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R E S E A R C H A R T I C L E

Design and *In-vitro* Characterization of Bromperidol Oral Thin Films

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A B S T R A C T

In present study oral thin films of Bromperidol were developed to have a faster on set of action. The oral thin films were developed by using polymers HPMC E5, HPMC E 15 and PVP K90.Oral thin films were prepared by employing solvent casting method. Propylene glycol was selected as permeation enhancer and plasticizer. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. Formulations were prepared with the varying concentrations polymers ranging from F1-F6, and all the formulations were evaluated for various physical parameters Physical appearance, Weight variation, Thickness, Folding endurance, Tensile strength, Drug content, Moisture uptake, Moisture content and all the results were found to be within the pharmacopeial limits, in-vitro drug release studies by using dialysis membrane. Among all the 6 formulations F1 formulation which contain HPMC E15 50mg and shown 97.2.% cumulative drug release within 30 min. And compared to HPMC E15, HPMC E5 and PVP K90, HPMC E 15 showed better drug release profile.

Keywords: Bromperidol, HPMC E15, HPMC E5, PVP K90 and HPMC E 15.

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

A strip or film can be defined as a dosage form that employs a water-dissolving polymer (generally a hydrocolloid, which may be a bio adhesive polymer), which allows the dosage form to quickly hydrate, adhere, and dissolve when placed on the tongue or in the oral cavity (i.e., buccal, palatal, gingival, lingual, or sublingual, etc.) to provide rapid local or systemic drug delivery.

2. Materials and Methods

Materials: Bromperidol, HPMC E15, HPMC E5, PVP K90, Propylene Glycol, Citric Acid, Aspartame all the chemicals used were lab grade.

Formulation: Development of Oral thin films: Oral thin films were prepared by solvent casting method.

Solvent casting method:

HPMC E5 and HPMC E15 were weighed in required ratios and they were then dissolved in water (Cold water) as solvent. Bromperidol (31.4mg), Propylene glycol was added

to the above dispersion under continuous stirring. The uniform dispersion was poured in the petri plate. The rate of evaporation of solvent was controlled by inverting cut funnel over the thin films. After 24h, the dried thin film were taken out and stored in desiccator. All the ingredients are taken in mg

Evaluation: Fast disintegrating oral films are evaluated for the following parameters: Thickness of the film, Disintegration time, Dissolution time, Folding endurance, pH, Percentage of moisture uptake, Tensile strength of the film.

3. Results and Discussion

Standard Calibration curve of Bromperidol:

It was found that the estimation of Bromperidol by UV spectrophotometric method at λmax 260 nm in 6.8 pH saline phosphate buffer and 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, 2-12µg/ml.

Evaluation of Bromperidol oral thin films:

Physical appearance: All the Oral thin films were visually inspected for colour, clarity, flexibility.

Flatness: All the Oral thin films was found to be flat without any foams. The prepared Bromperidol Oral thin films were evaluated by physical methods such as Physical appearance, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake and Moisture content and all the results were found to be within the pharmacopeial limits. **Tensile strength (F1):** The patches (10 samples of each) were dried at 60^0C for 24 hrs. Then they were placed in an isometric transducer and the force required for their rapture was measured by an oscillograph. The tensile strength of the patch was found to be **1.63 gm/cm^2.**

