Formulation and Evaluation of Taste Masked Oral Disintegrating Films of Tolterodine Tartarate

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ABSTRACT

Tolterodine tartarate is a widely used antimuscarinic agent that is used in the treatment of urinary incontinence. This study includes the formulation and evaluation of Oral Disintegrating Films of Tolterodine tartarate, which helps in obtaining the better dissolution rate, quick onset of action and improving the patient compliance. Tolterodine ODF were prepared by solvent casting method using water soluble polymers like HPMC E15, HPMC 5cps and HPMC 50cps in different ratios. These prepared films were evaluated for in-vitro disintegration time, film thickness, drug content, in-vitro drug release etc. Based on the results, the formulation containing HPMC E15 in 1:5 ratio was found to be as the best formulation. The in-vitro disintegration time was 20.02±0.32 sec and a drug release was found to be 99.61± 0.23 % in 15 minutes.

Keywords: HPMC, Oral disintegrating films, Tolterodine.

INTRODUCTION

Tablets, capsules and other oral solid dosage forms offer difficulty in swallowing for most of the pediatric and geriatric patients. Hence, an alternative for solid dosage forms like fast dissolving films, is in need. Oral disintegrating film or strip is a dosage form, when placed on the tongue or oral cavity dissolves quickly in saliva, and disintegrates within seconds, dissolves and releases the drug for oro-mucosal absorption. This stands good for the drugs which undergo the first pass metabolism extensively [1,2].

Oral drug delivery technology has improved from conventional dosage forms to modified release dosage forms to oral disintegrating tablet to the recent development of oral disintegrating films (ODF). Oral disintegrating film or strip can be defined as a dosage form, when placed on the tongue or oral cavity employs a water dissolving polymer which allows the dosage form to quickly hydrate by saliva, adhere to mucosa, and disintegrates within seconds, dissolves and releases the drug for oromucosal absorption[3,4,5]. Due to thin membrane and large veins, the sublingual mucosa is relatively permeable and because of its high blood flow it gives rapid absorption and instant bioavailability of drugs [6,7, 8]. Present study involves the formulation and evaluation of oral disintegrating films of Tolterodine tartarate.

Tolterodine tartarate is a competitive antagonist at muscarinic receptors. This causes the inhibition of bladder contraction, decrease in detrusor pressure, and an incomplete emptying of the bladder. The main effects of tolterodine includes increase in residual urine, reflecting an incomplete emptying of the bladder, and a decrease in detrusor pressure, consistent with an anti-muscarinic action on the lower urinary tract. It is used for the treatment of overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence.

Fast disintegrating films are formulated using film forming polymers. All excipients used in these formulations should be Generally Regarded as Safe (i.e. GRAS-listed) [9, 10] and should be approved for use in oral pharmaceutical dosage forms. Water dissolving polymers like Hydroxy Propyl Methyl Cellulose E15, 5cps and

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50 cps etc. are used in the formulation of films. These films are formulated using solvent casting technique. In solvent casting technique the excipients are dissolved in water, then water soluble polymers are added in it and lastly drug is added and this mixture is stirred to form homogeneous solution. Finally solution is casted in to the petri plate and dried.

MATERIALS AND METHODS

Materials

Tolterodine tartarate was obtained as a gift sample from Hetero Drugs Pvt. Ltd., Hyderbad. Hydroxy propyl methyl cellulose was obtained from Qualikem Fine Chem. Pvt. Ltd., Vadodara. Polyethylene glycol 400 from SD Fine Chemicals Ltd, Mumbai, Sodium saccharine from Oxford Laboratories, Mumbai.

Method

Preparation of Oral Disintegrating Films of Tolterodine:

The oral dissolving films of Tolterodine tartarate using polymers were prepared by solvent casting method. Hydroxy Propyl Methyl Cellulose (HPMC) with different grades such as HPMC 5 cps, 50 cps, and E15 are known for their good film forming properties. Weighed quantity of HPMC E15/ 50 cps/ 5 cps was taken in a boiling tube. To this, 7 ml of water was added and vortexed, care should be taken to prevent the formation of lumps. The boiling tube was kept aside for 3 hours to allow the polymer to swell. After swelling, a weighed quantity of Tolterodine tartarate was dissolved in 5ml of water, then polymer solution and mixed thoroughly. Finally measured quantity of Poly ethylene glycol 400 was added to this mixture and vortexed. This was kept aside for some time in order to exclude any entrapped air bubbles and was then transferred into a previously cleaned anumbra petriplate. These films were dried in a dessicator. These dried films were carefully removed from the petriplate, checked for any imperfections and cut to the required size to deliver the equivalent dose (2×2 cm^2) per strip. Film samples with air bubbles, cuts, or imperfections were excluded from the study.

