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FORMULATION AND EVALUATION OF ORALLY DISINTEGRATING TABLETS OF ACECLOFENAC

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ABSTRACT

Novel drug delivery system and formulation research are oriented towards increasing safety and efficacy of existing drug molecule through novel concepts of drug delivery. Aceclofenac was formulated as an fast dissolving tablet as there is a need to develop a formulation for this drug which overcomes problem such as difficulty in swallowing, inconvenience in administration while traveling and better compliance. Aceclofenac Fast dissolving tablets were prepared by coprocessed method and different concentration of coprocessed super disintegrants like Polyplasdone XL and Solutab. A total of 10 formulations were prepared and evaluated for various pre and post compression parameters like angle of repose, bulk density, tapped density, carr's index, hausner's ratio, weight variation, hardness, friability, thickness, drug content, *in vitro* disintegration time, *in vitro* drug release. Among all the ten formulations F10 containing 40 mg of CP5 (Polyplasdone XL: Solutab 2:1) showed maximum drug release in within 15 mins due to less disintegration time. FTIR studies showed good compatibility between drug and excipients.

KEYWORDS: Aceclofenac, Co processed super disintegrants, Fast dissolving tablets.

INTRODUCTION

The Center for Drug Evaluation and Research defines MDT/FDT as "a solid dosage form

containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed under the tongue.

According to the US Food and Drug Administration Center for Drug Evaluation and Research (CDER) defines in the *Orange Book* an Fast dissolving tablet as

"**A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue".**

The European Pharmacopoeia however defines a similar term, *oro disperse,* as a tablet that can be place in the Fast where it disperses rapidly before swallowing (Brown 2003).[3] Fast dissolving is also called as Fast dissolving tablets, Orodispersible tablets, melt-in-Fast, Fast dissolving tablet, rapid melts, porous tablets, quick dissolving tablets [3]. Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage form.

METHOD AND MATERIALS

Preformulation studies

The goals of the Preformulation study are:

- To establish the necessary physicochemical characteristics of a new drug substance.
- To establish its compatibility with different excipients.

Hence, Preformulation studies on the obtained sample of drug include colour, taste, solubility analysis, melting point determination and compatibility studies and flow properties.

Analytical method development

Determination of absorption maximum (λ_{max})

Absorption maximum is the wavelength at which maximum absorption takes place. For accurate analytical work, it is important to determine the absorption maxima of the substance. Accurately weighed 10 mg of Aceclofenac and transferred to 10 ml volumetric flask, dissolved in 10ml methanol and the final volume was made up to 10 ml to get a stock solution (1000 µg/ml). From the stock solution, 1 ml was pipette out in 10 ml volumetric flask and the final volume was made up to 10 ml with pH 6.8 phosphahte buffer to get

100µg/ml (stock solution 2). From the stock solution 2, 1 ml was pipette out in 10 ml volumetric flask and the final volume was made up to 10 ml with pH 6.8 phosphate buffer to get 10µg/ml. Then this solution was scanned at 200-400nm in UV-Visible double beam spectrophotometer (UV-3200, Labindia, India) to get the absorption maximum (λ_{max}).

Evaluation Parameters

Pre compression parameters

Angle of Repose

It is performed to determine the flow rate of powder done by the funnel method. The powder was poured into a funnel which is fixed from height of 2cm of the plane surface.

Table 6.3: Angle of Repose values (as per USP).

Angle of Repose	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Bulk Density (LBD)

Loose bulk density was obtained by dividing the mass of powder by the bulk volume in cm^3. The sample of about 50 cm^3 of powder, previously been passed through a standard sieve no. 20, was carefully introduced into a 100 ml graduated cylinder.

It was calculated by using equation

$$Df = M / Vp$$

Df = bulk density ,M = weight of sample in grams,Vp = final volume of powder in cm^3

Tapped density (TD)

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times if the difference between these two volumes is less than 2%. If it is more than 2%, tapping was continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). It is expressed in g/ml and is given by

$$Do = M / Vp$$

Hausner's ratio

The Hausner ratio is a number that is correlated to the flowability of a powder or granular

material. The Hausner ratio is calculated by the formula.

$$H = \rho_t / \rho_b$$

Post Compression Parameters

Shape and colour

The tablets were examined under a lens for the shape of the tablet and colour by keeping the tablets in light.

Uniformity of thickness

Randomly 10 tablets were taken from formulation batch and their thickness (mm) was measured using a Digital micrometer.

