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ESTIMATION OF DICLOFENAC SODIUM PELLETS(EXTENDED RELEASE) IN COMMERCIAL DOSAGE FORMS USING A SIMPLE AND CONVENIENT SPECTOPHOTOMETRIC METHOD

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ABSTRACT

In this study, UV spectrophotometric method at 282nm was developed for determination of Diclofenac sodium in commercial dosage forms. Optical Density (OD) measurement was used in calculating the concentration of the drug samples drawn from dissolution test (temp 37 ± 0.5˚C) at intervals of 1, 4, and 8hrs. The results were in agreement with the values obtained from HPLC methods. The proposed method was validated in terms of linearity, reproducibility, and accuracy. Linearity was obeyed in the range 0.5–2.5 mg of Diclofenac sodium, while the repeatability (%RSD 2.5) was satisfactory.

Keywords: Diclofenac sodium; Analgesic; Anti-inflammatory.

INTRODUCTION

Diclofenac sodium is used as an Analgesic; anti-inflammatory. Chemically Diclofenac sodium is known sodium 2-[(2,6-dichlorophenyl)amino]phenyl]acetate. A survey of literature reveals that HPLC methods[1,2,3] are reported for the determination of HPLC Analysis of Relationship between swelling, erosion and drug release in hydrophillic natural gum mini-matrix formulations, Effect of betamethasone and diclofenac sodium on serum and tissue concentration of amoxicillin, *In vivo* study in rats. How ever there is no UV method reported, so for its estimation in commercial dosage form. Hence a UV method for the determination of diclofenac sodium in pharmaceutical solid dosage forms is described.

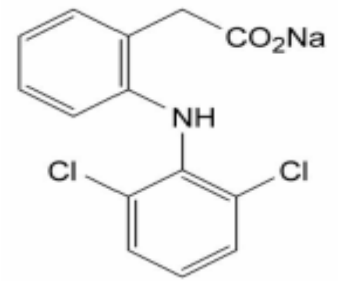

Fig.-1: Diclofenac Structure

EXPERIMENTAL

Process used Ingredient

Diclofenac sodium 35g (API), Sucrose 30g, Mannitol 15g**,** Hydroxy propyl cellulose 2g, Microcrystalline cellulose 13g, Ethyl cellulose N50 4.0g, and Talc 1.0mg. Total 100.0g.

Method

Instrument: UV-VIS spectra, Shimadzu 2450 . UV Probe Soft ware.

Chemicals and Reagents

Reference standard Diclofenac sodium is procured from M/S.RA Interchem .,Water (Distilled water), Absolute alcohol AR grade (make Hayman.)

Apparatus	: USP 23, method1 (Basket)
RPM	: 100
Medium	: Phosphate buffer pH 6.8, 1000ml
Temp	: 37 ±0.5°C

Place the stated volume of dissolution medium in the vessel of apparatus specified in the individual monograph, assemble the apparatus. Equilibrate the dissolution medium to 37 ±0.5°C, and remove the thermometer. Place the 6 samples in the apparatus, taking care to exclude air bubbles from the surface of dosage-form unit, and immediately operate the apparatus at the rate specified in the individual monograph. with in the time interval specified, withdraw a specimen from a zone midway between the surface of dissolution medium and the top of rotation blade, not less than 1 cm from the top of the rotation blade, not less than 1 cm from the vessel wall. Replace the aliquots withdrawn for analysis with equal volumes of fresh dissolution medium at 37^{O}C.

Procedure

Filter both standard and sample solution through 0.45 micron nylon filter. Check the absorbance at 282 nm.

Calculate the percent of Diclofenac Sodium. In 1st hour, 4th hour and 8th hour intervals based on the assay content.

RESULTS AND DISCUSSION

Dissolution

5ppm of standard and sample solutions checked into an UV spectra. The amount of Diclofenac sodium calculated by comparing the absorbance, with that of the standard.

Recovery studies

To study the linearity, accuracy and precision of proposed method, recovery experiments were carried out. Known quantities of standard at two different levels were added to pre-analyzed sample, recovery was estimated to be more than 99%.

LINEARITY

The linearity of Diclofenac sodium is established by plotting a graph of absorbance of standard solutions versus concentration. The linearity is found to be between 0.5 to 2.5mg.

Table-1

Semi formulation	Release rate in Hours	Bowl	% Drug Release	% Drug Release 6 bowls average value	SD	RSD
PELLETS	1nd hour	1,2,3,4,5 and 6	30.2,31.4,32.3,30.9,30.7 and 30.5	31.00	0.7536	2.43
	4th hour	1,2,3,4,5 and 6	73.2,73.4,72.9,74.8,73.7 and 72.8	73.46	0.7312	0.995
	8th hour	1,2,3,4,5 and 6	90.3,91.1,90.8,91.7,90.2 and 91.4	90.91	0.5980	0.657

Concentration	Absorbance
0.5	0.138
1.0	0.268
1.5	0.356
2.0	0.489
2.5	0.652

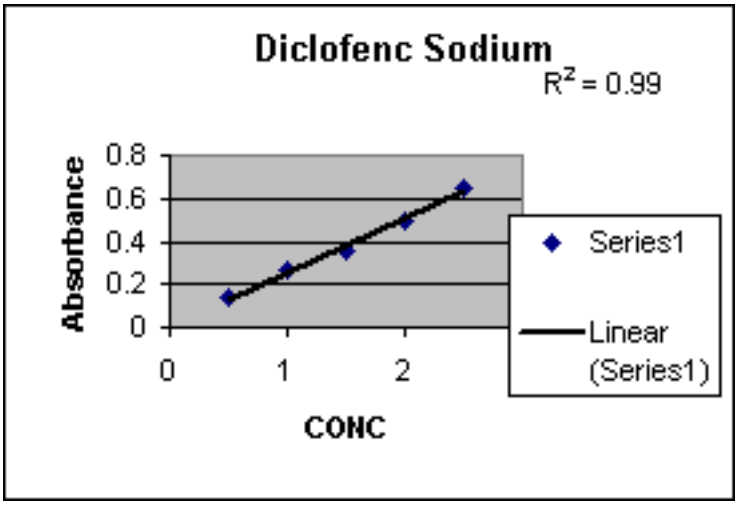

Fig.-2

The concentration of Diclofenac found to be with in limits and the RSD values are reasonably low.

Table-2

S.NO	Parameter	Diclofenac Sodium
1	RSD Of 5 samples	0.752

The precision of the method is studied by making 5 samples of standard and very low RSD values indicate good precision. The reproducibility and reliability of the method has been tested by performing recovery studies which showed good results.

CONCLUSION

The proposed method is very simple, rapid and now here involves use of complicated sample preparation. High percentage of recovery shows that the method is free from interferences of the excipients used in the semi formulations. There fore the method can be useful in routine quality control analysis.

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