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DESIGN, FORMULATION AND EVALUATION OF BUCCOADHASIVE FAST DISSOLVING ORAL FILMS CONTAINING 5-HT3 RECEPTOR ANTAGONIST DRUG

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ABSTRACT
Oral route is most preferred route by medical practitioners and manufacturer due to highest acceptability of patients. About 60% of all dosage forms available are the oral solid dosage form. The lower bioavailability, long onset time and dysphagia patients turned the manufacturer to the Parenterals and liquid orals. Fast dissolving oral films (FDOFs) are the most advanced form of oral solid dosage form due to more flexibility and comfort. It improves the efficacy of APIs by dissolving within minute in oral cavity after the contact with saliva without chewing and no need of water for administration. It gives quick absorption and instant bioavailability of drugs due to high blood flow and permeability of oral mucosa is 4-1000 times greater than that of skinFast dissolving Oral film of Granisetron Hydrochloride was formulated by using solvent casting method with different concentrations of HPMC-E3, E6 and E15. Film forming property of various grades of HPMC was investigated based on preliminary characteristics of various batches of FDOFs. Formulations with HPMC E3 were not evaluated for other physical parameters due to their poor film forming ability, tack property and ease of handling or peeling. The bitter taste of the drug was masked by Aspartame and Vanilla flavour. Formulations with HPMC E6 and E15 were evaluated for their physical characteristics, thickness, folding endurance, tensile strength, disintegration time, drug content uniformity and drug release characteristics. Dissolution studies were performed for FDOFs excluding batches that showed poor film forming property. Among the prepared formulations F9 showed minimum disintegration time 12 sec. Formulation F9 released 97.8% of drug within 8 min when compared to the other formulations. Based on the physicochemical properties like tensile strength, folding endurance, thickness, disintegration results and dissolution studies, it was concluded that F9 finalized as optimized formulation. DSC and FTIR data revealed that no interactions takes place between the drug and polymers used in the optimized formulation. The *in vitro* dissolution profiles of marketed product and optimized formulation was compared and found to be the drug.

INTRODUCTION
Oral route is most preferred route by medical practitioners and manufacturer due to highest acceptability of patients. About 60% of all dosage forms available are the oral solid dosage form. The lower bioavailability, long onset time and dysphagia patients turned the manufacturer to the Parenterals and liquid orals. Fast dissolving oral films (FDOFs) are the most advanced form of oral solid dosage form due to more flexibility and comfort. It improves the efficacy of APIs by dissolving within minute in oral cavity after the contact with saliva without chewing and no need of water for administration. It gives quick absorption and instant bioavailability of drugs due to high blood flow and permeability of oral mucosa is 4-1000 times greater than that of skin.

The concept of oral dissolving film
This system has a thin-film. When placed on tongue, immediately it dissolves within few seconds (sec) therefore avoids first- pass metabolism, hence increase bioavailability of drug.

Accessibility of larger SA leading quick disintegration & dissolution in mouth. FDFs dissolves in mouth as a cotton candy.

Methodology- Preparation of Granisetron Hydrochloride films

It was aimed to prepare to Fast Dissolving Oral Films of Granisetron Hydrochloride whose dose was 1.12mg per 4cm2 film. The procedure was carried out on a digital magnetic stirrer using a medium sized magnetic bead. Film forming polymers hypromellose and maltodextrin were weighed accurately, added to a small amount of water in a small beaker, covered with an aluminium foil and soaked for 24 hours to ensure complete hydration. Xanthan gum was added the next day in small amounts and the solution was stirred on a magnetic stirrer at 75rpm amounts and the solution was stirred on a magnetic stirrer at 75rpm 51 for first half an hour and later 50rpm for 1.5 hours. Then, propylene glycol was added and stirring continued for 30min at 50rpm. Granisetron Hydrochloride drug, Aspartame, citric acid, vanillin and amaranth were dissolved in sufficient quantity of water and added to the polymer mixture. This film forming solution then stirred well to obtain a homogenous solution. Dry and clean petri dish was selected and the solution was poured into it. Drying was carried out at 45ºC in a hot air oven for 6 hours. The Petri dish was then removed and left aside to cool down to room temperature. The film was then peeled carefully using a surgical scalpel by making a small incision in the film on one side of the Petri dish. Small films of 4cm2 were cut from one big film and packed primarily in a aluminium foil and secondarily in a self-sealing polythene to ensure least moisture penetration. The formulation was carried out using three different polymers, Hypromellose E3, E6 and E15 and the resulting films were evaluated.

