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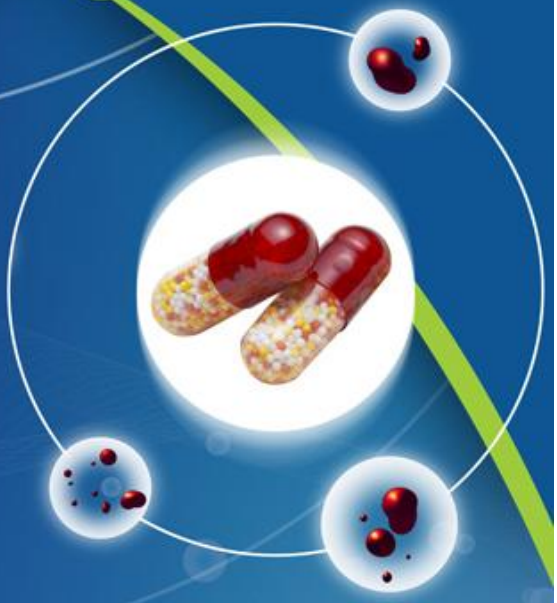

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Research Article

MULTICOMPONENT SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS QUANTITATION OF RANITIDINE HYDROCHLORIDE, DOMPERIDONE AND MAGALDRATE IN TABLETS

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ABSTRACT:

A fast simple precise multicomponent analytical method has been proposed for simultaneous estimation of Ranitidine hydrochloride, Domperidone and Magaldrate in tablet dosage form. Multicomponent analytical method uses inbuilt software of Spectrophotometer for measuring the absorbances at various wavelength intervals, processing and storing the data. The mixed standard and sample solutions were prepared in mixture of dilute HCl and water and scanned in the range of 200-400 nm. The absorbances were measured at four different wavelengths like 220 nm, 280 nm, 340 nm and 400 nm and concentration of each analyte was self-determined by instrument. Ranitidine hydrochloride, Domperidone and Magaldrate were found to be in the range of 99.4 - 101%, 98.8 - 100.74% and 102.2 - 103.5% respectively in the tablet dosage form. The method was validated in accordance with ICH guidelines and the results were found within the limits.

Key Words: - *Ranitidine hydrochloride (RH), Domperidone (DM), Magaldrate (MG), Multicomponent analysis.*

INTRODUCTION:

Antacids[1] are very commonly prescribed formulation as a consequence of our regular fancy lifestyle. For better and faster action, market is flooded with various combinations of antacids. Fixed dose combination containing H_2 receptor blocker, D_2 blocker and acid neutraliser gives a synergistic effect and leads to faster relief from acidity. Ranitidine hydrochloride[2] (RH) chemically 1, 1-ethenediamine-N-[2[[5 (dimethylamino) methyl]-2-furanyl] thio ethyl]-N-methyl-2-nitro mono hydrochloride, is a type of H_2 blocker where it blocks the H_2 receptors in stomach and hence decreases the release of excess acids.

Domperidone[3] (DM) is white or almost white powder, chemically it is 5-chloro-1-[1-[3-(2,3-dihydro-2-oxo-1H-benzimidazole-1yl) propyl-4-piperidinyl]-1,3-dihydro-2H-benzimidazole-2-one acts by blocking the D_2 receptors which triggers the CTZ, mainly responsible for vomiting.

Magaldrate[4] (MG) is a mixture of Aluminium and Magnesium hydroxide which works by neutralising the excess acid of the stomach

For routine analytical purpose, there is a necessity to establish methods capable of analyzing large number of samples in a short time period with accuracy and precision.

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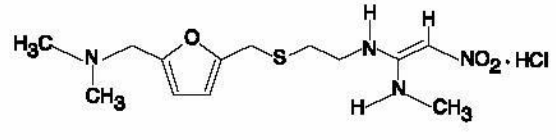
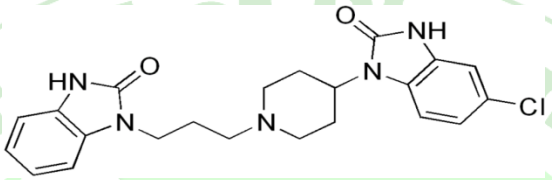
Literature survey cites many methods for determination of RH, DM and MG individually or in combination of drugs. There is no Spectrophotometric analysis method has been reported for the simultaneous estimation of the drugs RH, DM and MG. So an attempt has been made to develop accurate, precise, fast and economical multicomponent mode analysis method for estimation of above drugs.