Table 1: Formulation codes of ODF

Formulation code	Polymer used	Drug polymer ratio
F1 F2 F3 F4 F5	HPMC-E15 HPMC-E15 HPMC-E15 HPMC-E15 HPMC-E15	1:1 1:2 1:3 1:4 1:5
F6 F7 F8 F9 F10	HPMC-5cps HPMC-5cps HPMC-5cps HPMC-5cps HPMC-5cps	1:1 1:2 1:3 1:4 1:5
F11 F12 F13 F14 F15	HPMC-15cps HPMC-15cps HPMC-15cps HPMC-15cps HPMC-15cps	1:1 1:2 1:3 1:4 1:5

Evaluation of Oral Disintegrating Films:

Various quality control tests were performed for all the formulations.

Weight variation test

Twenty films were randomly selected from each formulation and their average weight was calculated using

digital balance. Individual weight of each film was also calculated using the same and compared with the average weight.

Thickness measurement

Randomly 10 films were taken from each formulation and their thickness was measured using a digital screw gauge. The individual film was placed between two anvils of the screw gauge and sliding knob was rotated until the film was tightly fitted. The digital reading displayed was noted.

Assay

Five films were randomly selected, weighed and added to 100 ml of phosphate buffer (6.8 pH) in a conical flask. Conical flask was placed on a sonicator for 30 min. An aliquot of solution was centrifuged and supernatant was filtered through a 0.22 µ filter. Absorbance of the resulted supernatant solution was measured using UV Visible spectrophotometer at 216 nm. Absorbance were measured and amount of drug present in the formulation was calculated.

In vitro disintegration studies

The film as per the dimensions (2 × 2 cm^2) required for dose delivery was placed in a petri dish containing 10ml of phosphate buffer (6.8 pH). The time required for the film to break was noted as in vitro disintegration time.

In vitro dissolution test

Method: Drug release from ODFs was studied by dissolution apparatus. ODFs of desired formulations were taken and placed in the vessels of dissolution apparatus. Samples were collected from the vessels at different time intervals, replenished with same volume of the blank solution and analyzed using UV – visible spectrophotometer. Drug concentration was calculated from the standard graph and expressed as % of drug dissolved or released. The release studies were performed in 3 replicates and mean values were taken.

RESULTS AND DISCUSSION

The Oral disintegrating films were prepared by solvent casting technique using HPMC – E15, HPMC – 5cps, HPMC – 50cps. The strips were evaluated for drug content, film thickness, *in vitro* disintegration time and *in vitro* dissolution studies.

Drug content

Assay was performed and percent drug content of F5, F10 and F15 was found to be 98±0.86%,

97.5±0.73% and 97.25±0.95% of Tolterodine tartarate, which was within the acceptable limits.

Film thickness

All the batches were evaluated for thickness using screw gauge. As all the formulations contain different amount of polymers, hence the thickness was gradually increased with the amount of polymers. All the batches were found to have thickness in range of 0.50 to 0.58mm.

In vitro disintegration time

Disintegration test was performed for all the batches and the disintegration time was recorded less than 23 sec for all batches. The disintegration time of formulation F5 containing HPMC – E15 was found to be lower (20.02 sec) and was selected as the best ODF formulation among the other formulations.

In vitro dissolution studies

In vitro dissolution studies of the prepared ODFs was performed in pH 6.8 phosphate buffer using USP dissolution apparatus type 2. Results showed all the batches release more than 90% of drug within 8 min. Formulations F5, F10 and F15 have shown drug release of 99.61±0.23%, 97.56±0.42 and 98.77±0.26 respectively, at the end of 15 min.

Among the ODF formulations prepared by HPMC – E15 (F5), HPMC – 5cps (F10), HPMC – 50cps (F15), formulation F5 was found to be best formulation because it disintegrates within 20.02 sec and it showed 99.61±0.23% drug release within 15 min.

