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FORMULATION AND *INVITRO* EVALUATION OF FAST DISSOLVING BUCCAL FILMS OF DOMPERIDONE HYDROCHLORIDE USING DEHYDRATED BANANA POWDER, A NEW NATURAL POLYMER

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ABSTRACT

The objective of the present work is to formulate and evaluate buccal films of domperidone using natural(dehydrated banana powder, Hibiscus mucilage), synthetic(sodium starch glycolate) and semi synthetic(Croscarmellose) super disintegrants. Preliminary studies were conducted for the pure drug and other excepients. The FTIR studies revealed that there was no interaction between drug and excepients. As Domperidone belongs to BCS class II having low solubility, its solubility gets enhanced by complexation with Hydroxy propyl beta cyclodextrin by kneading method. These complexes were used to prepare buccal films by solvent casting method. The prepared buccal films were evaluated for Disintegration time,folding endurance,weight variation etc.The dispersion studies were done in pH 6.8 phosphate buffer. The work has done to study the effect of super disintegrants on the disintegration time of the buccal films.

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INTRODUCTION

Oral route of drug administration is a most preferred routedue to its ease of administration, non-invasiveness, adaptability, patient compliance and acceptability.Regarding the oral route of drug administration, many substitutes have continuously been presented by using recent novel technologies for pediatrics, geriatrics, nauseous and non-compliance patients. Bioadhesive mucosal dosageforms including adhesive tablets, gels and patches are outcomes of technological development.[1]

Recently, fast-dissolving drug delivery systems have started gaining popularity and acceptance as new drug delivery systems, which aim to enhance safety and efficacy of a drug molecule by formulating it into a convenient dosage form for administration and to achieve better patient compliance. When put on the tongue, this film disintegrates instantaneously, releasing the drug which dissolves in the saliva. Some drugs are absorbed from the mouth, pharynx, and esophagus as the saliva passes down into the stomach. In such cases, the bioavailability of the drug is significantly greater than that observed for conventional tablets[2].

Extraction of Hibiscus mucilage

The fresh young leaves of Hibiscus rosa-sinensis were collected, washed with water to remove dirt and debris, and shade dried for 25 days. The dried leaves were ground to a fine powder and the leaf powder.The leaf powder (10 gm) soaked in 100 ml water was squeezed through an eight - fold muslin cloth bag to remove the marc from the solution. The resultant filtrate was collected in a beaker. Acetone (150 ml) was added to the beaker in a quantity three times the volume of the total filtrate. The precipitated mucilage from the beaker was taken out by gently spooling it out with a glass rod and collected in a petri-dishe. The mucilage was then dried by keeping the dishes in an oven (at 50 °C). The dried mucilage powder was scraped out and grounded using a mortar and pestle and weighed. The powder so obtained was then stored in a desiccators[4].

Preparation of Domperidone and Hydroxypropyl beta cyclodextrin Complexes By Kneading Method:

Based on the previous studies hydroxyl propyl beta cyclodextrin results in more Domperidone and beta cyclodextrin were taken in a different ratio such as 1:1 ,1:2,1:3 and the mixture was triturated well for an half hour. Water was incorporated to the mixture in different levels like 75%,50%,25% w/v in divided proportions and 0% (no water addition but the mixture was triturated continuously) after each part of water addition the mixture was triturated well for 10 minutes and dried using hot air oven over for 30 minutes at 50^0 c and sieved using sieve no : 44 .The complex mixtures were then dissolved in phosphate buffer and diluted and absorbances were measured using UV spectrophotometer and the solubility values were calculated.The results have shown that the Drug and Cyclodextrin at a ratio of 1:3 has 5 fold increase in solubility when compared to aqueous solubility of pure drug.Hence that ratio was selected for further formulations[5].

Preparation of Buccal Films

Buccal films of Domperidone were prepared by solvent casting technique using film forming mucoadhesive polymers and various super disintegrants. HPMC was weighed (200 mg) accurately and dissolved in 2 ml of ethanol. The beaker containing polymer and ethanol was kept aside for 5 min for swelling of the polymer. Further 3 ml of ethanol was added to the above polymer solution and the dispersion was stirred. Then one drop of (0.029 g) PEG (6000 for DBF1 to DBF3 was added,and for DBF4 to DBF6, PEG400 was added)to the polymer solution. Simultaneously sodium saccharin, citric acid, (are used as sweetner, stimulizing agent respectively) are accurately weighed in quantity then dissolved in 1 ml of ethanol in another beaker[6,7].

