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Original Article

Development and Validation of Prochlorperazine Maleate in Bulk and Pharmaceutical Dosage Form by UV Spectroscopic Method

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ABSTRACT

Background: Prochlorperazine maleate is an antipsychotic and antiemetic drug that is available as tablets on the market for oral administration. The main object of this research work is to develop and validate the easiest UV spectroscopic method for the determination of Prochlorperazine maleate for tablet formulation (marketed formulation). **Materials and Methods:** A simple, reproducible and efficient method for the determination of Prochlorperazine maleate in bulk and tablet formulations have been developed. The developed method is based on the estimation by UV-Visible spectroscopy. In this method, 0.3M HCL was selected as the solvent. A Wavelength selected for estimation of Prochlorperazine maleate was 254 nm. **Results:** Linearity was found in the concentration range 2-16µg/ml (R^2=0.9909). A recovery study was found to be 98.01-99.79% for Prochlorperazine maleate. The method was found to be precise as % RSD was low in repeatability, intermediate precision, and reproducibility. LOD and LOQ were found to be 0.58 and 1.75 respectively. **Conclusion:** The method was found to be very simple, and precise. It also had a good recovery. The Developed method can be used for further routine analysis and stability study of a Prochlorperazine maleate.

Keywords: Prochlorperazine maleate, Validation, UV-Visible spectroscopy, Analytical method validation

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INTRODUCTION

Prochlorperazine maleate is a chemically phenothiazine derivates. Prochlorperazine maleate is an antipsychotic drug which acts by dopamine receptor blockade.[1-5] Prochlorperazine maleate is used in the prevention and treatment of nausea and vomiting associated with radiotherapy, chemotherapy, surgery and acute migraine.[6-12]

A review of the literature revealed that several studies involving method development and estimation of Prochlorperazine maleate have been carried out of RP-HPLC, LC-MS and UV spectrophotometers.[13-27] So it was thought of interest to develop a simple, precise, accurate and cost-effective method for estimation of Prochlorperazine maleate in bulk and tablet Formulations.

MATERIALS AND METHODS

Materials

Prochlorperazine maleate was obtained as a gift sample from Mehta pharmaceutical industry (Mumbai, India). All solvent and other chemicals used were A.R. grade. Double distilled water (fresh) was used during the work.

Preparation and Standard Solution

Standard stock solution of Prochlorperazine maleate

Accurately weighed 100mg quantity of Prochlorperazine maleate was transferred into 100ml volumetric flasks, dissolved, and diluted up to mark with 0.3M HCl to get 1000µg/ml solution for Prochlorperazine maleate. This 1000µg/ml stock solution was further diluted to obtain 100µg/ml solution for Prochlorperazine maleate.

Selection of Wavelength

The standard solution of Prochlorperazine maleate was scanned between 200-400 nm and λ_{max} for Prochlorperazine maleate was selected to 254nm.

Preparation of the Calibration Curve

The concentration range of 2,4,6,8,10,12,14,16 µg/ml of Prochlorperazine maleate was prepared from standard stock solution by taking appropriate aliquots into a series of 10ml. The absorbance of the above solution was measured at 254 nm and the calibration curve of absorbance against concentration was plotted.

Preparation of sample solution (For accuracy or recovery) for tablet formulation

The tablets of Prochlorperazine maleate were powdered and from the triturate, tablet powder equivalent to 100mg of Prochlorperazine maleate was weighed and transferred into a 100ml of the volumetric flask, dissolved, and diluted up to mark with HCl. The solution was filtered. Transferred 1ml aliquot of above solution into a 10ml volumetric flask and diluted up to mark with 0.3M HCl. From the above solution, prepare a solution containing 10µg/ml of Prochlorperazine maleate by proper dilution with 0.3M HCl.

Method Validation

Linearity

The linear response of Prochlorperazine maleate was found by analyzing the standard level of the calibration curve in the range of 2-16µg/ml.

Accurately measured standard working solutions of Prochlorperazine maleate were transferred to a series of 10ml volumetric flask and diluted up to the mark with 0.3M HCl. Absorbance was measured at a wavelength of 254nm. From the above result, it was concluded that the developed method follows the Beer's and Lambert's law in the concentration range of 2-16µg/ml.

