RESEARCH PAPER

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Sustained Release Flurbiprofen Beads

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Pan coating procedure for dried edible ripened plant seeds coated with flurbiprofen followed by ethylcellulose were developed for designing oral controlled drug delivery preparations of flurbiprofen.

FOR preparation of non pareil seeds generally sugar, lactose and cellulose are being used currently[1]. In this investigation, an attempt has been made to substitute the non pareil seeds with locally available cheaper edible ripened plant seeds. Many brands of oral controlled release preparations of flurbiprofen are available in the market.

In the present study, the circular edible seeds of **Paspalum scrobiculatum** linn (family gramine, available abundantly in Uttar Pradesh, India) were used as non pareil cores to develop SR flurbiprofen formation.

MATERIALS AND METHOD

Eighteen g of seeds were loaded in the coating Pan fitted with IL glass bowl (locally fabricated) of 12 cm diameter. A seal coart was given using shellac 10% w/v solution in alcohol. This was followed by a film of shellac (10% w/v) and polyvinyl pyrollidone 20% w/v in alcohol. The % increase in seed weight was 10.56. Then coats of solution of 4g of flurbiprofen in alcohol were given (% in increase was 19.10%). The seeds were weighed and one third was removed. To the remaining two third, a coat of ethylcellulose 5% w/v in alcohol was applied (1st coat). The % increase in weight was 8.23. Again one fourth of the coated seeds were removed and remaining were given 2nd coat of ethylcellulose solution. The % increase in weight was 8.96. The coat thickness was 0.16 ± 0.05mm. The various portions of the uncoated and coated seeds containing flurbiprofen were mixed and evaluated for dissolution and bioavailability studies after filling in empty gelatin capsules.

The Composition was as follows:

Formulation	Uncoated Portion equivalent to flurbiprofen (Mg)	Amount of seeds equivalent to flurbiprofen (mg)		Total Flurbiprofen (mg)
		1st Coat	2nd coat	
A	100	100	—	200
B	65	35	100	200
C	65	70	65	200

*For Correspondence.

Table 1: Percentage Drug Released at the End of 12th Hour

Formulation		% Drug Released	
		Basket Method	Paddle method
Coated Seeds	A	100.00 (within 8th hr)	98.80 (within 6th hr)
	B	74.32	75.06
	C	88.12	89.17
Marketed Product		92.39	94.45

ANOVA - Significant Difference in Drug Release ($P < 0.05$) among the coated seed formulation A, B and C.

Table 2: Bioavailability Parameters of Pan Coated and Marketing Flurbiprofen Preparation

Formulation	Cmax mcg/ml	Tmax hr	AUC^{24} mcg/hr/ml	Kel hr^{-1}	$t_{1/2}$ hr
Coated seeds of Flurbiprofen filled in capsules	8.60	4	70.64	0.114	6.18
Marketed product of flurbiprofen	9.48	6	75.66	1.101	7.59

Non significant difference in AUC and Kel between the two groups ($P > 0.05$)

In vitro dissolution studies were carried out both by the basket method and by paddle method using 1000 ml of simulated gastric fluid of pH 1.2 for 2 hours, duodenal fluid of pH 6.0 for 1 hour and intestinal fluid of pH 7.2 upto 12 hours (2 & 3). 5 ml of the sample was withdrawn at different time intervals and analysed for the drug content after suitable dilutions spectrophotometrically at 247nm[4].

Bioavailability studies of the seed coated formulation and marketed product of flurbiprofen was carried out in six healthy human volunteers. 5 ml of the blood samples was collected at different time intervals upto 24 hours after oral administration of the products. The plasma samples were separated from haparanized blood and kept frozen at -20°C until analysed. The flurbiprofen content in plasma samples was determined by spectrophotometric method at 247 nm.[4]

RESULTS AND DISCUSSION

The dissolution of seeds coated with drug was 100% at the end of 4th hour, 100% at the end of 8th hour for 1st coated seeds and 82% at the end of 12th hour for 2nd coated seeds.

Based on the dissolution characteristics of uncoated and 1st and 2nd coated seeds and combination of these formulation C was selected for in

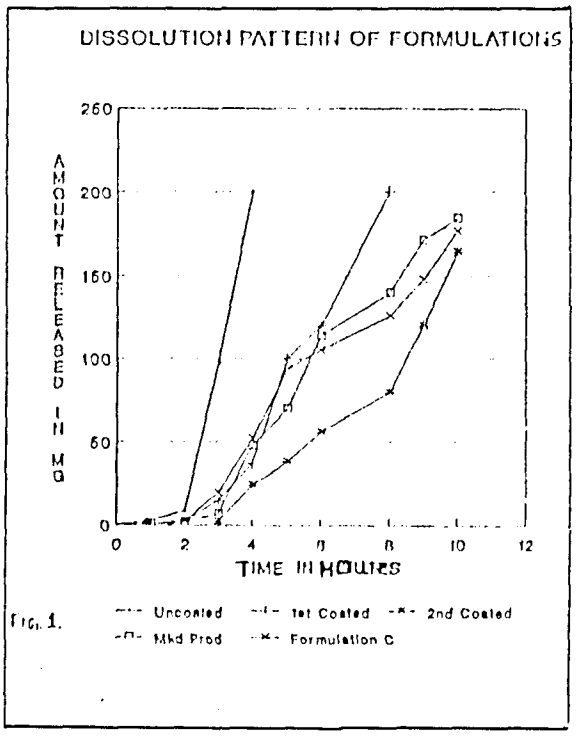

Fig. 1.

vivo studies. The dissolution behaviour of formulation C and marketed preparation are shown in **Fig.I**

From the dissolution data it is evident that the seeds coating with ethylcellulose and PVP it is possible to achieve desirable dissolution pattern which is comparable with that of marketed product. The dissolution pattern of the marketed and experimental product were assessed by both the USP I and II methods and these were found to be comparable **(Tabel 1)**.

The bioavailability studies data % revealed that the preparation of the coated seeds was comparable to the marketed product (**Table 2**). There was non-significant difference in AUC and Kel between the pan coated formulaion and marketed product.

CONCLUSION

Pan coating of edible dried ripened seeds with shellac, PVP and ethylcellulose may yield suitable oral controlled release preparations for flurbiprofen which will be very useful for treating inflammation and arthritis.

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