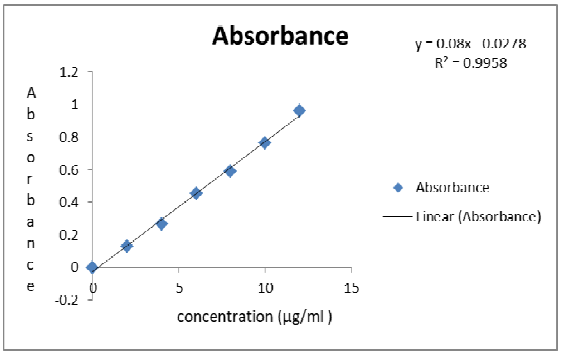

Fig 1: Standard graph of Bromperidol in pH 6.8 Phosphate buffer

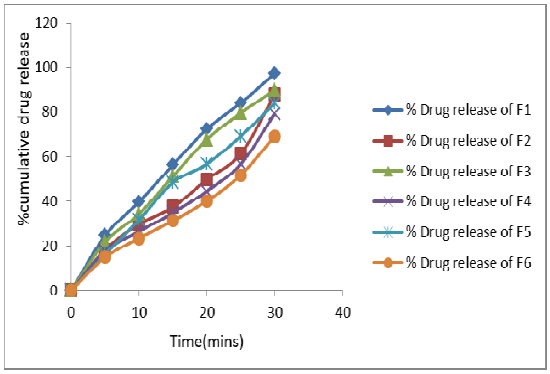

Fig 2: Dissolution graph of all formulations (F1-F6)

The prepared Bromperidol oral thin films were evaluated for In-vitro drug release studies, Among all the 6 formulations F1 formulation which contain HPMC E 15 had shown 97.2% cumulative drug release with in 30 min.

Table 1: Formulations of Bromperidol oral thin film

S.No	Ingredients	F1	F2	F3	F4	F5	F6
1	Drug(mg)	100	100	100	100	100	100
2	HPMC E 15 (mg)	50	100	---	---	---	---
3	HPMC E 5 (mg)	---	---	50	100	---	---
4	PVP K90	---	---	---	---	50	100
4	Propylene glycol(ml)	0.3	0.3	0.3	0.3	0.3	0.3
5	Citric Acid	0.1	0.1	0.1	0.1	0.1	0.1
6	Aspartame	0.1	0.1	0.1	0.1	0.1	0.1
6	Water	15ml	15ml	15ml	15ml	15ml	15ml

Table 2: Concentration and absorbance obtained for calibration curve of Bromperidol in (pH 6.8)

S. No.	Concentration (µg/ml)	Absorbance* (at 259 nm)
1	2	0.128
2	4	0.267
3	6	0.456
4	8	0.589
5	10	0.762

6	12	0.963

Table 3: Evaluation of Oral thin films by physical methods

Formulation	Thickness (mm)	Folding endurance	Drug content (%)	Moisture uptake (%)	Moisture content (%)	Weight variation
F1	0.3569	20	45	7.98	3.77	27.46
F2	0.3520	25	65	25.05	9.2	32.57
F3	0.3470	27	57.5	13.09	5.16	29.21
F4	0.3496	24	60	15.63	5.66	33.65
F5	0.3460	30	67.5	11.73	4.87	28.39
F6	0.3517	32	92.5	19.65	12.67	35.53

Table 4: *In-Vitro* Drug Release

Time (Min)	F1	F2	F3	F4	F5	F6
5	24.6	18.2	21.7	17.7	16.2	14.8
10	39.7	29.7	34.3	26.4	31.6	23.4
15	56.3	37.3	51.2	34.8	48.4	31.2
20	72.4	49.8	67.7	44.5	56.7	40.1
25	84.1	61.3	79.6	56.7	69.2	51.7
30	97.2	87.8	89.9	79.2	83.9	69.2

Table 5: Disintegration time

S.No	Disintegration Time (Sec)
F 1	39
F 2	47
F 3	43
F 4	56
F 5	59
F 6	68

4. Conclusion

In present study oral thin films of Bromperidol were developed to have a faster on set of action. The oral thin films were developed by using polymers HPMC E5, HPMC E 15 and PVP K90.Oral thin films were prepared by employing solvent casting method. Propylene glycol was selected as permeation enhancer and plasticizer. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. Formulations were prepared with the varying concentrations polymers ranging from F1-F6, and all the formulations were evaluated for various physical parameters Physical appearance, Weight variation, Thickness, Folding endurance, Tensile strength, Drug content, Moisture uptake, Moisture content and all the results were found to be were found to be within the pharmacopeial limits, invitro drug release studies by using dialysis membrane. Among all the 6 formulations F1 formulation which contain HPMC E15 50mg and shown 97.2.% cumulative drug release within 30 min. And compared to HPMC E15, HPMC E5 and PVP K90 , HPMC E 15 showed better drug release profile.

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