Table **2:** Formulae of Tolterodine ODF prepared by Solvent Casting Method with various polymers in different ratios

Ingredients	**F1**	**F2**	**F3**	**F4**	**F5**
Tolterodine(mg)	34.13	34.13	34.13	34.13	34.13
HPMC- E15 (mg)	34.13	68.26	102.39	136.52	170.65
Poly Ethylene Glycol – 400 (mL)	0.125	0.25	0.125	0.25	0.125
Orange flavour (mg)	10	10	10	10	10
Sodium saccharin (mg)	10	10	10	10	10
Water (mL)	12	12	12	12	12
Ingredients	**F6**	**F7**	**F8**	**F9**	**F10**
Tolterodine(mg)	34.13	34.13	34.13	34.13	34.13
HPMC 5cps(mg)	34.13	68.26	102.39	136.52	170.65
Poly Ethylene Glycol – 400 (mL)	0.125	0.25	0.125	0.25	0.125
Orange flavour (mg)	10	10	10	10	10
Sodium saccharin (mg)	10	10	10	10	10
Water (mL)	12	12	12	12	12
Ingredients	**F11**	**F12**	**F13**	**F14**	**F15**
Tolterodine(mg)	34.13	34.13	34.13	34.13	34.13
HPMC 50 cps (mg)	34.13	68.26	102.39	136.52	170.65
Poly Ethylene Glycol – 400 (mL)	0.125	0.25	0.125	0.25	0.125
Orange flavour (mg)	10	10	10	10	10
Sodium saccharin (mg)	10	10	10	10	10
Water (mL)	12	12	12	12	12

All batches were casted on Petri plate to provide 15 strips with dimension 2 × 2 cm^2 after drying.

Table **3:** Mean weight, Mean thickness, Disintegration time and Assay of Tolterodine ODF formulations

Formulation Code	**Mean weight(mg)**	**Mean thickness(mm)**	**Disintegration time(sec)**	**Assay(%)**
F5	25± 0.42	0.50± 0.23	20.02±0.32	98±0.86
F10	26± 0.53	0.56± 0.23	22±0.21	97.5±0.73

F15	26.8± 0.32	0.58± 0.23	22.5±0.32	97.25±0.95

Table **4:** Cumulative percent release of Tolterodine tartarate ODF formulations

Time(min)	Cumulative % release of Tolterodine tartarate ODF formulations		
	F5	**F10**	**F15**
2	78.28±0.31	53.41±0.27	45.74±0.52
4	89.32±0.42	68.47±0.23	72.72±0.41
6	92.51±0.52	82.43±0.81	79.43±0.42
8	95.62±0.82	90.23±0.42	91.44±0.17
10	99.73±0.72	95.41±0.35	95.31±0.22
15	99.61±0.23	97.56±0.42	98.77±0.26

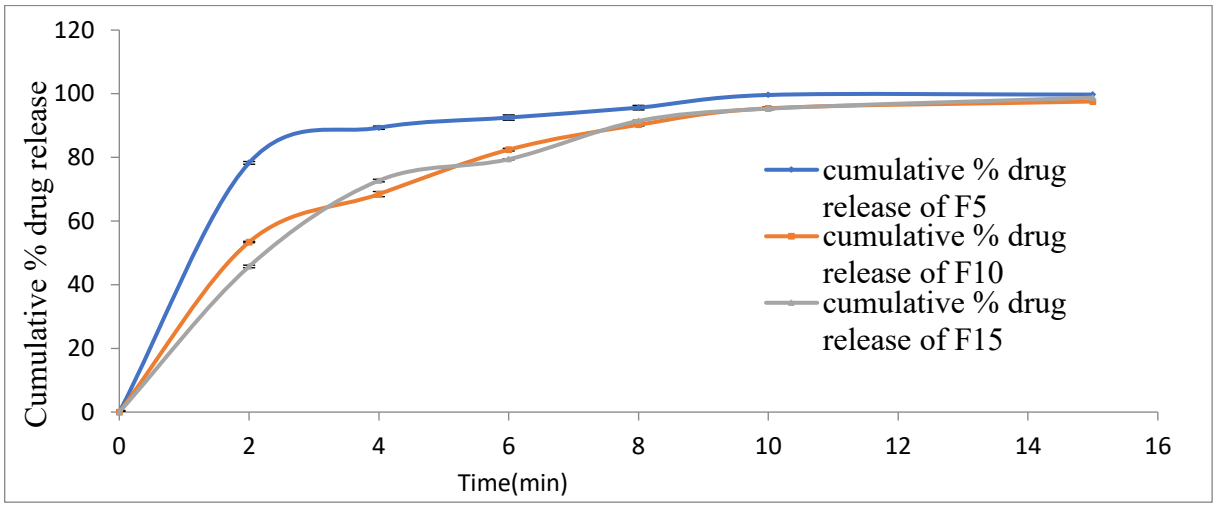

Figure 1: Graphical representation of Cumulative Percent Release of Tolterodine tartarate ODF formulations

