



Original Research Article

Formulation and evaluation of fast dissolving film of haloperidol

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ABSTRACT

The present research work was designated towards formulation development of fast dispersible films of Haloperidol that possesses acceptable taste, mechanical strength and rapid disintegration to provide desired drug release property and pleasant mouth feel, for improving patient compliance, especially in pediatric and geriatric population. The aim of the study is to formulate Mouth dissolving film of Haloperidol an antipsychotic drug to improve the efficacy and patient compliance. In the present work, an attempt is made to develop Mouth dissolving film of Haloperidol with the use of hydroxymethyl cellulose (HPMC) as polymer, xanthan Gum as binder, polyethylene glycol (PEG) as polymer, Citric acid as preservative, sacralose as sweetening agent and menthol as flavoring agent. Solvent casting technique was used to prepare the mouth dissolving film. The formulated fast dissolving film of Haloperidol was evaluated for different parameters: weight variations, thickness, folding endurance, percentage of drug content, surface pH, disintegration test, in vitro drug release and Stability study. Based on this physiochemical characterization in vitro drug release studies of Haloperidol showed 99% of drug at the end of 8 th minutes. The evaluation test for films of Haloperidol suggest that it is promising to be developed as fast dissolving films with above mentioned excipients which can enhance the release of drug and thereby the bioavailability may be improved and formulations were found to be stable.

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1. Introduction

Haloperidol, a butyrophenone, is widely used neuroleptic. Though haloperidol is well absorbed after oral dosing, there is a first pass metabolism leading to a reduced bioavailability of the drug (60-70%). Therefore, the present investigation is concerned with the development of fast dispersible oral films of haloperidol.

Haloperidol preparations available in the market are in the form of tablets, suspension and suppositories. The fast dispersible films will be intended to meet the requirements of providing fast dissolution and pleasant mouth feeling to the patient. Thus, such a dosage form will not only suppress

vomiting, but it will also be convenient and acceptable to use. Such a dosage form will be beneficial to the geriatric and pediatric patients, certain young individuals with underdeveloped muscular and nervous system, mentally ill and developmentally disabled patients, non co operative patients, people who are bed ridden, people who do not have access to water (e.g. travelers and army men). Various methods currently employed to produce fast dispersible films are Solvent casting, Semisolid casting, hot melt extrusion, Solid dispersion extrusion, and rolling.¹

The present study included solvent casting method for formulation of fast dissolving film as it is the most popular and cheap method. The present study was aimed at developing fast dispersible films, which would include.

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(a) A water soluble film former to disintegrate the film rapidly & a sweetener to mask bitter taste of drug.

(b) Auxiliary ingredients like plasticizers and surfactants. The film when placed in mouth, it will disintegrate and dissolve giving a rapid onset and pleasant mouth feels.

The development of a new pharmaceutical formulation by trial and error technique leads to a satisfactory formulation rather than an optimal one. The optimization techniques, on the basis of a few experiments and statistical analysis of the results can provide an efficient and economical method for prediction of the optimal composition.

Hence the present research work was designated towards formulation development of fast dispersible films of Haloperidol that possesses acceptable taste, mechanical strength and rapid disintegration to provide desired drug release property and pleasant mouth feel, for improving patient compliance, especially in pediatric and geriatric population. The concept of mouth dissolving drug delivery system emerged from the desire to provide patient with more conventional means of taking their medication. It is difficult for many patients to swallow tablets and hard gelatin capsules.

Hence, they do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy. In some cases such as motion sickness, nausea, vomiting or coughing and unavailability of water, swallowing conventional tablets may be difficult. Such problem can be resolved by means of fast dispersing films when put on tongue these films disintegrate and dissolved rapidly in saliva without need of drinking water.²

The faster the drug disintegrates in to solution, the quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as saliva passes down into stomach. In such case, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form.³

2. Materials and Methods

2.1. Materials

Haloperidol pure drug sample was generously gifted by Cypco Company ,Rau, Indore (M.P). Hydroxymethyl cellulose (HPMC) from Qualichem. Xanthan Gum from LOBA Ltd. PEG from HIMEDIA. Citric Acid from Merck Ltd. Sacrolose from Zydus Pharmaceuticles, Ahmedabad. Menthol from Raj Shah Pharmaceuticles. Methanol and water used were analytical grade.

