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Development and validation of spectrophotometric methods for quantitative estimation of Meloxicam in bulk and pharmaceutical dosage forms

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ABSTRACT

Three Simple, precise and economical UV methods have been developed and validated for the quantitative for the estimation of Meloxicam in bulk and pharmaceutical dosage forms. Meloxicam has the absorbance maxima at 360 nm (Method A), and in the first order derivative spectra and second order derivative spectra, shows sharp peaks at 338 nm (Method B), 281nm (Method c) respectively. Beer's law was found to be obeyed in the concentration range of 5-25 µg/mL for the Method A, B and C. The developed method was validated according to ICH guidelines and was found to be accurate and precise. The proposed method can be successfully applied for the estimation of Meloxicam in bulk and pharmaceutical dosage forms. Results of the analysis were validated statistically and by recovery studies.

Keywords: Meloxicam, UV Spectrophotometry, Derivative Spectroscopy.

INTRODUCTION

Meloxicam [1], an oxicam derivative, is a member of the enolic acid group of nonsteroidal anti-inflammatory drugs (NSAIDs) with analgesic and antipyretic properties. Prostaglandins are substances that contribute to inflammation of joints. Meloxicam inhibits prostaglandin synthetase (cylooxygenase 1 and 2) and leads to a decrease of the synthesis of prostaglandins, therefore, inflammation is reduced. Meloxicam is chemically designated as 4-hydroxy-2-methyl-*N*-(5-methyl-2-thiazolyl)-2*H*-1,2-benzothiazine-3-carboxamide-1,1-dioxide. The literature survey, it was found that Meloxicam estimated by analytical methods such reversed-phase high-performance liquid chromatographic (HPLC) method [2-3] and HPTLC method [4]. Apart from the above no other methods such as zero and first and second order derivative spectrophotometric

method was reported for the quantitative determination of Meloxicam in pharmaceutical dosage forms. The developed method was simple, precise, specific and accurate. The statistical analysis proved that method is reproducible and selective for the analysis of Meloxicam in bulk drug and tablet formulations.

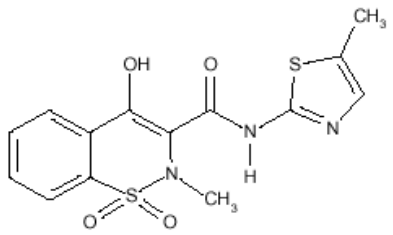

Fig 1: Structure of Meloxicam

MATERIALS AND METHODS

2.1 Instruments and reagents

A Shimadzu UV-1800 UV/VIS spectrophotometer was used with 1 cm matched quartz cell. Meloxicam tablet brand name is M-com and label claim is 7.5mg, it is soluble in 0.1NaoH and it is prepared by using distilled water.

2.2 Preparation of working standard drug solution

The standard Meloxicam (100 mg) was weighed accurately and transferred to volumetric flask (100 ml). It was dissolved properly and diluted up to the mark with 0.1N NaoH to obtain final concentration of 1000 µg/ml and the resulting solution was used as working standard solution.

2.3 Analysis of marketed formulations

For the estimation of Meloxicam in tablets formulations, 20 tablets accurately weighed and triturate to fine powder. Tablet powder equivalent to 100 mg of Meloxicam for each was weighed and transfer into 100 ml volumetric flask than dissolved with 0.1N NaoH and further diluted with 0.1N NaoH. It was kept for ultra-sonication for 30 min; this was filtered through Whatman filter paper No. 41 and then final dilution was made with 0.1N NaoH to get the final stock solution of 1000 µg/ml. From this stock solution, various dilutions of the sample solution were prepared and analysed**.**

Method A: Absorption Maxima Method

For the selection of analytical wavelength, 15 µg/mL solution of Meloxicam was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. From the spectra of drugs (Figure 2), λ max of meloxicam, 360 nm was selected for the analysis. The calibration curve was prepared in the concentration range of 5-25 µg/mL at 360 nm. By using the calibration curve, different concentrations of the sample solution were calculated

