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Formulation and *In-vitro* Evaluation of Tropisetron Oral Thin Films

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A B S T R A C T

In present study oral thin films of Tropisetron were developed to have a faster on set of action. Among all the 6 formulations F1 formulation which contain HPMC E15 300mg and shown 98.2 % 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: Tropisetron, oral thin films

A R T I C L E I N F O

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1. Introduction

Oral medicated strips/films

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. A drug can be administered via a many different routes to produce a systemic pharmacological effect. The most common method of drug administration is via per oral route in which the drug is swallowed and enters the systemic circulation primarily through the membrane of the small intestine. The oral route of drug administration is the most important

method of administering drugs for systemic effect. The parenteral route is not routinely used for self–administration of medication. It is probable that at least 90 % of all drugs used to produce systemic effects are administered by the oral route. Tropisetron is an indole derivative with antiemetic activity. As a selective serotonin receptor antagonist, tropisetron competitively blocks the action of serotonin at 5HT3 receptors, resulting in suppression of chemotherapy-and radiotherapy-induced nausea and vomiting. Tropisetron appears to be well tolerated with the most frequently reported adverse effect being headache. Extrapyramidal side effects are rare upon using tropisetron.

2. Materials and Methods

Tropisetron, 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. Tropisetron, 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.

3. Results and Discussions

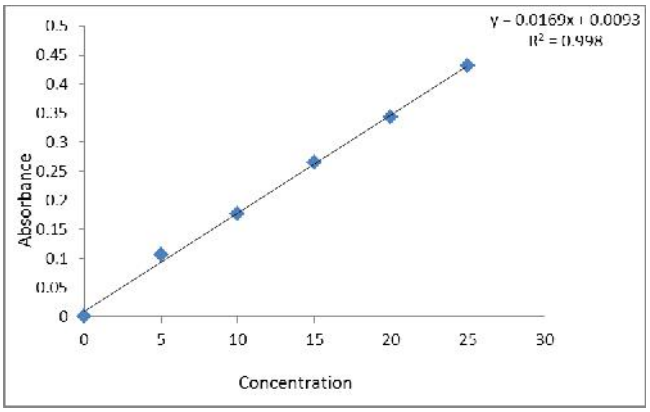

Figure 1: Standard graph of Tropisetron in pH 6.8 Phosphate buffer

Evaluation of Tropisetron 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 Tropisetron 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.

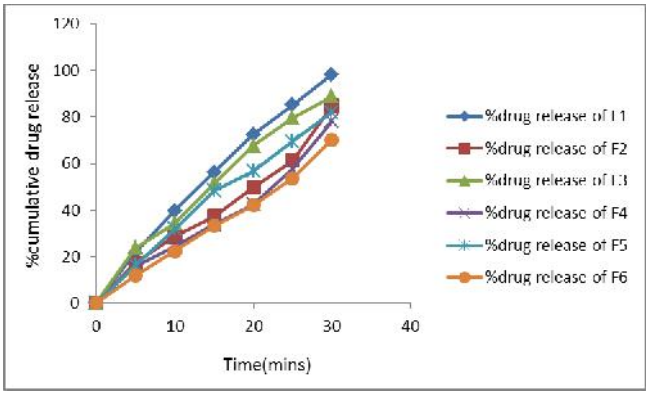

Figure 2: Dissolution graph of all formulations (F1-F6)

The prepared Tropisetron 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 98.2% cumulative drug release with in 30 min.

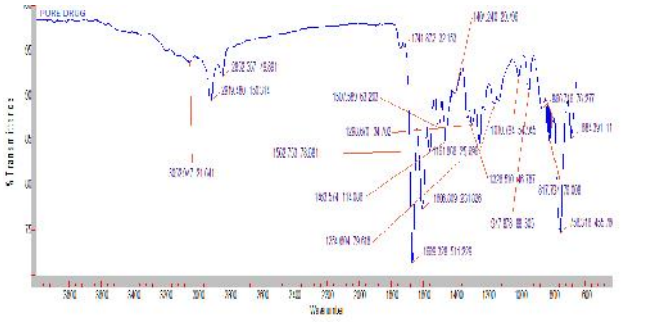

Figure 3: FT-IR Spectrum of pure drug

Figure 4: FT-IR spectrum of optimized formulation

Table 1: Formulations of Tropisetron oral thin film

S.No	Ingredients	F1	F2	F3	F4	F5	F6
1	**Drug(mg)**	50	50	50	50	50	50

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 Tropisetron in (pH 6.8)

S. No.	Concentration (µg/ml)	Absorbance* (at 259 nm)
1	5	0.106
2	10	0.177
3	15	0.265
4	20	0.344
5	25	0.431

Table 3: Evaluation of Oral thin films by physical methods

Formulation	Thickness (mm)	Folding endurance	Drug content (%)	Moisture uptake (%)	Moisture content (%)	Weight variation
F1	0.3563	20	46	7.92	3.77	27.46
F2	0.3420	26	66	23.16	9.2	32.57
F3	0.3570	25	58.5	12.08	5.16	29.21
F4	0.3696	25	59	15.63	5.66	33.65
F5	0.3560	29	66.5	11.73	4.87	28.39
F6	0.3517	31	91.5	18.65	12.67	36.53

Table 4: In-Vitro Drug Release

Time (Min)	F1	F2	F3	F4	F5	F6
5	21.6	17.2	23.7	15.7	16.3	11.8
10	39.7	28.7	34.3	24.4	31.7	22.4
15	56.3	37.3	51.2	33.8	48.3	33.2
20	72.4	49.8	67.7	42.5	56.76	42.1
25	85.1	61.3	79.6	57.7	69.5	53.7
30	98.2	84.8	88.9	78.2	82.1	70.2

Table 5: Disintegration time

S.No	Disintegration Time (Sec)
F 1	33
F 2	46
F 3	45
F 4	57
F 5	56
F 6	67

4. Conclusion

In present study oral thin films of Tropisetron 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, in-vitro drug release studies by using dialysis membrane. Among all the 6 formulations F1 formulation which contain HPMC E15 300mg and shown 98.2% 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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