2.2. Method

2.2.1. Melting point

Melting point of drug sample was determined by using melting point apparatus. The drug sample was taken and placed in a thin walled capillary tube; the tube was

approximately 10-12 cm in length with 1mm in diameter and closed at one end. The capillary was placed in melting point apparatus and heated and when drug sample was melted the melting point of sample powder was recorded.⁴ The melting point of Haloperidol is shown in the table 5.3.2.

2.3. Identification of drug by

2.3.1. UV Spectroscopic characterization

Identification of the drug, Haloperidol was done by UV Spectrophotometric method using Systronics Spectrophotometer 2201. A standard stock solution of Haloperidol (100 μ g/ml) was prepared by dissolving 10mg of drug in 10 ml of methanol in a 100ml of volumetric flask and then volume was made upto mark with phosphate buffer (pH 7.4). The dilutions of this stock solution (100 μ g/ml) were made by diluting the required aliquot with phosphate buffer to obtain standard solutions in the range of 2- 20 μ g/ml. An UV spectroscopic scanning (200–400nm) was carried out with drug solutions to determine the wavelength of maximum absorption (λ_{max}) using same diluent as blank.⁵ The UV spectrum of Haloperidol drug is shown in fig. 5.3.3.

2.4. Preparation of calibration curve of haloperidol

Standard curve of Haloperidol in phosphate buffer pH 7.4 at 247 nm was plotted using various concentrations against the absorbance values found at respective concentrations. The standard curve of Haloperidol was found to be linear in the range of 2-20 μ g/ml, which means that present drug sample was obeying Beers- Lamberts range (2-20 μ g/ml) and coefficient of correlation was found to be 0.999.⁶ The observations of calibration curve are shown in table 5.3.4. The calibration curves of Haloperidol are.Figures 3, 4 and 5

2.5. Preparation of simulated saliva

The ingredients mentioned in table 5.4 were dissolved in 1 liter of distilled water and pH was adjusted to 7.4 with Sodium Hydroxide.

Table 1: Composition of simulated saliva

Ingredients	Quantity
Potassium dihydrogen phosphate (KH ₂ PO ₄)	12 m M(1.6g)
Sodium chloride (NaCl)	40 m M(2.3g)
Calcium chloride (CaCl ₂)	1.5 m M(0.17g)
Sodium Hydroxide (NaOH)	q.s.topH7.4

2.6. Partition coefficient

Partition Coefficient of Haloperidol was determined by simple shaking flask method. 10 mg of drug was dissolved

in 25 ml of distilled water and 25 ml of octanol in the separating flask. The flask was stoppered and shaken for 1 hr and kept aside for phase separation for at least 24 hrs to attain equilibrium. Two phases of octanol and water sample was separated by separating funnel. Aqueous phase containing Haloperidol was filtered through whatman filter paper. The filtered aliquote was measured spectrophotometrically after suitable dilution at 247 nm. The partition coefficient was measured by the given fomulea.⁷

$$\log P_{\text{oct/wat}}^I = \log \left(\frac{[\text{solute}]_{\text{octanol}}^I}{[\text{solute}]_{\text{water}}^I} \right).$$

The value of partition coefficient is shown in the table: 5.3.6.

2.7. Drug-excipient compatibility

Drug-excipient compatibility tests were performed to model for clinical and commercial development a chemically stable formulation. In preformulation, drug-excipient compatibility tests are performed to identify the most suitable excipients, test the compatibility of the active ingredients with the selected excipients, and prove that the chosen excipients are compatible with the active ingredient. In the chosen proportions, the active ingredients and the excipients are combined with a mortar and pestle. The mixtures are transferred into glass vials and sealed. The samples were kept at 40°C±2°C/75%±5% RH for four weeks.⁸ The samples were analyzed for physical and chemical incompatibilities (Table 5.3.7)

2.8. Formulation of fast dissolving films

In the present study fast dissolving films of Haloperidol were prepared by solvent casting technique. Flat, square-shaped, aluminum foil-coated glass molds with 6.25 cm² surface area were used for casting the films.