Hardness test

The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in Kg/cm^2. Six tablets were randomly picked from each formulation.

Friability test

It is the phenomenon whereby tablet surfaces are damaged and/or show evidence of lamination or breakage when subjected to mechanical shock or attrition. The friability of tablets was determined by using Roche friabilator (Lab India, FT 1020). It is expressed in percentage (%). Ten tablets were initially weighed [$W_{(initial)}$] and transferred into friabilator. The friabilator was operated at 25 rpm for 4 min. The tablets were weighed again [$W_{(final)}$].

Table 5.1: List of Materials Used.

Name of the material	Source
Aceclofenac	Gift sample by squib lab ltd
Microcrystalline cellulose	Signet Chemical Corporation, Mumbai, India.
Polyplasdone XL	Merck Specialities Pvt Ltd, Mumbai, India.
Solutab	Merck Specialities Pvt Ltd, Mumbai, India.
Magnesium stearate	Merck Specialities Pvt Ltd, Mumbai, India
Talc	Merck Specialities Pvt Ltd, Mumbai, India

RESULTS AND DISCUSSION

Standard Calibration curve of Fosinopril

It was found that the estimation of Aceclofenac by UV spectrophotometric method at λ_{max} 205 nm in pH 6.8 phosphate buffer had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 5- 25µg/ml.

In vitro Dissolution studies

In vitro dissolution studies were carried out by using 900ml of pH 6.8 phosphate buffer in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 60 min.

From the tabular column 1.1 it was evident that the formulations prepared with different concentration of coprocessed super disintegrate CP1, CP2, CP3, CP4 and CP5. Formulation F1-F5 was containing 20mg of Coprocessed blend (CP1 to CP5). Among five formulations F5 was showed maximum % drug release in 30 min i.e. 99.46 ± 1.58%.

Formulation F6-F10 containing 40 mg of coprocessed blend (CP1 to CP5) in that F10 formulation containing 40mg of CP5 showed maximum % drug release in 15 mins i.e 99.46 ± 1.47%. Formulation F7-F9 was containing different concentrations of CP3 in that F9 containing 7.5mg of CP3 showed maximum % drug release in 15 mins i.e 98.56%.

Table 1.1: *In vitro* dissolution data.

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
5	24.45	19.07	17.8	25.3	43.5	34.91	33.16	45.23	49.48	50.63
10	38.97	23.75	24.72	47.6	66.3	46.45	41.03	61.57	69.33	73.41
15	41.28	40.46	33.33	56.3	75.2	59.23	53.15	73.61	80.56	99.46
20	51.53	50.25	42.58	67.3	89.8	72.34	66.28	89.21	99.31	
30	72.04	67.1	52.05	80.3	99.46	85.73	79.72	99.46		
45	87.1	79.3	69.47	95.1		99.47	87.43			
60	98.6	90.34	82.34	95.7			99.75			

Among all the ten formulations F10 containing 40 mg of CP5 (Polyplasdone XL: Solutab 2:1) showed maximum drug release in within 15 mins due to less disintegration time. Hence it is considered as optimised formulation.

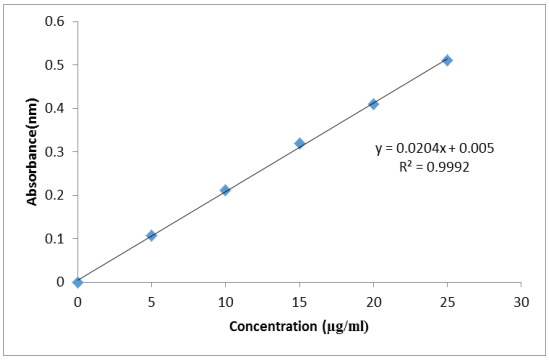

Fig: Standard graph of Aceclofenac in pH 6.8 phosphate buffer.

SUMMARY

The present study was carried out on Aceclofenac Fast dissolving tablets using coprocessed method. In this study coprocessd agents were Polyplasdone XL and Solutab and remaining exciepients Magnisium stearate, Talc and Micro crystalline cellulose were also used. Those all ingredients weighed and blended properly and compressed directly using rotary tablet compression machine (Lab Press) using 8mm punches.

CONCLUSION

Fast dissolving tablets of Aceclofenac formulated using coprocessed super disintegrant Polyplasdone XL and Solutab study concluded that all the formulations were shown good pre compression and post compression parameters. Among all formulations F10 formulation shown optimum drug release which was enclosed with polyplasdone XL and Solutab(CP5 2:1).

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