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RESEARCH ARTICLE

A REVIEW ON DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF COMBINATION OF DRUGS

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ABSTRACT

This article provides information about the work done for the method development and validation of combination of drugs like (Tiotropium Bromide and Salmeterol xinafoate), (Clarithromycin and Paracetamol), (Montelukast sodium and Fexofenadine hydrochloride) used in the pharmaceutical dosage forms. Similarlythe above work can also be done for herbal extracts like (*Camellia sinensis, Phyllanthus emblica, Myristicamalabarica, Piper betle, Picrorhizakurroa)* andthe results were recorded for different validation parameters such as Accuracy, Precision, Linearity, Robustness, Ruggedness, Retention time, % recovery, Limit of Detection(LOD), Limit of Quantification(LOQ) and Sensitivity by RP-HPLC method under suitable conditions like the type of column, pH, flow rate, mobile phase, and the detectors used.

Key words:Validation parameters, combined drugs.

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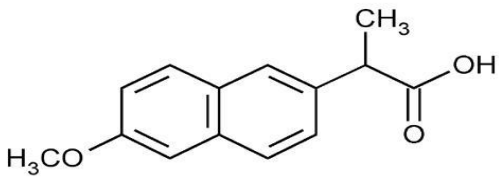
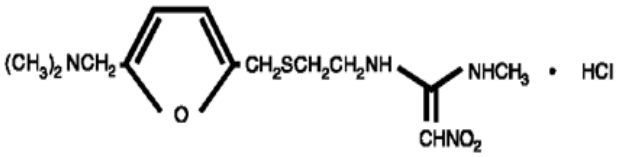
INTRODUCTION

Naproxen (2S)-2-(6-methoxynaphthalen-2-yl)propanoic acid is a Nonsteroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. It's mechanism of action is cyclo-oxygenase inhibitor which works by reducing hormones that cause inflammation and pain in the body. Naproxen is used to treat pain or inflammation caused by conditions such as arthritis, ankylosing spondylitis, tendinitis, bursitis, gout, menstrual cramps.



Ranitidine Hydrochloride (E)-1-N^1-[2-[[5-[(dimethylamino)methyl]furan-2-yl]methylsulfanyl]ethyl]-1-N-methyl-2-nitroethene-1, 1-diamine; hydrochlorideis a member of the class of Histamine H_2- receptor antagonists with antacid activity. Ranitidine is a competitive and reversible inhibitor of the action of histamine, released by enterochromaffin- like (ECL) cells, at the histamine H_2-receptors on parietal cells in the stomach, thereby inhibiting normal and meal-stimulated secretion of stomach acid.



Principle of RP-HPLC: The Principle involved in High Performance Liquid Chromatography (HPLC) testing is the separation of compounds in a mixture more efficiently and also quickly than that of traditional column chromatography. Segregation of compounds is due to their relative differences in travel through the column on the application of pressure exerted through the mobile phase or carrying liquid. The compounds of the mixture travel at different rates due to their relative affinities with the solvent and stationary phase either by isocratic elution or high pressure gradient mode of elution.A non-polar stationary phase like n-octadecyl, n-octyl, ethyl, phenyl diol, cyano propyl, hydrophobic polymers and polar mobile phase such as acetonitrile, methanol, phosphate buffer, Tetra hydro furan. Compound with a higher affinity towards the stationary phase of the column moves slowly and vice-versa. The above principle is similar to that of column chromatography but in HPLC, the separation is more efficient due to greater surface area achieved due to a tiny particle size of stationary phase in comparison to that used in column chromatography. The decrease in particle size has a greater disadvantage that it proportionately enhances the flow time and run time due to increased surface area.