Weighed quantities of polymers (HPMC) and Xanthan gum was separately kept for swelling overnight in 5 ml distilled water and dissolved. The drug and aspartame were added to the HPMC solution directly in formulation F1 to F3 while in Xanthan gum solution in formulation F4 to F8 along with glycerol as a plasticizer and mixed thoroughly to form a homogenous mixture. Finally, the polymer solution was added to the Xanthan gum solution, and volume made up to 10 ml with distilled water. Entrapped air bubbles were removed by applying vacuum.⁹

2.9. Evaluation of Fast Dissolving Film of Haloperidol

2.10. Weight variation

Mouths dissolving oral films were weighed on a digital balance, and the average weight was determined for each film. It is desirable that films should have nearly constant weight. It is useful to make sure that a film contains the right amount of excipients and API.¹⁰

2.11. Thickness of Films

By using micrometer screw gauge, the thickness of the film was measured at 5 totally different places; an average of 3 values was calculated. This is essential to ascertain uniformity within the thickness of the film which is directly associated with the accuracy of dose within the film.¹¹

2.12. Folding endurance

The folding endurance is expressed as the number of folds (number of times the film is folded at the same place) required to break the specimen or to develop visible cracks. This also indicates the brittleness of the film. A strip of 2.5 cm x 2.5 cm was subjected to folding endurance by folding the film at the same place repeatedly several times until a visible crock was observed, and the values were reported.

2.13. Drug content uniformity

The prepared fast-dissolving film was dissolved in 10ml methanol and 40ml PBS pH 7.4 mixtures and filtered through Whatman filter paper. After suitable dilutions, the concentration of the drug was determined by measuring the absorbance at 247 nm.

2.14. Surface pH

The film to be tested was placed in a Petri dish and was moistened with 0.5 ml of distilled water and kept for 30s. The pH was noted after being the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min. The average of these determinations for each formulation was done.¹²

2.15. In vitro Disintegration time

Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva. For a fast-dissolving film, the time of disintegration should be in the range of 5-30 s. The test was performed with disintegration test apparatus. 6.25 cm³ film was placed in the basket, raised and lowered in such a manner that the complete up and down rate equivalent to thirty times a minute. The time required by the film when no traces of film remain above the gauze was noted.¹³

Table 2: Formulation of fast dissolving film of Haloperidol

Code	F1	F2	F3	F4	F5	F6	F7	F8
Haloperidol (mg)	25	25	25	25	25	25	25	25
HPMC (mg)	40	42	46	48	-	-	-	-
Xanthan gum (mg)	-	-	-	-	40	42	46	48
PEG	10	8	6	4	4	6	8	10
Citric acid(mg)	5	5	5	5	5	5	5	5
Sucralose(mg)	6	6	6	6	6	6	6	6
Menthol (ml)	5	5	5	5	5	5	5	5
Distilled Water qs (ml)	10	10	10	10	10	10	10	10

2.16. In vitro Dissolution study

In vitro Dissolution study was carried out using USP type II basket type apparatus with PSB 7.4 as a dissolution medium. The temperature was maintained at a $37 \pm 0.50^\circ\text{C}$ with 50 rotation per minute 5 ml of aliquots were withdrawn at different time interval and same amount of fresh dissolution medium was replaced to maintain sink condition. The aliquots were analyzed for drug content for λ max 247 nm wavelength using UV-spectrophotometer.¹⁴ The cumulative percentage drug release was calculated and reported.

2.17. Stability Studies

The stability study of the formulated fast-dissolving films was carried out under different environmental conditions of $2-8^\circ\text{C}$ (45% RH), $25-30^\circ\text{C}$ (60% RH), and $45-50^\circ\text{C}$ (75% RH) for a period of 45 days.¹⁵ The films were characterized for the drug content during the stability study period.

