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A novel analytical method development and validation of estimation of meclizine HCL by UV spectroscopic method

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Abstract
A new simple, accurate, rapid, precise, reproducible and cost-effective spectrophotometric method for the quantitative estimation of Meclizine Hcl. The developed UV spectrophotometric method for the quantitative estimation of meclizine HCl is based on measurement of absorption at maxima wavelength 232nm using Methanol: DMF (40:60). The standard and sample solution were prepared by using Methanol: DMF as a solvent. Quantitative determination of the drug was performed at wavelength range 228-234nm.The linearity was established over the concentration range 5, 10, 15, 20, 25, µg/ml for the meclizine HC l with correlation coefficient value of 0.999 Precision studies showed that 1% relative standard deviation was within range of acceptable limits. The mean percentage recovery was found to be 98.9%. The proposed method has been validated as per ICH guidelines.

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Keywords: Meclizine HCl, UV visible spectrophotometer, Method development, Validation, Accuracy, Precision

Introduction

MECLIZINE (RS)-1-[(4-Chlorophenyl) (phenyl) methyl]-4-(3-methylbenzyl) piperazine Vomiting is a centrally regulated reflex mechanism that initiates from the vomiting center and the chemoreceptor trigger zone (CTZ) located in the medulla. Motion sickness is also regulated by CTZ. The blood-brain barrier near the CTZ is relatively permeable to circulating mediators and CTZ can transmit impulses to vomiting centre located in the brainstem. Different receptors responding to different factors, including histamine, 5-HT, enkephalins, substance P, and dopamine, are expressed along the brainstem to activate respective pathways and contribute to the control of vomiting. Histamine H1 receptors are expressed on the vestibular nuclei and nucleus of the solitary tract (NTS) that are activated by motion sickness and stimuli from the pharynx and stomach. When activated, H1 receptor signalling from these nuclei is transmitted to the CTZ and vomiting centre.

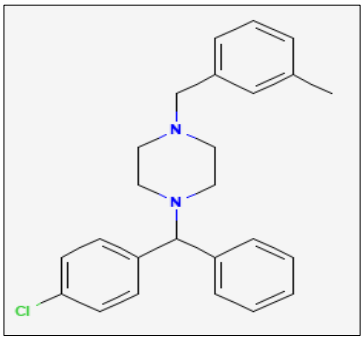

Fig 1: Structure of Meclizine

Through its antagonistic action on the H1 receptors, meclizine primarily works by inhibiting signalling pathway transduction through histaminergic neurotransmission from the vestibular nuclei and NTS to the CTZ and medullary vomiting center. Meclizine may also decrease the labyrinth excitability and vestibular stimulation.

Materials and Methods

Chemical and Reagents: -Methanol: DMF (40:60)
Instrument: SHIMADZ UV 1601UV -VIS Spectrophotometer, Electronic Balance (CITIZEN BALANCE BL-220H), Ultra Sonicator (ANALYTICAL), and P^H Analyzer (INFRA DIGI IR 501), Distillation Unit (BOROSIL), Vacuum filtration unit (BOROSIL).

Reagents and solutions

Diluent preparation: In 10ml Volumetric flask take 40:60 Methanol: Dmf

Preparation of Sample Solutions:

Take 20 Tablets average weight and crush in mortar in a mortar by using pestle and weight powder 100 mg equivalent weight of meclizine sample into a 100ml equivalent weight of meclizine sample in to a sample in to a 100 ml clean dry volumetric flask, dissolve and make up to volume with diluent. Further dilution was done by transferring 0.1ml of the above solution in to a 10ml volumetric flask and make up to volume with diluent.

Determination of wavelength of maxima absorbance of Meclizine

The Determination of wavelength of maximum absorbance for Meclizine. The absorbance of the final solution scanned in the UV spectrum in the range of 220-234 against solvent mixture as blank.

Optimization of selection of Solvent

It is well known that the solvents do exerts a profound effect on the quality and the shape of the peak. The choices of solvents for UV method development are: Methanol, Ethanol, Dmf, DMSO etc. First optimize the different solvents. From that solvents Methanol: DMF combination satisfied the all the optimized conditions.

