



ChemTech

## International Journal of ChemTech Research

CODEN (USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555  
Vol.11 No.02, pp 176-186, 2018

# A Novel LC-MS/MS Method for Simultaneous Determination of Ivabradine and its Active Metabolite N-Desmethyl Ivabradine in Human Plasma: Its Pharmacokinetic Application

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**Abstract** : The method was new simple, rapid, sensitive and simultaneous liquid chromatography/tandem mass spectrometry assay method for the determination of Ivabradine and N-Desmethyl Ivabradine in human plasma using Ivabradine-d<sub>6</sub> and N-Desmethyl Ivabradine-d<sub>6</sub> as internal standards (IS). Analyte and the internal standards were extracted from the human plasma *via* Solid phase extraction (SPE) using Strata™ X 33μM polymeric sorbent cartridges (1cc/30mg). The chromatographic separation was achieved on a Kromasil 100-5 C<sub>18</sub>, 100 x 4.6 mm, 5 μm columns by using a gradient programme at a flow rate of 0.60 mL/min with a total runtime of 3.0 min and the elution was monitored by multiple reaction monitoring modes using electrospray ionization. The calibration curve obtained was linear ( $r^2 \geq 0.99$ ) over the concentration range of 0.20–201 ng/mL for Ivabradine and 0.10–15.14 for N-Desmethyl Ivabradine. Method validation was performed as per FDA guidelines and the results met the within the acceptable limits. The proposed method was found to be applicable to pharmacokinetic studies.

**Keywords** : Ivabradine, N-Desmethyl Ivabradine, Solid Phase Extraction, LC-MS/MS, Validation, Human plasma, Pharmacokinetics.

Vasu Babu Ravi *et al* /International Journal of ChemTech Research, 2018,11(02): 176-186.

DOI= <http://dx.doi.org/10.20902/IJCTR.2018.110222>

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