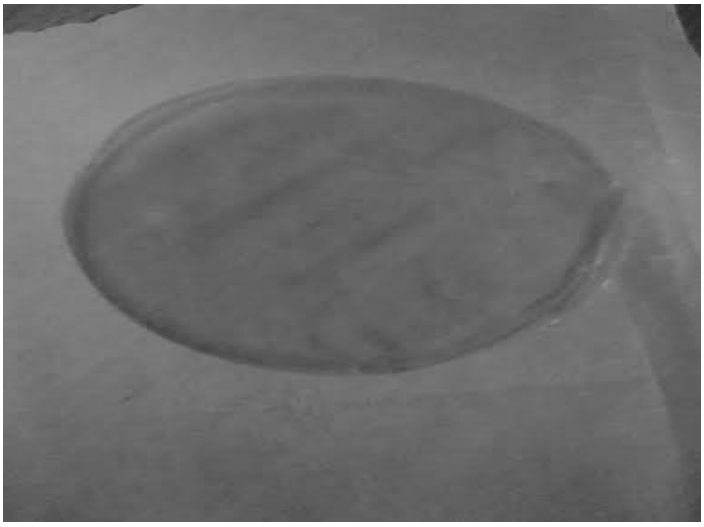

Figure 1: Granisetron Hydrochloride film.

Table 1: Formulation Trails Using (HPMC-E3).

FORMULATION CODE & INGREDIENTS	F1	F2	F3	F4
GRANISETRON HYDROCHLORIDE (mg)	17.92	17.92	17.92	17.92
HPMC E3(mg)	225	250	275	300
MALTODEXTRIN (mg)	130	120	110	100
XANTHAN GUM (mg)	10	10	8	8
ASPARTAME (mg)	20	20	20	20
AMARANTH	Q. S	Q.S	Q. S	Q. S
PROPYLENE GLYCOL	50	60	70	80
CITRIC ACID (mg)	10	10	10	10
WATER	Q.S	Q.S	Q.S	Q.S
VANILLA	Q.S	Q.S	Q.S	Q.S

Table 2: Preparation Trails By means of HPMC-E6.

FORMULATION CODE/ INGREDIENTS	F5	F6	F7	F8	F9	F10	F11	F12
GRANISETRON HYDROCHLORIDE (mg)	17.92	17.92	17.92	17.92	17.92	17.92	17.92	17.92
HPMCE6 (mg)	200	210	220	230	240	250	260	270
MALTODEXTRIN (mg)	180	180	170	170	160	160	150	150
XANTHANGUM (mg)	10	10	8	8	8	6	6	6
GLYCERINE (mg)	70	70	80	80	90	90	100	100
ASPARTAME(mg)	20	20	20	20	20	20	20	20
CITRIC ACID(mg)	10	10	10	10	10	10	10	10
WATER (ml)	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
VANILLA	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
AMARANTH	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Table 3: Formulation trails using HPMCE15.

FORMULATION CODE & INGREDIENTS	F13	F14	F15	F16	F17	F18
GRANISETRON HYDROCHLORIDE (mg)	17.92	17.92	17.92	17.92	17.92	17.92
HPMCE15 (mg)	170	180	190	200	210	220
MALTODEXTRIN (mg)	190	180	170	170	160	150
XANTHANGUM (mg)	10	8	7	6	5	5
GLYCERINE (mg)	90	100	100	110	110	100
ASPARTAME(mg)	20	20	20	20	20	20
CITRIC ACID(mg)	10	10	10	10	10	10
WATER (ml)	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
VANILLA	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
AMARANTH	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

RESULTS AND DISCUSSION

Calibration curve of Granisetron Hydrochloride

Absorption spectrum of Granisetron-Hydrochloride

λmax was found to be 302nm in SHIMADZU UV- 1800 spectrophotometer.