Chemical structure of Ranitidine hydrochloride



Chemical structure of Domperidone

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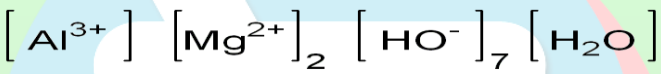


Chemical formula of Magaldrate

Material and Method

Instrument-

A Shimadzu UV- Visible double beam spectrophotometer model 1700 (Japan) with 1 cm matched quartz cells connected to a PC computer running UV-Probe 2.3.4 software for absorbance measurements and treatment of data was used along with Sartorius digital balance Acculab ALC 210.10 for weighing.

Material

Standard gift samples of RH and DM were procured from Allied Chemicals and Pharmaceuticals Pvt. Ltd, New Delhi and MG was provided by SPI Pharma, Bangalore in the form of gift sample.

Pretreatment of Drug Sample- Magaldrate is hygroscopic in nature. So before carrying out the experiment MG was kept inside the hot air oven at 70˚ C for 15 min then cool in the room temperature and kept in the desiccator.

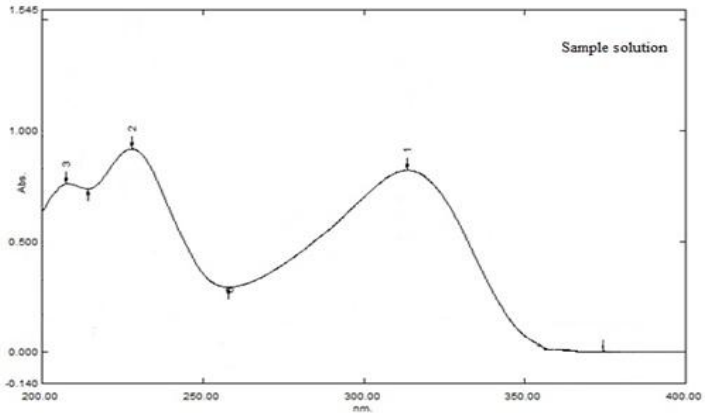
Preparation of mixed Standard stock Solution

All drugs were dried in the hot air oven at 70˚C for 15 min and cooled in the desiccator. Accurately weighed quantity 225 mg, 15 mg and 300 mg of RH, DM and MG were transferred in 50 mL volumetric flask respectively. The analytes were dissolved by sonicating in 3 mL of dilute HCl and volume was made up with distilled water. The stock solution was further diluted to get the concentration of 45:0.3:6, 9:0.6:12, 13.5:0.9:18, 18:1.2:24, 22.5:1.5:30 and 27:1.8:36 µg/mL of RH, DM and MG respectively.

Analysis of commercial formulation

Twenty tablets were accurately weighed and crushed to fine powder. The tablet powder equivalent to 225 mg, 15 mg and 300 mg of RH, DM and MG were transferred in 50 mL volumetric flask respectively, dissolved by adding 3 mL of dilute HCl with sonication and finally make up to mark with distilled water. The solution was further diluted to attend the concentrations ranging from 45:0.3:6, 9:0.6:12, 13.5:0.9:18, 18:1.2:24, 22.5:1.5:30

and 27:1.8:36 µg/mL. The sample solution was scanned at medium speed in multi-component mode in the range of 200-400 nm with wavelength interval (Δλ) of 60 nm. The absorbance values were recorded and processed by inbuilt software. Further the standard solution was scanned in the same way and the concentration of each component was estimated by analysis of spectral data of sample solution with respect to that of mixed standards by the instrument.