Accuracy

The accuracy study was performed by spiking previously analyzed samples of the Prochlorperazine maleate (6µg/ml) solution with three different concentrations of the level at 80%, 100% and 120% and the absorbance of all solution were taken at 254nm and percentage recovery of Prochlorperazine maleate was calculated. The method was repeated three times.

Precision

Repeatability

Repeatability measurement was carried out by analyzing solutions containing 10µg/ml of Prochlorperazine maleate six times. Pipette out 1ml aliquot from the stock solution and transfer it to a 10ml volumetric flask. Dilute up to mark with 0.3M HCl. The absorbance of six aliquots of the same concentration was measured and % RSD was calculated.

Intraday Precision

The intraday precision was determined for the standard solution of Prochlorperazine maleate (10µg/ml) three times on the same day. The results were reported in terms of % RSD and it should be less than 2%.

Interday precision

The interday precision was analyzed for the standard solution of Prochlorperazine maleate (10µg/ml) three times on different days. The % RSD was calculated.

Reproducibility

Reproducibility was performed by preparing the standard solution of Prochlorperazine maleate (10µg/ml) and analyzing them by the different analysts.

The limit of detection (LOD) and Limit of Quantification (LOQ)

The limit of detection and the limit of quantification was measured according to the ICH guideline. It was measured by the following equation.

$$LOD = 3.3\ \sigma/S$$

$$LOQ = 10\ \sigma/S$$

Where, σ = the standard deviation of response

S = the slop of the calibration curve

Assay

Prochlorperazine maleate was finely powdered and powdered equivalent to 5mg of Prochlorperazine maleate was dissolved in 0.3M HCl and then sonicated for 5 min. Further dilution was carried out to obtain a 10µg/ml concentration of Prochlorperazine maleate. The % drug content was calculated.

RESULTS

Melting Point

The point of Prochlorperazine maleate was found to be 206-209(°C). The melting point of the drug sample corresponds to the reported melting range, indicating the authenticity of the drug sample.

Wavelength selection

UV spectra Prochlorperazine maleate was taken in 0.3M HCL (Table 1) and λ_{max} was observed at 254nm. Hence λ_{max} for Prochlorperazine maleate was found to be 254nm.

Linearity and Range

The Linearity graph of Prochlorperazine maleate is shown in Figure 1,2. Calibration graph at 254 nm is shown in Figure 3 as per Table 2. The linearity range of Prochlorperazine maleate was found to be 2 to 16µg/ml. The linearity equation was found to be y = 0.0514x –0.0231. The Correlation coefficient for PCM was 0.9909 which indicates the purposed method is linear.

Precision

Repeatability

Data of Repeatability is given in Table 3 % RSD was found to be 0.612% which indicates the purposed method is precise.

Table 1: Trial and Error of Solvents.

Selection of Solvent	Inference
Methanol	Insoluble
Acetone	Insoluble
NaOH	Insoluble
Water	Slightly soluble
Ammonium acetate 0.1M HCL	Insoluble
0.2M HCL	Spectrum was not proper
	Spectrum was obtained but not precise (wavelength 257nm)
0.3M HCL	Proper spectra was observed

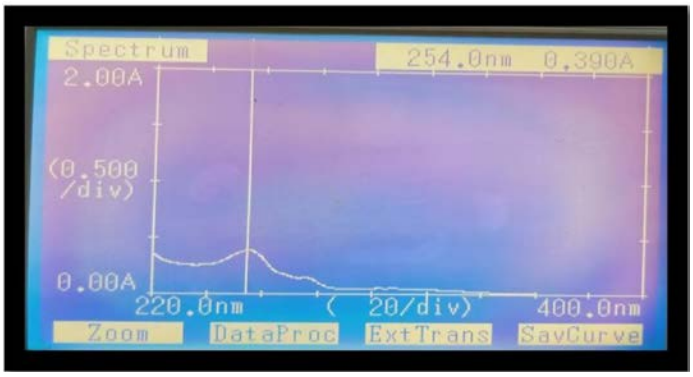

Figure 1: Spectra of Prochlorperazine maleate for wavelength estimation.

