J Anal Bioanal Techniques 2012, 3:7
http://dx.doi.org/10.4172/2155-9872.S1.010

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference and Exhibition on
Analytical & Bioanalytical Techniques

November 22-24, 2012 Hyderabad International Convention Centre, India

Development and validation of mass spectrometry method for estimation of Memantine in human plasma

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Introduction: Memantine Hydrochloride, 1-amino-3, 5 dimethyladamantane hydrochloride, is an adamantine derivative administered orally for many neurologic disorders, including Alzheimer's disease. A novel high performance liquid chromatography positive ion electrospray ionization tandem mass spectrometry method was developed and validated for the quantification of Memantine in human plasma.

Method: The analyte in the plasma sample was extracted using liquid-liquid extraction. The analyte was separated using an isocratic mobile phase on a reverse phase column to meet the demands of the clinical laboratory for speed of analysis and chromatographic resolution. Detection was carried out by MS/MS in the multiple reaction monitoring mode using the respective $(M+H)^+$ ions, m/z 179.9→162.9 and 151.8 → 134.8 for analyte and the internal standard respectively. The developed method was validated as per the US FDA guidelines for bioanalytical method validation (May2001).

Results: The assay exhibited a linear dynamic range of 0.2-46 ng/ml for Memantine in human plasma. The lower limit of quantification was 0.2 ng/ml with a relative standard deviation of less than 10.7%. No interference by endogenous substances or matrix effect was observed. The intra-day and inter-day accuracy and precision (%CV) values were in the range of 94.8-104.4% (3.7 – 11.2%) and 93.2-97.4% (3.8-10.5%) respectively. The spiked plasma samples were found to be stable at ambient temperature for 4 hrs, after long-term storage at -80°C for 90 days, and after 3 freeze-thaw cycles. The processed plasma samples were found to be stable in autosampler for 24hrs at 5°C. A very short run time (1.5min) for each sample made it a high throughput method for estimation of clinical samples. Thus the developed and validated method for estimation of Memantine in human plasma could be successfully used to evaluate plasma concentration profiles in human subjects.

Simultaneous spectrophotometric determination of sitagliptin and metformin in pharmaceutical dosage form

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Simple, precise and economical spectroscopic improved method has been developed for the simultaneous estimation of Sitagliptin phosphate and Metformin hydrochloride in bulk and pharmaceutical dosage form. Method is based on measurement of absorption at maximum wavelength of 266 nm and 232 nm for Sitagliptin phosphate and Metformin hydrochloride respectively. Linearity for detector response was observed in the concentration range of 5-25µg/ml for Sitagliptin phosphate and 8-40µg/ml for Metformin hydrochloride. The accuracy of the methods was assessed by recovery studies and was found to be 99.68±0.91 % and 98.84±0.94 for Sitagliptin phosphate and Metformin hydrochloride. The developed method was validated with respect to linearity, accuracy (recovery), precision and specificity. The proposed methods were successfully applied for the determination of sitagliptin and metformin in pharmaceutical dosage Form.

Biography

Shaik Sharfuddin is a student of JSS College of Pharmacy, JSS University, Mysore. He has completed his B. Pharm from Azad College of Pharmacy, Moinabad, Ranga Reddy,A.P. Presently he is pursuing M.Pharm Degree in the branch of Pharmaceutical analysis. His current area of research is on simultaneous determination of some combinational dosage form.

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