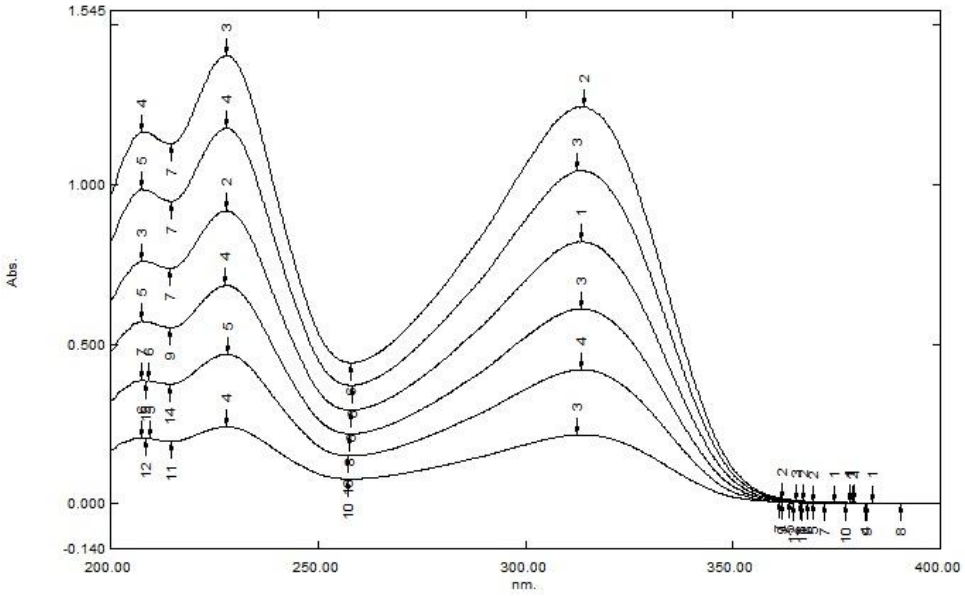


Spectrum of Sample solution

Preparation of Calibration curve

Solution of 45 µg/mL of RH, 3 µg/mL of DM and 60 µg/mL of MG were prepared separately. All the prepared solutions were scanned from the range of 200nm to 400nm. The maximum absorbance was observed at 227.8nm and 314nm respectively.

The linearity showed from 4.5µg/mL to 27µg/mL and 0.3µg/mL to 1.8µg/mL and 6µg/mL to 36µg/mL of RH, DM and MG respectively.



The overlain spectra of RH, DM and MG

Six different concentrations standard solutions were prepared and scanned from 200nm to 400nm. The wavelengths were selected 220nm, 280nm, 340nm and 400nm. The sampling wavelengths were selected by trial and error basis. The entire six solutions were scanned in the range of 200nm to 400nm. The mixed standard solutions of the combination of the drugs scanned on the entire selected wavelength to study the range of Beer's Lambert range.

Results and Discussion

The new method has developed for estimation of RH, DM and MG by Multicomponent analysis method. The scanning range 200nm to 400nm selected on the basis of the drugs. 220nm, 280nm, 340nm, 400nm are the sampling wavelength which are selected on the trial and error basis.

The linearity range was found 4.5 µg/mL to 27 µg/mL for RH, 0.3 µg/mL to1.8 µg/mL for DM and 6 µg/mL to 36 µg/mL for MG respectively which obeys the Beer Lambert's range.

The percentage assay of the drug in laboratory mixture with± S.D. was found to be 100.5±0.65, 100±0.74 and103±0.5 for RH, DM and MG respectively. The percentage assay of drug in marketed formulation± S.D. was found to be 100±0.60, 99.5±0.70 and 102.7±0.50 for RH, DM and MG respectively.

The accuracy of the proposed developed method was evaluated by the percentage recovery of drugs by standard addition method. The average recovery found to be100.5%, 99.99% and 103% for RH, DM and MG respectively. The obtained results lie in between the prescribed limit of 99 to 103%, showing the method is free from the interference of excipients.

Conclusion

The obtained results for the Multicomponent mode method for the simultaneous estimation of RH, DM and MG indicate the accuracy and reproducibility of the new developed method and hence can be conveniently adopted for the routine quality control analysis from its pharmaceutical formulations and bulk drug.

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