3. Results and Discussion

3.1. Preformulation

3.1.1. Melting point

The melting point of drug sample was determined by using melting point apparatus. The melting point was found to be in the range of $147^\circ-152^\circ\text{C}$, which is found to be similar as given in the reference.¹⁶ The melting point of Haloperidol is shown in the Table 2.

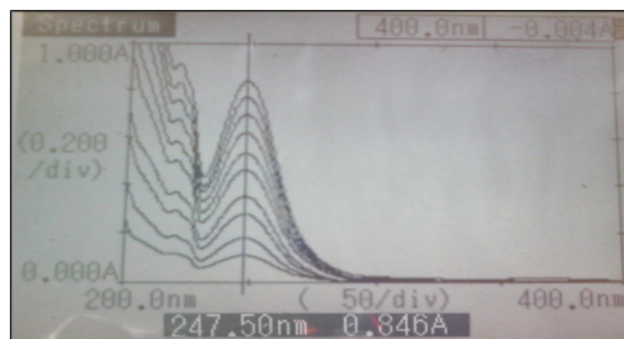
3.2. Identification of drug by

4. UV Spectroscopy

The λ max of Haloperidol was obtained at 247 nm. This found to be similar as given in the reference.¹⁷ Which shows that drug is pure. The UV spectrum of Haloperidol drug is shown in the Figure 4.

C. Preparation of standard Calibration curve of Haloperidol in Phosphate buffer pH 7.4 (λ max 247 nm)

Calibration curve of Haloperidol was prepared in phosphate buffer pH 7.4 at 247 nm. The absorbance values (mean of three determinations) with their standard deviation at different concentration in the range of 2-20 $\mu\text{g/ml}$ for

**Figure 1:** Spectrum of haloperidol by UV spectroscopy

phosphate buffer pH 7.4 are tabulated. The drug obeys Beer's Lambert law in the concentration range. Linear regression analysis for all calibration curves of Haloperidol is given in Table. So, this equation was used for the calculation of the solubility of the drug in different solvent, drug content and drug release.¹⁸ The calibration curve of Haloperidol is shown in Figure 5.

Table 4: Data of standard calibration curve of Haloperidol in phosphate buffer 7.4

S. No.	Concentration ($\mu\text{g/ml}$)	Absorbance (nm)
1.	0	0
2.	2	0.103
3.	4	0.178
4.	6	0.261
5.	8	0.362
6.	10	0.440
7.	12	0.515
8.	14	0.607
9.	16	0.691
10.	18	0.768
11.	20	0.846

4.1. Partition coefficient

The LogP value of Haloperidol was found be 8.5.¹⁹ The value is recorded in the table: 6.

Table 3: Melting point of haloperidol

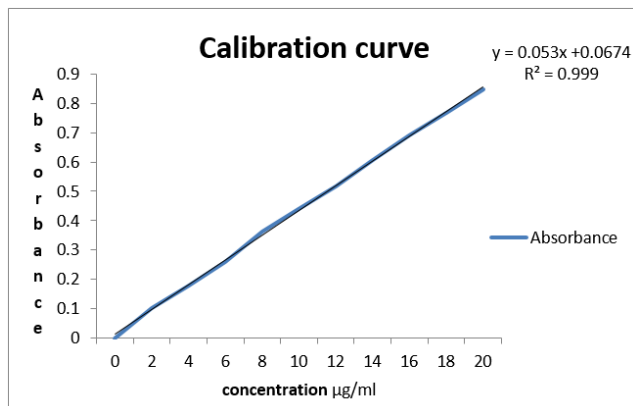
Drug	Observed	
Haloperidol	150 ⁰ C	147-152 ⁰ C

Table 6: Drug excipients compatibility

Name of drug/excipients	Initial Description	Test parameters		
		Refrigerator (2-8°C)	Room temperature	40°C±75%RH
PD	white to faint yellow	NoChange	NoChange	No Change
PMT+Citricacid	White Powder	NoChange	NoChange	NoChange
PMT+HPMC	White Powder	NoChange	NoChange	NoChange
PMT+Sacralose	White Powder	NoChange	NoChange	NoChange
PMT+Citricacid+HPMC+ Menthol	Off White Powder	NoChange	NoChange	NoChange