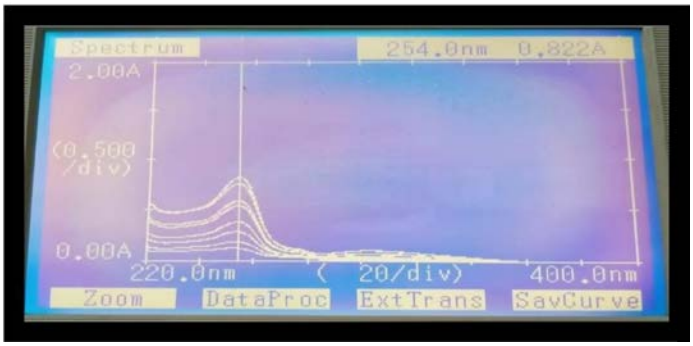

Figure 2: Spectra of Prochlorperazine maleate for linearity.

Table 2: Data of Calibration curve for Prochlorperazine maleate.

Sl. No.	Concentration µg/ml	Mean ABS.±SD
1.	2	0.113±0.0085
2.	4	0.187±0.0087
3.	6	0.274±0.0092
4.	8	0.389±0.0075
5.	10	0.428±0.0135
6.	12	0.588±0.008
7.	14	0.718±0.0097
8.	16	0.810±0.0061

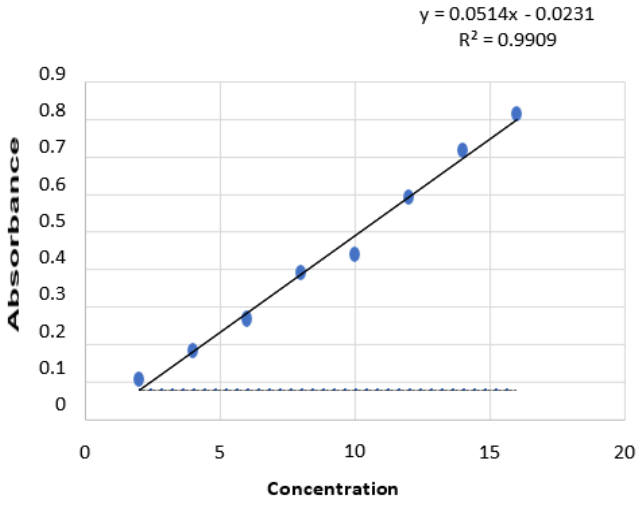

Figure 3: Calibration Graph of Prochlorperazine malate.

Table 3: Repeatability data by UV spectrophotometry.

Sl. No.	Concentration (µg/ml)	Absorbance	Average	STDEV	% RSD
1.	10	0.478			
2.	10	0.482			
3.	10	0.484	0.4815	0.0029	0.612
4.	10	0.478			
5.	10	0.485			
6.	10	0.482			

Intermediate precision

Intraday precision

Intraday precision is given in Table 4. % RSD was found to be 0.633 % which indicates the purposed method is precise.

Interday precision

Interday precision is given in Table 5. %RSD was found to be 0.3181% whichindicates the purposed method is precise.

Reproducibility precision

Reproducibility precision was found to be Table 6 % RSD was found to be 0.829 % which indicates the purposed method is reproducible.

Table 4: Intraday precision data of Prochlorperazine maleate.

Sl. No.	Concentration (µg/ml)	Absorbance	Average	STDEV	% RDS
1.	10	0.479			
2.	10	0.483	0.4823	0.0030	0.633
3.	10	0.485			

(n=3)

Table 5: Interday precision data of Prochlorperazine maleate.

Sl. No.	Interday	Concentration (µg/ml)	Absorbance	Average	STDEV	% RSD
1.	Day 1	10	0.482			
2.	Day 2	10	0.479	0.4806	0.0015	0.3181
3.	Day 3	10	0.481			

(*n*=3)

Table 6: Reproducibility precision data of Prochlorperazine maleate.