Table **5:** Comparison of disintegration times of different formulations of ODFs

Formulation Code	Disintegration Time (sec)
F5	20.2±0.32
F10	22±0.21
F15	22.5±0.32

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Figure **2:** Graphical representation of comparison of disintegration times of different formulations of ODFs

Fourier Transform Infrared Spectroscopy (FTIR) Studies

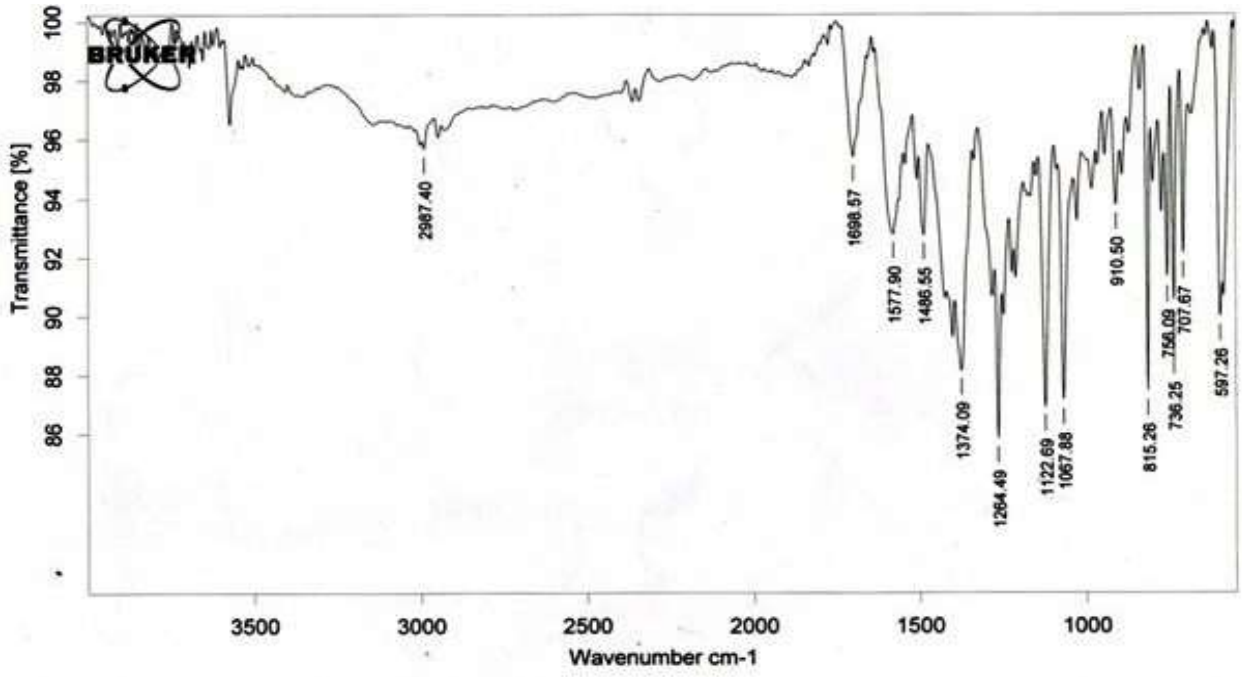

Figure 3: FTIR spectra of Tolterodine Tartrate

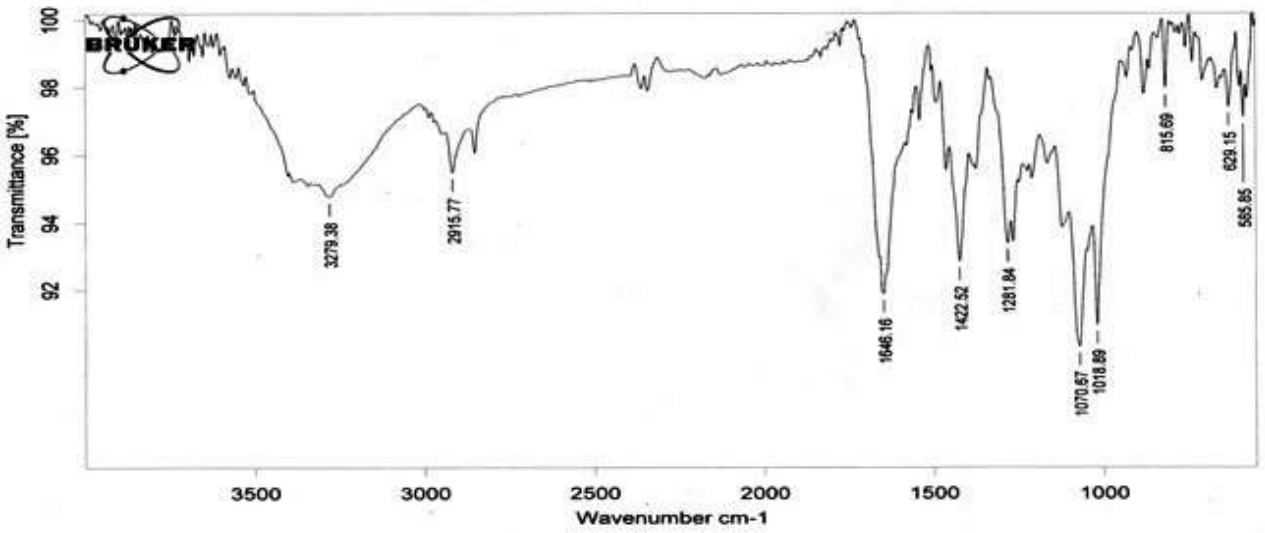

Figure 4: FTIR spectra of optimized formulation

Table **6:** Peaks of Functional groups of Tolterodine tartarate along with the excipients

IR Spectra	Peak of Functional groups [Wave length (cm-1)]				
	C-H Stretching (Alkane)	C=O Stretching (Phenols)	C-O Stretching (ester)	C=C Stretching (aromatic)	C-N Stretching (amide)
Tolterodine Tartarate	2987.40	1698.57	1264.49	3210.67	1122.69
Optimised ODF formulation	2915	1680	1210	3277	1076

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The above peaks were considered as characteristics peaks of Tolterodine tartarate. These peaks were not affected and prominently observed in IR spectra of drug and excipients. This indicates that there is no interaction between the drug and excipients.

Taste Masking:

Eight volunteers were selected to check out whether the bitter taste of Tolterodine tartarate in the formulated ODFs has been masked or not. Each volunteer was given a single film randomly, and asked for the extent of taste masking and mouth feel. The report was as follows:

Table **7:** Taste and Mouth feel test on different volunteers

S.No	Formulation code	Taste				Mouth feel			
		V1	V2	V3	V4	V5	V6	V7	V8
1	F5	++	++	++	++	++++	++++	++++	++++
2	F10	++	++	++	++	+++	++++	++++	+++
3	F15	++	++	++	++	+++	+++	+++	++++

NOTE:

F : Formulation code

V : Volunteer

++++ : Pleasant

+++ : Unpleasant

++ : Very good

+ : Good