The drug solution was added to the polymer solution and was mixed thoroughly with the help of a magnetic stirrer. The whole solution was poured into the glass Petri dish placed over a flat surface. Inverted funnel was placed over the dish to avoid sudden evaporation. The mould containing polymeric solution of drug was kept 12 h at room temperature for drying. After drying, the films were observed and checked for possible imperfections upon their removal from the molds. They were covered with wax paper and preserved in desiccators till the evaluation tests were performed. These new films were examined in order to select the film having the best characteristics[8,9].

Formulation table:

Table No.1 Composition Table.

Composition	DBF1	DBF2	DBF3	DBF4	DBF5	DBF6	Purpose
Domperidone + hydroxipropylbetacyclodextrin	2.2g	2.2g	2.2g	2.2g	2.2g	2.2g	Antiemetic
HPMC K15	520mg	520mg	520mg	-	-	-	Film forming agent
Eudragit s100	-	-	-	300mg	300mg	300mg	Film forming agent
Hibiscus mucilage	-	-	50mg	-	-	50mg	Natural super disintegrant
Cross carmellose sodium	50mg	-	-	50mg	-		
Avicel	-	50mg	-	-	50mg	-	
PEG6000	160mg	160mg	160mg	-	-	-	Plasticizer
PEG400	-	-	-	0.06ml	0.06ml	0.06ml	Plasticizer
Sodium saccharin	32mg	32mg	32mg	32mg	32mg	32mg	
Ethanol	10ml	10ml	10ml	10ml	10ml	10ml	
Citric acid	2mg	2mg	2mg	2mg	2mg	2mg	
Water	q.s	q.s	q.s	q.s	q.s	q.s	

Evaluation tests:

Weightvariation:

This test ensures the uniformity of the formed film. From the whole film three small pieces workat randomly, each of 1 cm2 (1 cm*1 cm) area and were weighed individually.

Foldingendurance:

Determinationoffoldingenduranceofthefilmwasdonebyfoldingasmallstripoffilm(2cm*2 cm) at the same place repeatedly until it broke. The no. of times the film could be folded at thespecificplacewithoutbreakinggivesthefoldingendurancevalue[10].

Potencydetermination:

The drug assay was performed to ensure proper drug loading in each film. Assay was performedbytakingouta4cm2(2cm*2cm)areaoffilmfromthewholefilm.Itwasdissolvedin50mlof pH 6.8 phosphate buffer with the aid of stirring. This solution was filtered by using Whatmanfilter paper, the filtrate was diluted to with the same buffer up to 100 ml in volumetric flask. Thesolution was analyzed in double beam UV spectrophotometer at a wavelength of 284nm , whichis the λ max of DPH against the blank. This test was performed in triplicates with three differentfilmstoensurereproducibility[11].

Invitro disintegration test:

5 ml of Ph 6.8 phosphate buffer was taken in a petriplate and the film was placed on the surface of it. The time taken for disintegration of the film was measured as the disintegration time. This test was followed in the present study, evaluation was done in triplicatesandthe standard deviation fromthe mean value was reported.

Dispersion studies:

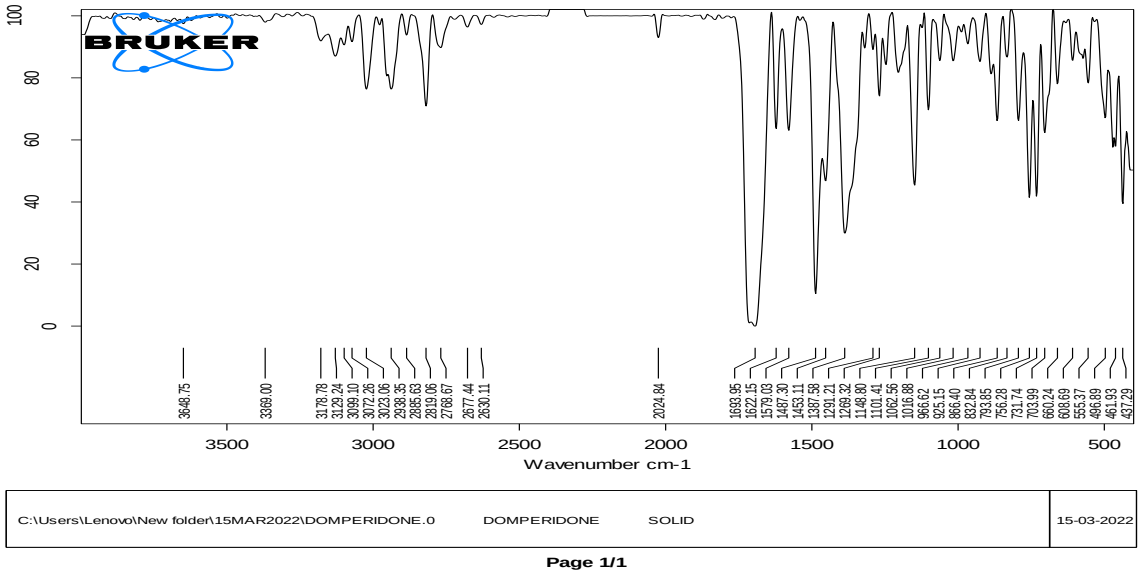
30 ml of Phosphate buffer(pH6.8)was placed in petri plate. The buccal films prepared with different superdisintegrants were placed on the surface of buffer. Initially at 0 min how much drug is dispersed was recorded. Afterthat, from 30 ml of phosphate buffer removed 5ml of buffer and replaced with 5ml of phosphate buffer to maintain sink condition.The dispersed drug was analysed using UV spectrophotometer at a wavelength of 284nm which is the λ max of DPH against the blank