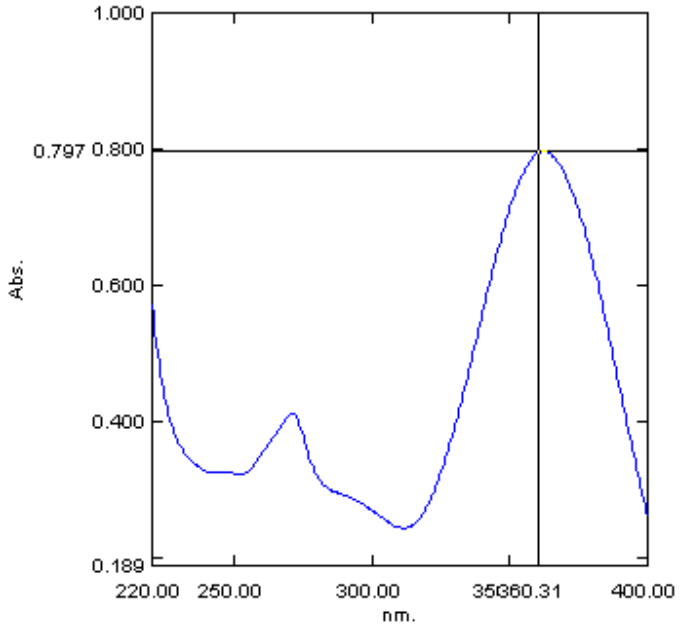

Figure 2: Zero order spectra of meloxicam

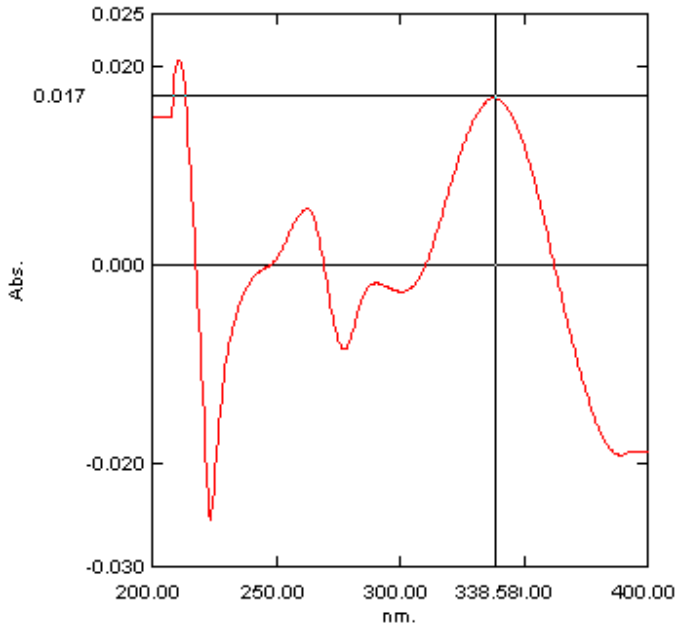

Figure 3: First order spectra of Meloxicam

Method B: First Order Derivative Spectroscopic method

In this method, 15 µg/mL solution of Meloxicam was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. The Absorption spectra thus obtained were derivatized from zero to first order. The first order derivative spectra showed sharp peak at 338 nm and linearity was measured at 338 nm (Figure 3). The calibration curve for Meloxicam was plotted in the concentration range of 10-50 µg/mL

at wavelength 338 nm. Similarly absorbances of samples solution were measured and amount of Meloxicam was determined from standard calibration.

Method c: second Order Derivative Spectroscopic method

In this method, 15 µg/mL solution of Meloxicam was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. The Absorption spectra thus obtained were derivatized from zero to first order. The first order derivative spectra showed sharp peak at 281nm nm and linearity was measured at 281nm nm (Figure 4). The calibration curve for Meloxicam was plotted in the concentration range of 5-25 µg/mL at wavelength 232 nm. Similarly absorbances of samples solution were measured and amount of Meloxicam was determined from standard calibration.

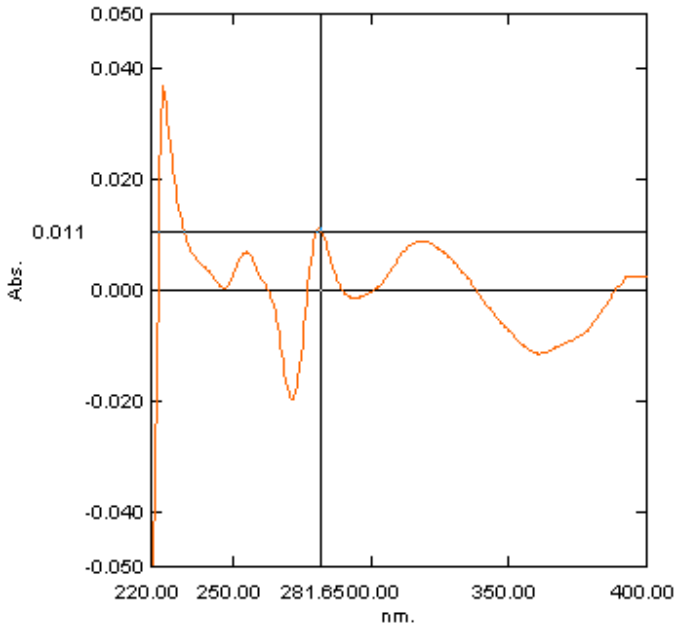

Figure 4: Second order spectra of Meloxicam

RESULT AND DISCUSSION

Meloxicam showed a broad spectrum, the derivative spectroscopy method applied has the advantage that it locates hidden peak in the normal spectrum. It eliminates the interference caused by the excipients and the degradation products present, if any, in the formulation. The method was validated according to International Conference on Harmonization guidelines for validation of analytical procedures [9-11].