Table 7: Thickness, folding endurance, drug content and surface ph of fast dissolving film of haloperidol

Formulation	Thickness (μm)	FoldingEndurance (mm)	% Drug content	Surface pH
F1	98±1.4	106	85.12	6.28
F2	100±3.4	102	90.43	6.34
F3	102±2.4	64	93.52	6.25
F4	101±2.2	103	94.25	6.51
F5	105±4.2	61	91.44	6.44
F6	109±2.2	50	93.17	6.67
F7	99±1.4	110	97.27	6.71
F8	106±3.6	101	99.80	6.72

**Figure 2:** Calibration curve of haloperidol in phosphate buffer 7.4.**Table 5:** Partition coefficient value of Haloperidol

Drug	Observed	
Haloperidol	8.5	8.7

4.2. Drug-excipient compatibility

Evaluation of Fast Dissolving Film of Haloperidol

4.3. In vitro Disintegration time

Disintegration test for all prepared formulations was carried out using disintegration test apparatus. F1-F8 showed a

disintegration time of 8 to 25 sec. From the results obtained, by increasing the concentration of polymer, disintegration time was increased. The disintegration time of F8 was found to be 8 seconds which took less time as compared to all other formulations (F1-F8). From the results obtained from the above formulations, another than F5, F6, F8 disintegration time of all films was found to be within the limit as 5-30 seconds as per specification (USP 2007). Based on the disintegration time alone, F8 can be lead to develop as fast dissolving film (Table 9).

Table 8: Disintegration time of fast dissolving film of haloperidol

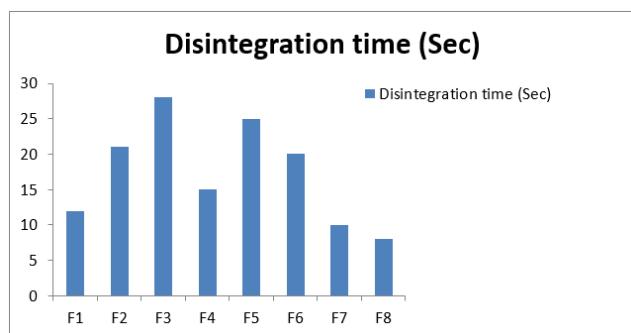
Formulation	Disintegration time (Sec)
F1	12
F2	21
F3	28
F4	15
F5	25
F6	20
F7	10
F8	8

4.4. In vitro drug release study

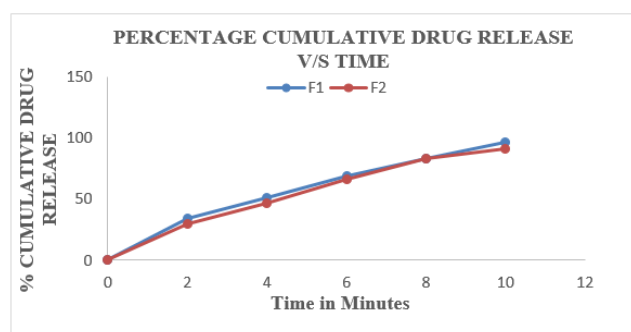
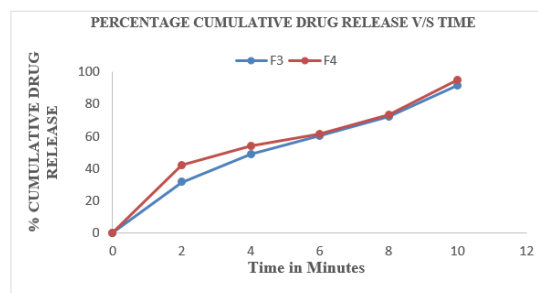
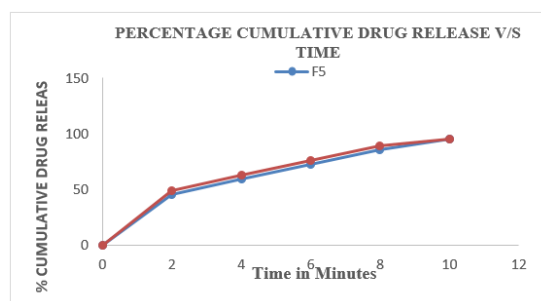
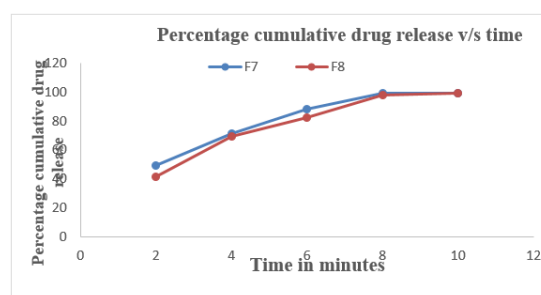
From the in vitro drug release, it was observed that in formulations containing a single polymer, the drug release was found to be faster and films formed of HPMC resulted