Wavelength Selection

The standard solutions are preparing by transferring the standard drug in a selected solvent or mixture of solvent and finally diluting with the same solvent or diluent. That prepared solution is scanned in the visible wavelength range of 220-234nm.This has been performed to know the maxima of Sofosbuvir. While scanning the Sofosbuvir solution we observed the maxima at 230 nm. The visible spectrum has been recorded on (SHIMADZU UV-1601) make UV–Vis spectrophotometer model UV-1601.The scanned visible spectrum is attached in the following page. The λmax of the Sofosbuvir was found to be 230nm in diluents as solvent system.

Method Validation

Accuracy

Recovery study: To determine the accuracy of the proposed method, recovery studies were carried out by adding different amounts (75%, 100%, and 125%) of pure drug of Meclizine Hcl were taken and added to the pre-analysed formulation of concentration 10µg/ml. From that percentage recovery values were calculated. The results were shown in Table-1.

Precision

Repeatability: The Precision of each was method ascertained separately. From the peak areas & retention times obtained by actual determination of six replicates of a fixed amount of drug. Meclizine (API) the percent relative standard deviations were calculated of Meclizine revealed that the proposed method is precise. The results were shown in Table-2.

Intermediate Precision

Inter-assay& inter-assay

The intra & inter day variation of the method was carried out & the high values of mean assay & low values of standard deviation & % RSD (% RSD < 2%) within a day & day to day variations for Sofosbuvir revealed that the proposed method is precise. The results were shown in Table-3.

Linearity & Range

The calibration curve showed good linearity in the range of 5-25µg/ml, for Meclizine HCl (API) with correlation coefficient (R^2) of 0.999. A typical calibration curve has the regression equation of y = 0.0743x - 0.0052 for Meclizine HCl.

Standard solutions of Meclizine in the concentration range of 5 µg/ml to 25 µg/ml were obtained by transferring (5,10,15,20 and 25 ml) of Meclizine Hcl stock solution (100ppm) to the series of clean & dry 10 ml volumetric flasks. The volumes in each volumetric flask were made up with the solvent system and mixed.

The absorbances of the solutions were measured at 230 nm against the solvent system as blank and calibration curve is plotted. The Lambert-Beer's Law is linear in concentration range of 5 to 25 µg/ml at 230nm for Meclizine Hcl. The results were shown in Table-4.

Method Robustness

Robustness of the method was determined by carrying out the analysis under different Wavelength i.e., at 228 nm, and 232 nm. The respective absorbances of 10µg/ml were noted SD < 2%) the developed UV-Spectroscopic method for the analysis of Meclizine (API). The results were shown in Table-5.

LOD & LOQ

The LOD and LOQ were calculated by the use of the equations LOD = 3.3 × σ / S and LOQ = 10 × σ / S where σ is the standard deviation of intercept of Calibration plot and S is the average of the slope of the corresponding Calibration plot.

The Minimum concentration level at which the analyte can be reliable detected (LOD) & quantified (LOQ) were found to be 0 0.395µg/ml and1.185µg/ml Respectively.

Results and Discussion

The standard solutions of Meclizine Hcl with Methanol: Dmf (10µg/ml) subjected to a scan individually at the series of wavelength of 220-234nm. Absorption maxima of Meclizine Hcl was found to be at 230nm.Therefore, 230nm was selected $_{\lambda}$max of Meclizine for the present study. The calibration curve of Meclizine can be determined without interference of ant irrelevant substance in single component pharmaceutical products. The used technique was initially attempted on bulk

drugs in their synthetic sample and concentrations were estimated.

The % recovery was carried out at 3 levels, 75%, 100% and 125% of Meclizine Hcl standard concentration. Three samples were prepared for each recovery level. The solutions were then analyzed, and the percentage recoveries were found to be satisfactory within the acceptable limits as per the content of the label claim for marketed tablet dosage form. The newly developed method was validated according to the ICH guidelines and the method validation parameters.

The developed method was subjected to do the various method validation parameters such as specificity, accuracy, precision, linearity and range, limit of detection and limit of quantification, robustness and ruggedness etc.