Sr.no.	Reproducibility	Concentration (µg/ml)	Absorbance	Average	STDEV	% RSD
1.	Analyst 1	10	0.482			
2.	Analyst 2	10	0.478	0.482	0.004	0.829
3.	Analyst 3	10	0.486			

(*n*=3)

Accuracy

% Recovery data obtained by the proposed method are shown in the following Table 7. All the data shows the purposed method is accurate.

Assay

No any interference excipient for λ_{max} of Prochlorperazine maleate. Hence the purposed method is applicable for routine estimation of Prochlorperazine maleate in the tablet dosage form. The result is shown in following the Table 8. The % purity of Prochlorperazine malate was found to be 95.35%.

LOD and LOQ

LOD and LOQ are calculated based on standard derivation and slop of calibration curve and the data are shown in following Table 9.

DISCUSSION

The main objective of this work was to develop a simple method for the estimation of Prochlorperazine maleate in bulk and tablet dosage forms. First for the identification, a melting point study was performed. The melting point of the drug sample corresponds to the reported melting range, indicating the authenticity of the drug sample. UV spectra Prochlorperazine maleate was taken in 0.3M HCL and λ_{max} was observed at 254nm. Hence λ_{max} for Prochlorperazine maleate was found to be 254nm. The linearity range of Prochlorperazine maleate

Table 7: % Recovery of Prochlorperazine maleate.

Sl.No.	Level	Conc. of test solution	Conc. standard solution	ABS	Conc. (µg/ml)	% recovery	Average	STD	% RSD
1.	80	6	4.8	0.52	10.624	98.37			
				3		0.523	0.002	0.38	
2.	80	6	4.8	0.52	10.585	98.01		2	
				1					
3.	80	6	4.8	0.52	10.663	98.73			
				5					
1.	100	6	6	0.58	11.869	98.91			
				7		0.588		0.001	0.25
2.	100	6	6	0.59	11.928	99.40		9	
3.	100	6	6	0.58	11.889	99.07			
				8					
1.	120	6	7.2	4	0.65	13.173	99.79		
						0.653	0.002	0.00	3
2.	120	6	7..2	1	0.65	13.114	99.35		
3.	120	6	72	5	0.65	13.192	99.49		

(*n*=3)

Table 8: Assay Prochlorperazine in tablet dosage form by UV.

Formulation	Label claim (mg/tablet)	Amt Found (mg/tablet)	Drug content (%) ± SD
Prochlorperazine	5mg	4.765mg	95.35±0.065

(*n*=3)

Table 9: Data of LOD & LOQ.

Drug	LOD (µg/ml)	LOQ(µg/ml)
Prochlorperazine maleate	0.58	1.75

Table 10: Summary of validation parameters.

Sl. No.	Parameters	Prochlorperazine Maleate
1.	Melting point of the drug (°C)	202-206
2.	Linearity (µg/ml)	2 - 16
3.	Correction coefficients (R^2)	0.9909
4.	Precision	
	1.Repeatibility (%RSD) (*n*=6)	0.612
	2.Intraday (%RSD) (*n*=3)	0.633
	3.Interday (%RSD) (*n*=3)	0.318
	4.Reproducibility precision (%RSD) (*n*=3)	0.829
5.	Accuracy (% Recovery) (*n*=3)	98.01-99.79
6.	Assay (%)	95.35
7.	LOD (µg/ml) (*n*=6)	0.582
8.	LOQ (µg/ml) (*n*=6)	1.756

was found to be 2 to 16µg/ml. The linearity equation was found to be y = 0.0514x –0.0231. The Correlation coefficient for PCM was 0.9909 which indicates the purposed method is linear. The data of repeatability, intermediate precision and reproducibility indicated that the optimized method was found to be precise. It also found to be accurate as per result of the recovery. The % purity of Prochlorperazine malate was found to be 95.35% which is within a limit. (Table 10)

CONCLUSION

UV spectrophotometry method for Prochlorperazine maleate was developed and validated as per ICH guidelines. The standard derivation and %RSD calculated for the developed method is within a specification, indicating good precision. The result of the recovery study performed indicates the method is accurate. Hence, it can be concluded that the developed spectrophotometry method was simple, accurate, and precise. It can be successfully used for routine analysis and further studies like stability study for prochlorperazine maleate in bulk and its tablet formulation.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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