Table 9: In vitro drug release

Time (min)	Cumulative %drug release							
	F1	F2	F3	F4	F5	F6	F7	F8
2	42±1.1	36±0.9	32±0.8	33±1.0	31±1.2	30±1.2	49±0.8	41±1.3
4	69±1.7	66±2.5	62±1.6	65±1.3	58±1.6	55±2.5	71±2.5	69±2.1
6	81±1.8	78±2.9	76±2.1	77±1.8	76±2.2	75±3.1	88±3.7	82±3.1
8	94±2.2	91±3.1	90±2.8	92±2.7	89±2.9	89±3.4	99±2.8	98±3.4
10	98±3.4	98±3.5	97±3.6	98±2.6	97±3.1	96±2.8	99±3.1	99±2.8

**Figure 3:** Disintegration time of fast dissolving film of Haloperidol

in a fastest release of drug. Further, as the concentration of the polymer increased, the drug release was found to be decreased due to the increase in the time required for wetting and dissolving the drug molecules present in the polymer matrices. The drug release was found to be in the following order. F1>F2>F4>F3>F5>F6. For the group of formulations containing a combination of polymers, the drug release was found to be in the following order: F7>F8>F9. Among the eight formulations (F1 to F8) prepared, formulations F8, F7, and F4 were found to be the best formulations in terms of drug release.

**Figure 4:** In vitro drug release of F1 and F2**Figure 5:** In vitro drug release of F3 and F4**Figure 6:** In vitro drug release of F5 and F6**Figure 7:** In vitro drug release of F7 and F8

4.5. Stability study

Stability study for the prepared film was carried out for 45 days at different temperature and humidity conditions. Fast-dissolving films were found to be physically and

chemically stable as they showed no significant change in terms of physical characteristics and drug content at a lower temperature and room temperature. However, when stored at 45- 50°C for 45 days, films became brittle.

Table 10: Stability of formulations

S.No.	Parameter	Initial	1 month	2 month	3 month
1	Thickness	99±1.6	99±1.6	99±1.6	99±2.2
2	Weight variation	35.12 ±2.6	35.12 ±2.6	35.12 ±2.6	35.62 ±0.8
3	Folding endurance (mm)	110	110	110	106
4	Disintegration time (sec)	8	8	9	10
5	Drug content (%)	99.80	99.76	99.06	98.96
6	Surface pH	6.71	6.70	6.71	6.71

5. Summary and Conclusion

Haloperidol fast dissolving films have been successfully prepared by solvent casting method. Haloperidol an anti-psychotic drug was selected for the preparation of fast dissolving films. HPMC and Xanthan gum were used as polymers for the preparation of Haloperidol fast dissolving films. Based on this physiochemical characterization in vitro drug release studies of Haloperidol showed 99% of drug at the end of 8th minutes. The evaluation test for films of Haloperidol suggest that it is promising to be developed as fast dissolving films with above mentioned excipients which can enhance the release of drug and thereby the bioavailability may be improved.

6. Source of Funding

None.

7. Conflict of Interest

None.

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