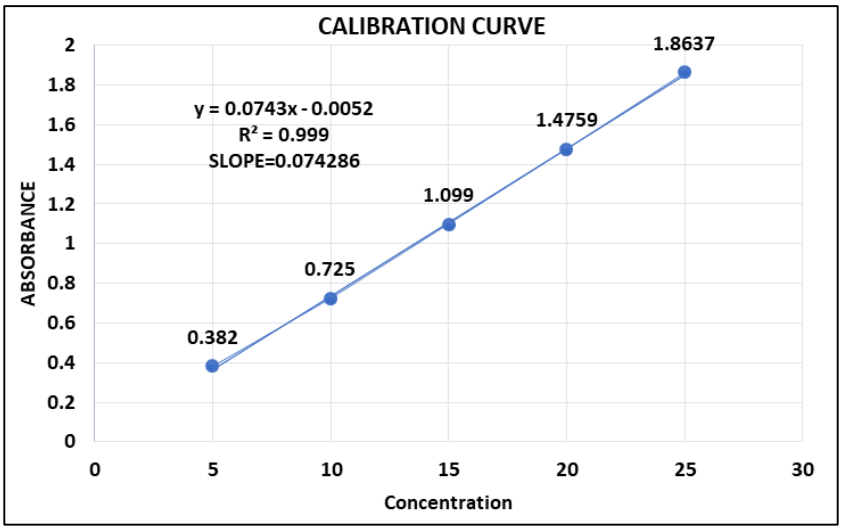

Fig 2: Calibration Curve of Meclizine Hcl

Table 1: Results of accuracy

Accuracy level	Sample conc(µg/ml)	Absorbance	amount Recovery (µg/ml)	% Recovery	Mean % Recovery
75%	7.5 µg	0.534	7.38	98.5	98.9
75%	7.5 µg	0.539	7.45	99.3	
75%	7.5 µg	0.537	7.43	99.0	
100%	10 µg	0.711	9.95	99.5	99.2
100%	10 µg	0.709	9.92	99.2	
100%	10 µg	0.704	9.87	98.7	
125%	12.5 µg	0.894	12.4	99.2	98.6
125%	12.5 µg	0.881	12.3	98.4	
125%	12.5 µg	0.887	12.3	98.4	

Acceptance criteria: correlation coefficient should not less than 0.999

Repeatability

Table 2: Results of Repeatability

S.NO	Conc(µg/ml)	Wavelength (nm)	Absorbance
1	10	230	0.714
2	10	230	0.706
3	10	230	0.719
4	10	230	0.711
5	10	230	0.723
6	10	230	0.716
Mean ± S.D.			0.714
Standard Deviation			0.005981
% RSD			0.8366

Table 3: Results of inter-Day & intra -Day

Conc. Taken (µg/ml)	Observed conc. Of Meclizine Hcl (µg/ml) by the prposed method			
	Intra day		Inter day	
	Absorbance	Statistical Analysis	Absorbance	Statistical Analysis
10	0.719	Mean=0.716	0.702	**Mean**=0.711
10	0.724	S.D = 0.008737	0.714	**S.D**=0.007937
10	0.707	%RSD=1.219	0.717	%RSD=1.1116

Table 4: Results of Linearity

S.NO	Concentration (µg/ml)	ABSORBANCE
1	5	0.382
2	10	0.725
3	15	1.099
4	20	1.475
5	25	1.863

Acceptance criteria correlation coefficient should not be less than0.999

Table 5: Result of Method Robustness

Concentration (µg/ml)	Wavelength	Absorbance	Mean= 0.708 S. D= 0.008907 %RSD= 1.258
10	228 (-2)	0.704	
10	228 (-2)	0.721	
10	232 (+2)	0.701	
10	232 (+2)	0.706	

Conclusion

From the experimental studies it can be concluded that first UV-Spectroscopic method is developed for Meclizine Hcl in marketed pharmaceutical dosage form. The developed method for the drug (Meclizine Hcl) was found to be accurate and precise.

The great features of spectrophotometric methods are their simplicity, economical and rapidity. In this method methanol and Dmf is used as diluent. The results of method validation showing that the developed analytical procedure is suitable for its intended purpose and meets the Guidelines given by the ICH.

The result shows the developed method is yet another suitable method for assay, purity which can help in the analysis of Meclizine Hcl in different formulations.

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