INTERNATIONAL JOURNAL OF PHARMACEUTICAL, CHEMICAL AND BIOLOGICAL SCIENCES

Available online at www.ijpcbs.com

Research Article

METHOD DEVELOPMENT AND VALIDATION OF METHOCARBAMOL IN BULK AND ITS FORMULATION BY UV SPECTROSCOPY

M. Nagamani*, H. Ramana, B. Bhadru and R. Vasanthi

Department of Pharmaceutical Analysis, Mohammadiya Institute of Pharmacy
Arempula, Khammam, Telangana-507163, India.

ABSTRACT

A new, simple, specific, sensitive, accurate, rapid and precise UV-Visible method was developed for the estimation of methocarbamol in bulk and pharmaceutical formulation. Methocarbamol used extensively in pharmaceutical solid unit dosage form as alone or combination with other active ingredient,for the estimation of methocarbamolin UV at λ_{max}274nm by using methanolas solvent. Detector response was linear in the concentration of 10-50µg/ml.The interand intraday variation was found to be less than 1%. The mean recovery of the drug from the solution was 100.24%.

Keywords: UV-Visible, Methocarbamol, Validation, Precision, Accuracy.

INTRODUCTION

Methocarbamol[1,2] is chemically 3-(2-methoxyphenoxy)-1,2-propanediol 1-carbone as in fig.1. It is a white powder, freely soluble in propylene glycol, soluble in alcohol, sparingly soluble in water and insoluble in benzene and n-hexane. It has the empirical formula$C_{11}H_{15}NO_5$ and molecular weight is 241.24. Methocarbamol is a carbamate derivative of guaifenesin, is a central nervous system (CNS) depressant with sedative and musculoskeletal relaxantsproperties. Literaturesurveyreveals that few spectroscopic and chromatographic methods have been reported for the quantitative estimation of methocarbamol in bulk and pharmaceutical formulations.[3-7] Hence an attempt has been made to develop UV-Visible spectroscopic method for its estimation in bulk and pharmaceutical formulation with good precision, linearity and reproducibility.

Methocarbamol tablet USP is available as 500mg and 700mg for oral administration. Methocarbamol tablet contains the following excipients sodium lauryl sulfate, sodium starchglycolate, povidone K90, polyethylene glycol, magnesium stearate, colloidal silicon dioxide, low substituted hydroxyl propyl cellulose and stearic acid.

EXPERIMENTAL

MATERIALS AND METHODS

Pc based ThermoGenesis'™10 double been spectrophotometer with a pair of 1cm quartz cell was used. All the chemicals used were of A.R.grade. Methocarbamol (API) was obtained as gifted sample. One strip of methocarbamol tablet was procured from the local market.

STANDARD PREPARATION

Preparation of stock solution (1000µg/mL)

Accurately weighed 100 mg of methocarbamol and transfer into 100 ml volumetric flask and dissolved with methanol, finally made up tothevolume with methanol, to obtain thestock solution of concentration 1000 µg/mL.

Preparation of standard solution (100µg/mL)

Accurately pipette out 10ml of methocarbamol stock solution and transferred it in to 100ml volumetric flask and made up to the volume with methanol, to get the standard solution of concentration 100 µg/mL.

Methocarbamol working standard

Accurately pipetted out 1,2,3,4 and 5 ml of methocarbamol standard solution and

transferred each into a separate 10 ml volumetric flasks and madeup to the volume with methanol to obtain the working standard solutions of concentration 10, 20, 30, 40 and 50 µg/mL respectively. Absorbances of these standard concentrations were measured at λ_{max} 274nm. Each dilutionwas measured five times and the average absorbance of each dilution was computed.Calibration graph was constructed by concentration of the drug on X-axis and absorbance on Y-axis, the graph was found to be linear in the concentration of 10-50 µg/mL of the drug. The relevant data was furnished in table 1.

A typical calibration plot was followed the Beer Lambert's law and which was shown in fig.2. The regression equation of this curve was computed. The regression equation was later used to estimate the amount of methocarbamol tablet.

Sample preparation

Weighed and finely powdered not more than 20 tablets. Accuratelyweighedand transferredequivalents to 100 mg of methocarbamol in to 100ml volumetric flask and sonicatedfor 30minutes with intermittent shaking and made up to the volume with methanol and filtered. Collect the above solution, from this solution accurately measured 5ml of solution and transferred in to 10 ml volumetric flask and made up to the volume with methanol, and the absorbance of the resulting solution was measured at λ_{max}274 nm.The actual concentration of the drug was determined from the standard curve.

Assay

% Assay = Std.Abs/Test.Abs×Std.dilution/Test.Dilution ×Avg.wt/Labelclaim×Potency/100×100 =100.20%

Validation of proposed method

After method development, validation of the proposed method was performed in accordance with USP requirement for assay. Quantization of methocarbamol was done by analytical methods like linearity, accuracy, precision and robustness.

Linearity

The drug concentrations were prepared as per given in the standard preparation. Calibration curve was constructed by taking concentration on X-axis and absorbance on Y-axis was shown in fig.2.

Accuracy

Accuracy was studied by using known amount of methocarbamol in the range of 1-10 µg/mL and the recovery has to be in the range of 99.17-101.36%. The results were given in the table.2.

Precision

We determined the precision of the method through its repeatability and reproducibility. We repeated the assay method for 5 times in the same day and 5 times for the next day by 2 different analysts and then we computed the relative standard deviation (RSD). The acceptance criteria demands that RSD should be less than 2% and theresults were given in the table 3.

Robustness

Robustness of this method was determined by analyzing the methocarbamol tablet in different day and different analyst. The given above data wasobserved that the method was robust enough to analyze the methocarbamoltablet, which was shown in table 4.

