Formic acid:ACN in the ratio of 55:45% v/v at flow rate 1.0 mL/min was shown sharp peak and good resolution between drug and its degradant. The detection wavelength was used at 254nm. Acid degradant was isolated by prep-HPLC by using Thermo (100 x 10mm i.d., 5 $\mu$ ) Hypersil Gold semi-preparative column at flow rate 4.0 mL/min. The complete spectral analysis IR, <sup>1</sup>H NMR, <sup>13</sup>C NMR and LC-MS confirmed the chemical structure of impurity.

**Keywords :** Ticagrelor, Method Development, Validation, Isolation and Characterization of Unknown Impurity.

Rajendra B. Kakde et al /International Journal of PharmTech Research, 2017,10(4): 225-236.

International Journal of PharmTech Research, Vol.10, No.4, pp 225-237,(2017)

http://dx.doi.org/10.20902/IJPTR.2017.10429

\*\*\*\*\*