SRDHS
SOCIETY FOR RESEARCH DEVELOPMENT IN HEALTH SCIENCE

Society for Research Development in Health Sciences (RDHS),
Sponsored

2nd International Conference

Organized By
Ambe Durga Education Society's
Dadasaheb Balpande College of Pharmacy
(Degree and Diploma),
Near Swami Samarth Dham Mandir, Besa,
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Theme:
"Invigorating Research in Pharmaceuticals: Reasonable Industrial Approach"

Venue: Hotel RE-GEN-TA, CENTRAL Nagpur. Jagnade Square, Nandanvan, Nagpur, Maharashtra, India.

Souvenir and Abstract Book

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FORMULATION AND EVALUATION OF FLUVASTATIN SUSTAINED RELEASE TABLET

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ABSTRACT

Sustained and controlled drug delivery systems significantly improve therapeutic efficiency of drugs. Drug-release-retarding polymers are the key performers in such system. To evaluate a combined Hydrophilic – Hydrophobic matrix system for sustaining the drug release of Fluvastatin.To study the effects of the following variables on the characteristics of Fluvastatin sustained release matrix tablets. Drug excipients compatibility testing was performed by mixing drug with polymer in equal proportion then, mixture was kept under accelerated stability condition (i.e. 40°C and 75±5% RH) for a period of 21 days in a glass vial. It was hermetically sealed with rubber stopper using molten carnauba wax. IR spectrum was noted for mixture after 21 days. More concentrated polymer in the formulation resulted in slow release rate. Formulations F3, F8 and F1 release the total drug in upto 10 hours while formulation F2, F5, F7 and F9 showed the sustained release of the drug, but as release rate was very low the whole amount of drug was not released. Formulation F6 releases the drug in 12 hours. The formulation F6 shows significant behavior pattern compared with other formulations. Stability studies at temperature 40°C/75% RH for 60,120 and 180 days on optimized batch showed no significant effect on physical properties, drug content, swelling behavior and drug release.

Keywords Sustain release tablet, Fluvastatin, matrix system

A NEW STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF SITAGLIPTIN AND ERTUGLIFLOZIN IN BULK AND TABLET DOSAGE FORM

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ABSTRACT

A new stability indicating High performance liquid chromatographic (RP-HPLC) method was developed for the simultaneous estimation of Sitagliptin (STG) and Ertugliflozin (ERTU) in bulk and tablet dosage form. The separation was achieved by using C18 column (Fortis, 4.6x100 mm and 2.5µm particle size) with mobile phase Methanol:0.1% OPA (75:25 v/v), retention time of Sitagliptin and Ertugliflozin were found to be 3.0 and 6.4 min respectively. A gradient programing has been done with flow rate 0.8ml/min. The common wavelength of absorption of Sitagliptin and Ertugliflozin was found to be 215.0nm. The proposed method was validated in terms of Linearity, Accuracy, Precision, Ruggedness, Robustness and Stability studies. The developed method exhibited good linearity concentration range 66-330µg/ml for Sitagliptin (STG) and 10-50µg/ml for Ertugliflozin (ERTU) respectively with linear regression coefficient (r2= 0.999). The stability studies were performed as per ICH guidelines under the acidic, alkali, oxidative and neutral conditions for different times. The developed RP-HPLC method was found to be linear over wider concentration range and therefore the developed RP-HPLC method can be applied for routine qualitative and quantitative analysis of Sitagliptin and Ertugliflozin in bulk and tablet dosage form and validated as per the ICH guidelines. Hence the proposed method could be employed for the stability studies on pharmaceutical preparation within pharmaceutical industry.

Keywords RP-HPLC, Sitagliptin (STG), Ertugliflozin (ERTU), Orthophosphoric acid (OPA), Stability study.