RESULTS AND DISCUSSION

Quantitative determination of methocarbamol was simple, accurate, robust and specific. Quantization was linear in the concentration range of 10-50 µg/mL. The regression equation of the linearity plot of methocarbamol over its absorbance was found to be Y=0.0228X (R^2=0.9997), where X is the concentration of methocarbamol (µg/mL) Y-is the corresponding absorbance. The $\lambda_{max}$of the drug for analysis was determined by taking scans of the drug solutions in the entire UV-Visible region. The replicate analysis of the standard solution was used to assess the accuracy, precision and reproducibility of the proposed method. The prepared methocarbamol analyzed with the relevant calibration curve to determine the intra and interday variability of the methocarbamol drug.

CONCLUSION

The proposed UV-Visible method wasrapid, sensitive, precise and accurate for the determination of methocarbamol and can be reliably adopted for routine quality control analysis of methocarbamol in its bulk and its formulation without any interference from the excipients.

ACKNOWLEDGEMENTS

The authors are thankful to Mohammadiya Institute of Pharmacy for providing the facilities to carry out the work.

Table 1: The drug concentrations

S.No.	Conc. (µg/mL)	Absorbance
1	10	0.222
2	20	0.463
3	30	0.692
4	40	0.909
5	50	1.137

Table 2: The drug concentrations

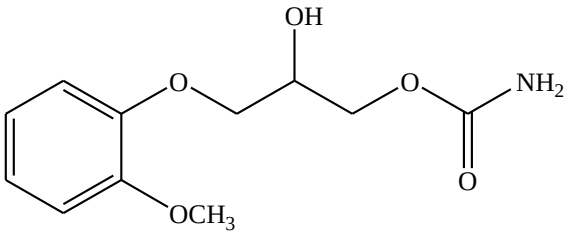
Conc. µg/mL	Conc. of recovery product	Concentration %
2	2.0	100.0
4	4.0	100.0
6	5.99	99.99
8	8.80	99.92
10	10.13	101.30

Table 3: The drug concentrations

Declared amount	Absorbance	%Assay
50mg(0.917g)	2.907	99.58
	2.903	99.00
	2.908	99.55
	2.903	99.00
	2.906	99.60
Drug 50mg (0.917g)	1.58	
Mean	2.905	
S.D	0.0009	
RSD	0.0003098	
%RSD	0.03098	

Table 4: The drug concentrations

Variable parameter		Assay results %
Analyst –I	Day-I	99.58
	Day-II	99.00
Analyst -II	Day-I	99.55
	Day-II	99.60



3-(2-methoxyphenoxy)-2-hydroxypropyl carbamate

Fig. 1:

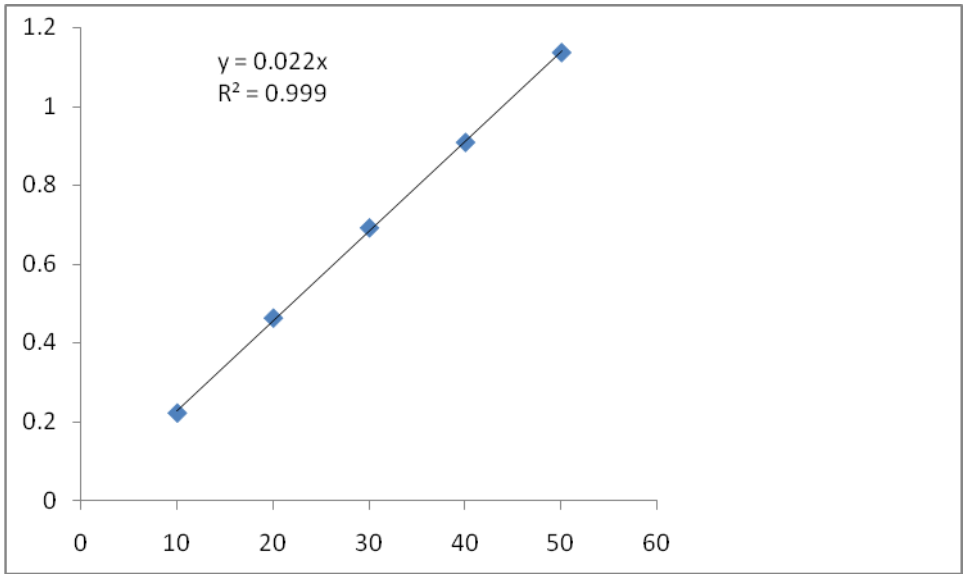


Fig. 2: Linearity of Methocarbamol (concentration in µg / ml)

REFERENCES

1. United State Pharmacopeia 2005, 28thEdn.
2. Indian Drug Review. September-October 2005.
3. Rajesh KP. Overview of pharmaceutical validation and process controls in drug development, Derpharmacia. 2010;1:11-19.
4. Chaityana Prasad and ManullapalliVani, Simple UV spectrophotometric for the estimation. Int Res J Pharm. 2013;4.
5. Jahnavi N and Sarvanan VS. Method development and validation for the determination of residual solvents in methocarbamol pure drug by HS-GC. IJPRC. 2012;2(2):456-466.
6. Manasa E, VanithaPrakash K, RaviPratap P and Susena S. Method development and validation of doxorubicin HCL in API and its formulation by Spectrophotometry. IJPCBS. 2013;3(4):1006-1009.
7. Deshmukh Hafsa, Chanda S, Pradnya and Prabhu J. Simultaneous HPLC determination of Methocarbamol, Paracetamol and Diclofenac Sodium. E-J Chem. 2011;8(4):160-1625.