Meloxicam has the absorbance maxima at 360 nm (Method A), In the first order derivative spectra, showed sharp peak at 338 nm (Method B), and in the second order derivative spectra, showed sharp peak at 281 nm (Method C). The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 5-25 µg/ml and given in Table 1. Recovery studies were carried out at three different levels i.e. 50 %, 100 %, and 150 % by adding the pure drug to the previously analysed tablet powder sample. Percentage recovery

for Meloxicam was determined by all the methods and they were found to be under acceptance criteria which are 98% to 102 % according to ICH guidelines [9-11]. The results are in Table 2,3,4. The percentage recovery value indicates non interferon from excipients used in formulation. The reproducibility and accuracy of the method was found to be good, which was evidenced by low standard deviation.

Table 1: Validation and Statistical Parameters

PARAMETERS	RESULTS		
	METHOD A	METHOD B	METHOD C
Absorption Maxima (nm)	360	338	281
Beer's-Lambert's range (µg/ml)	5-25	5-25	5-25
Regression equation (y)* Slope (b) Intercept (a)	 0.040 0.017	 0.009 0.003	 0.001 0.0007
Correlation coefficient	0.999	0.999	0.999
Sandell's sensitivity (mcg / cm^2-0.001 absorbance units)	0.025	0.097	0.068
Precision (% RSD) Intraday precision Interday precision	 0.130 0.113	 0.488 0.580	 1.39 1.13
Molar extinction coefficient	0.038	0.01	0.014
Limit of detection (µg / ml)	0.026	0.106	0.793
Limit of quantification (µg / ml)	0.078	0.3232	2.4054

**y = a + bx; when x is the concentration in mg/ml and y is absorbance unit.*

Analysis of Formulation: Table-2: (Method A)

S.No	Sample	Labelled Amount(mg)	ConcentrationTaken For Analysis (µg/ml)	Amount Of Substance(µg/ml)	% Recovery
1	Tablet	7.5	10	9.9	99
2	Tablet	7.5	15	14.8	98.66
3	Tablet	7.5	20	20.04	100.2

Each value is mean of six observations

Analysis of Formulation: Table-3: (Method B)

S.No	Sample	Labelled Amount (mg)	ConcentrationTaken For Analysis (µg/ml)	Amount Of Substance(µg/ml)	% Recovery
1	Tablet	7.5	10	10.12	101.2
2	Tablet	7.5	15	14.905	99.36
3	Tablet	7.5	20	19.813	99.06

Each value is mean of six observation

Analysis of Formulation: Table-4: (Method C)

S.No	Sample	Labelled Amount (mg)	ConcentrationTaken For Analysis (µg/ml)	Amount Of Substance(µg/ml)	% Recovery
1	Tablet	7.5	10	9.8	98
2	Tablet	7.5	15	14.359	98.726
3	Tablet	7.5	20	20.274	101.37

Each value is mean of six observations

CONCLUSION

The most striking features of three methods are its simplicity and rapidity, non- requiring consuming sample preparations such as extraction of solvents, heating, degassing which are needed for HPLC procedure. It can be concluded that the proposed methods are fully validated and found to be simple, sensitive, accurate, precise, reproducible, rugged and robust and relatively inexpensive. So, the developed methods can be easily applied for the routine Quality Control analysis of Meloxicam in pharmaceutical preparations.

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REFERENCES

[1] M.J.O Neil. The Merck Index. 13th edn. Merck Research Laboratories Station, NJ.**2006** P.1040
[2] Farzana, S., Bandarkar., Pradeep, R and Vavia., **(2009)**, *Tropi. J. Pharm.Res*., 8 (3): 257-264.
[3] Syed muhammad farid hasan, Muhammad Harris Shoaib, Fouzia Hassan and InamUr Rehman., **(2009),** *Pak. J. Pharm. Sci*, 22 (2): 199-204.
[4] Namita Desai., Purnima Amin., **(2001),** *Indi. J. Pharm. Sci*., 63 (3): 245-247.
[5] Seedher Neelam., Garg, A and Bhatia Sonu **(2003)**, *Indi. J. Pharm. Sci*., 65 (7): 685-688.
[6] International Conference on Harmonization (ICH), Validation of Analytical Procedures: Text on Validation of Analytical Procedures Q2A, **1994.**
[7] International Conference on Harmonization (ICH), Validation of Analytical Procedures: Methodology Q2B, **1996.**
[8] International Conference on Harmonization (ICH), Validation of Analytical Procedures: Text and Methodology Q2 (R1), **2005.**