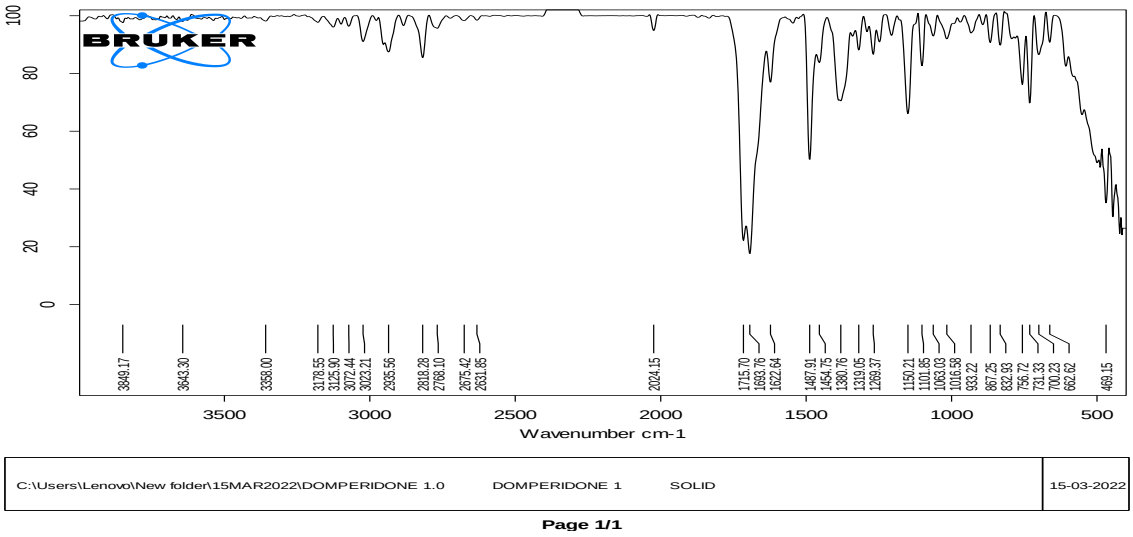
RESULTS AND DISCUSSION

Table No. 2 pre-Formulation studies of domperidone pure drug.

Properties	Results
Tapped Density	0.534
Angleof Repose	22.90
Melting Point	186

FTIR SPECTRA:

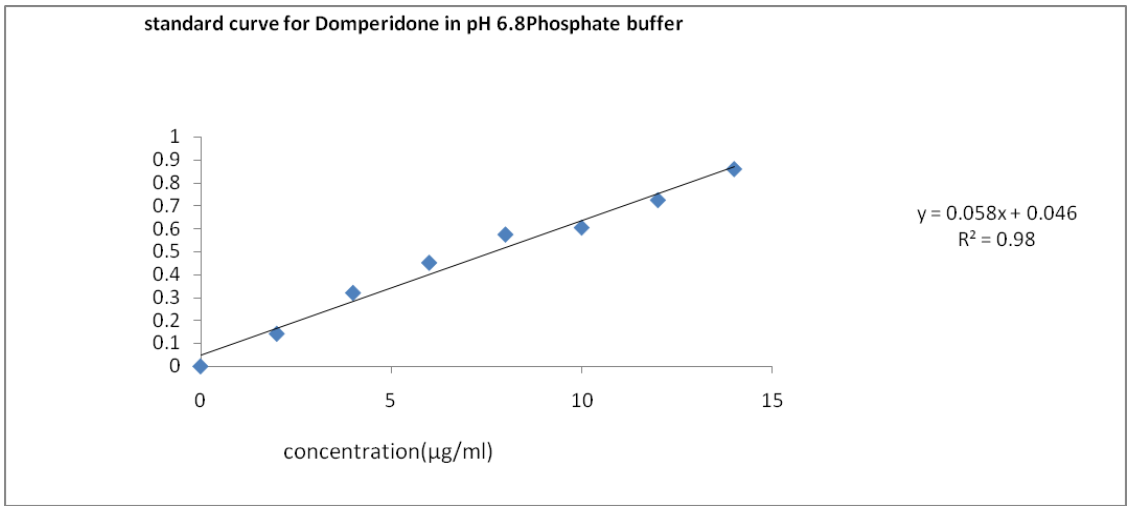




FTIR spectra for pure domperidone and in combination with the polymers(DBF6)
Discussion: the spectra for pure drug and optimized formulation showed that there is no interaction of drug with polymers.