Based on the above results, the ODF formulation F5, containing HPMC E15 as a polymer, Sodium saccharin as a sweetening agent and Orange as a flavouring agent was found to have very good taste with a pleasant mouth feel.

CONCLUSION

Tolterodine tartarate Oral Disintegrating Films were prepared by solvent casting method using different grades of Hydroxy Propyl Methyl Cellulose like E15, 5cps and 50cps. FTIR study showed no drug excipient interaction. Among these formulations, formulation F5 exhibited faster disintegration time (20.02sec) than formulations F10 and F15. Results showed that all the batches of ODF formulations released more than 90% of drug within 8 min. Moreover the formulation F5 showed 99.61±0.23 % drug release at the end of 15 min and it also resulted in a very good taste along with a pleasant mouth feel. Hence the ODF, formulated with HPMC E15 (F5) was found to be as the best formulation. Based on the disintegration and dissolution results it was concluded that the formulation F5 contained HPMC E15, Sodium saccharin as a sweetner, and Orange as a flavor was the best formulation among the all ODF formulations.

Future Scope:

By offering a quick-disintegrating, pleasant dosage form without the need for water, taste-masked oral disintegrating films of tolterodine tartrate have the potential to improve patient compliance, particularly in elderly and dysphagic patients. Advanced taste-masking methods, in-vivo bioavailability and pharmacokinetic assessment, and the development of in-vitro–in-vivo correlation can all be the subject of future research. Commercial potential can be increased through optimization employing QbD techniques, long-term stability tests, and scale-up viability. For better treatment of overactive bladder, this delivery method may also be expanded to include combination therapy or customized dose.

Conflict of interest: No financial interest held by any of the authors of this work has affected the findings or interpretation of this work.

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