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HPLC INSTRUMENTATION:

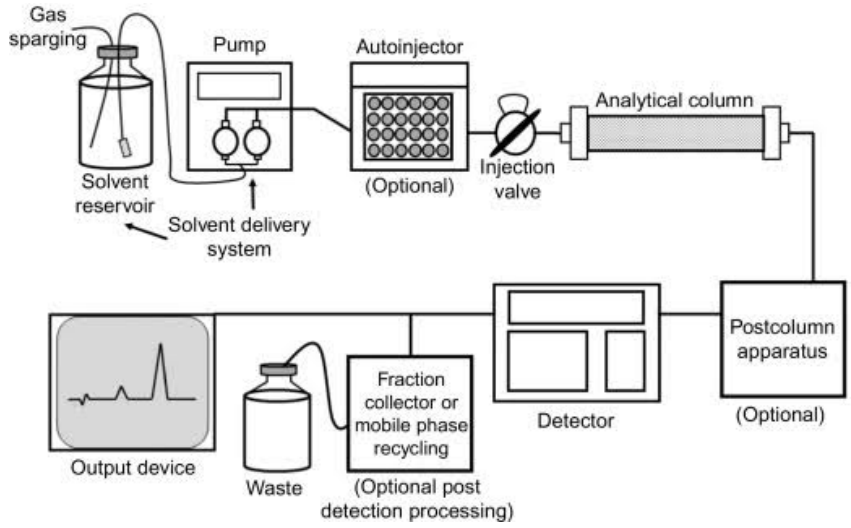

Table. No: 1.Discussion on different parameters by using Rp-HPLC method for combined dosage forms

Parameters	Naproxen and Ranitidine hydrochloride	Tiotropium Bromide and Salmeterol Xinafoate	Clarithromycin and Paracetamol	Montelukast Sodium and Fexofenadine Hydrochloride
Column	TM RP 18	Kromosil C_{18}	Kromosil C_{18} ODS	Hypersil ODS-C18
Mobile phase	0.1M Orthophosphoric acid: Methanol(35:65)	Buffer: Acetonitrile: Methanol(55:35:10)	Phosphate buffer: Acetonitrile(50:50)	Methanol: acetonitrile : 1% Trifluoroacetic acid(80:10:10)
pH	3.1	-	3.2	3.3-3.7
Flow rate	1.00ml/min	1.5ml/min	1.0ml/min	1ml/min
Retention Time	12.39min; 2.36min	1.214±0.01min; 5.101±0.02min	2.21min3.72min	5.1min; 3.7 min
Detector	UV detector	UV detector	UV detector	UV detector
Detection wavelength	240nm	235nm	205nm	210nm
Column oven temperature	-	50°c	25°c	23-27°c
Limit of Detection	0.77; 0.31	0.01; 0.100	5.230µg/ml; 5.232µg/ml	0.000265; 0.000177
Limit of Quantification	2.57; 1.04	0.02; 0.200	15.849µg/ml; 15.855µg/ml	0.000785; 0.000517
Linearity	5-35µg/ml; 1.5-12µg/ml	0.447-6.705µg/ml; 0.07-1.081µg/ml	75-175µg/ml 75-175µg/ml	2.5-15; 30-180
Coefficient correlation	-	0.99-1.0	-	0.998; 0.999

To minimize this obstacle, the high pressure is applied to the flow of HPLC mobile phase through the column by use of pumps such as reciprocating pumps, pneumatic pumps, screw driven syringe pumps. Sample injection systems like septum injector, stop flow injector, rheodyne injectors.

High Performance Liquid Chromatography (HPLC) instrumentation: High Performance Liquid Chromatography is a separation technique that involves injection of a mall volume of liquid sample into a tube packed with tiny particles (3-5µm) in diameter called stationary phase where individual components of the sample are moved down the packed column with a liquid (mobile phase) forced through the column by high pressure delivered by a pump. These components are separated from one another by the column packing that involves various chemical and\or physical interactions between the molecules and the packing materials. These separated components are detected at the exit of the tube(column) by flow through device(detector) that measures their amount.

Conclusion

By comparing the above standard parameters we have concluded that the validation procedure was an integral part of the analytical method development.The validated RP-HPLC method employed here has proved to be advantageous over the other HPLC methods due to fast analysis and simpler composition of mobile phase.

This method was accurate, precise, and robust, thus it can be used for routine analysis of otherdrug combinations. The above work was done for the combination of drugs like Naproxen and Ranitidine hydrochloride, Tiotropium Bromide and Salmeterol Xinafoate, Clarithromycin and Paracetamol, Montelukast Sodium and Fexofenadine Hydrochloride by RP-HPLC and it can be taken as a reference method for developing and validating the parameters for herbal drugs like *Isatisindigotica* root, *Terminalia bellirica, Diosgenein, Asteracanthalongifolia* and also for combined herbal dosage forms.

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