Calibration curve of Domperidone in pH6.8Phosphate buffer:

Concentration(µg/ml)	Absorbance(nm)
2	0.092
4	0.142
6	0.32
8	0.451
10	0.574
12	0.604
14	0.724
16	0.859



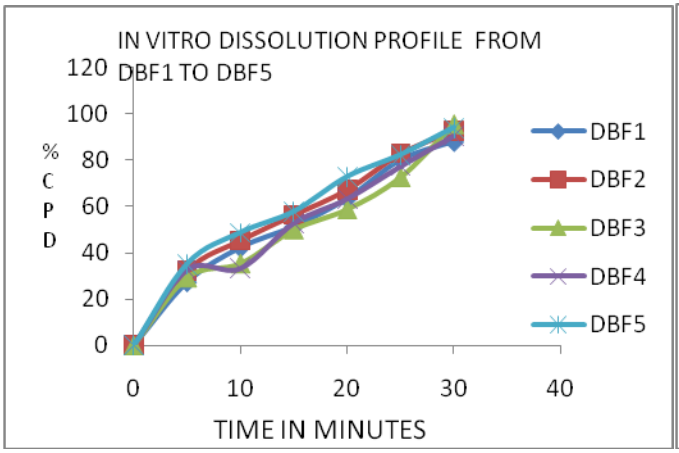
Evaluation of prepared buccal films:

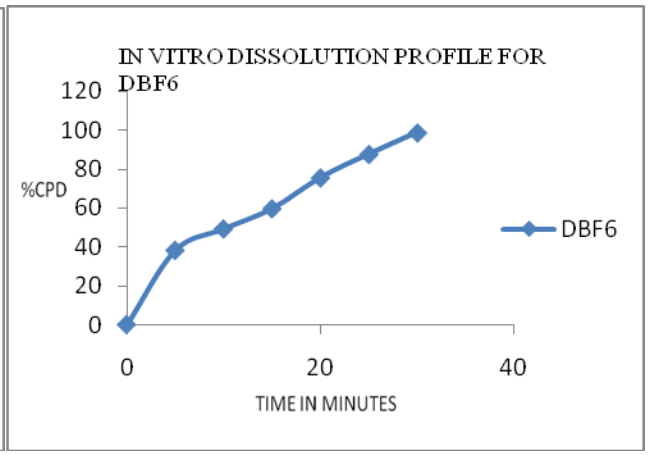
Table No.3 Evaluation Tests Reports For Domperidone Fast Dissolving Films.

Formulation	Weight variation	Foldingendurance	DisintegrationTime(seconds)
DBF1	100.33	235.4	25
DBF2	101.66	222.5	35
DBF3	98.63	279.0	59
DBF4	100.33	178.5	20
DBF5	99.63	257	37
DBF6	99.52	187.5	48

Table No.4: In Vitro Dissolution Data And Profiles.

S.No.	Time(min)	DBF1	DBF2	DBF3	DBF4	DBF5	DBF6
1.	0	0	0	0	0	0	0
2.	5	27.32	32.34	29.28	32.56	35.21	38.28
3.	10	42.21	45.32	25.32	33.15	48.69	49.32
4.	15	51.28	56.32	49.97	52.74	57.75	59.71
5.	20	63.37	67.27	58.74	63.19	72.74	75.63
6.	25	79.98	82.87	72.56	77.24	82.18	87.72
7.	30	87.97	92.78	95.41	90.34	93.96	98.81





DISCUSSION

From the evaluations of fast dissolving films of domperidone were given in the tables 3,4 and showed that formulation 4 had shown better results.

CONCLUSION

The buccal films of Domperidone were prepared by using different polymers and super disintegrants.The folding endurance values has shown that the films have good mechanical properties.Among the six formulations the formulations with crosscarmellose (DBF4 containing Eudragit as film former and PEG6000 as plasticizer) were disintegrated within 20sec.The formulation with Hibiscus mucilage(DBF6) has shown a 98.81%drug release in 30minutes.

Recommendation:

So it was strongly recommended that these natural polymers(Hibiscus mucilage and banana powder) can be used as super disintegrants.

Conflict of Interest:

Authors had no conflict of interest.

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