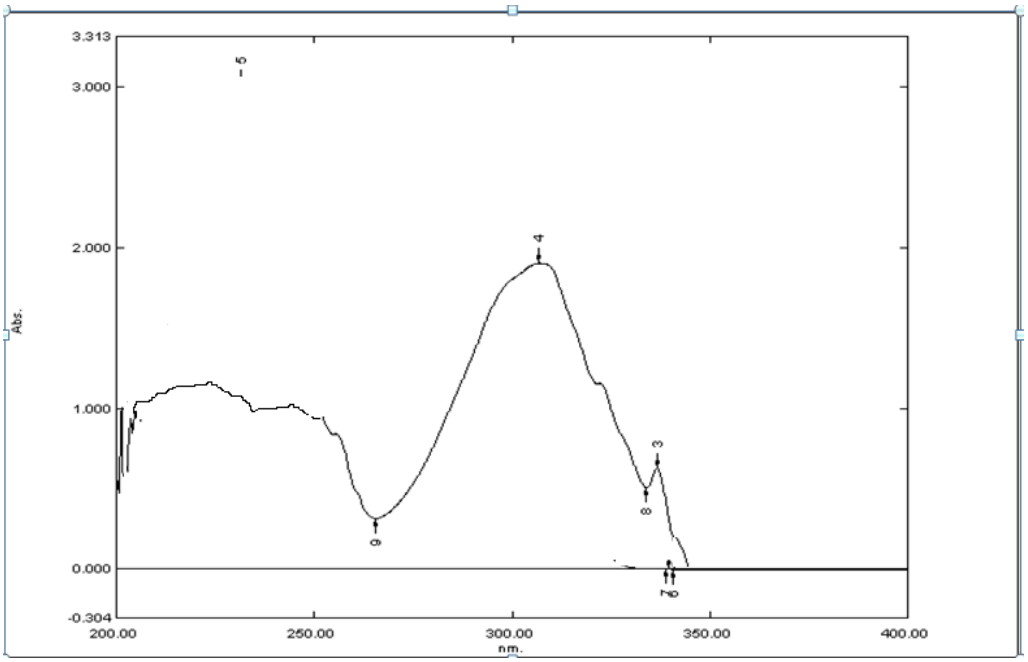

Figure 2: UV Spectrum of Granisetron Hydrochloride (2- 10µG/ML).

Table 4: Standard graph of Granisetron Hydrochloride.

Concentration(µg/ml)	Absorbance(308nm)
0	0
2	0.144
4	0.280
6	0.423
8	0.560
10	0.679

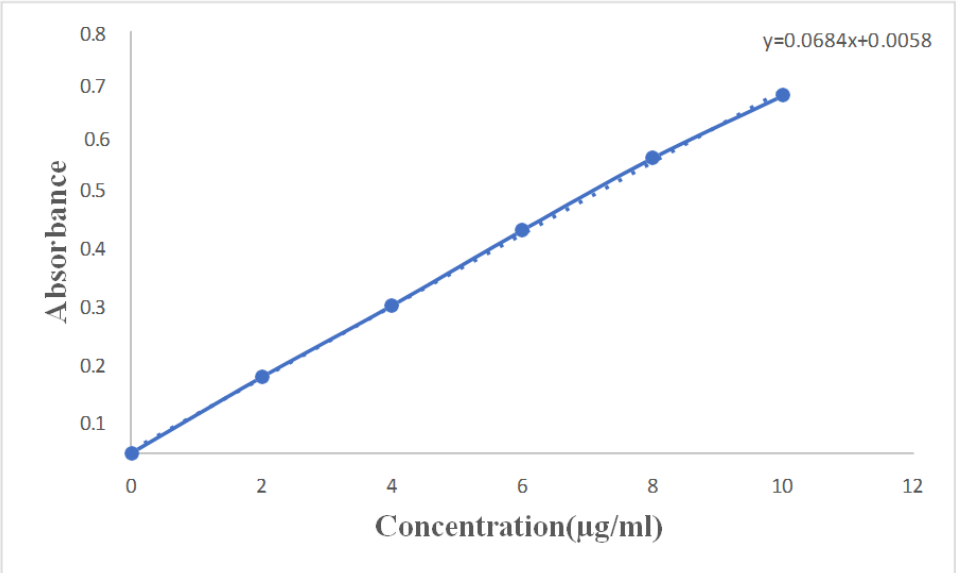

Figure 3: Standard Graph of Granisetron Hydrochloride (1- 10µg/ml).

Preliminary characterization of FDOFs

Physical characterization of FDOFs was carried out by visual inspection and the following was observed.

1. The films were evenly coloured and no migration of colour was observed.
2. F1 to F3, F5 to F10, F13 to F15 films with more

HPMC were foundto be thick.

3. F1 to F3, F5 to F8, F13 were found to be brittle in nature and difficult to peel whereas others separated easily.
4. Increased opacity and decreased transparency is due to increase in the amount of maltodextrin proportionately to HPMC. Slightly opaque and opaque formulations were found to be F6 to F8, F13 and F14.
5. The films obtained from all the formulations had smooth surface on either side.
6. F4,F8, F10, F14 were found to have more tackiness which indicates that the physical handling of these films is difficult. Also, soft films as in F14 and F18 are difficult to handle.

Because of poor film forming property of formulations F1-F4 did not proceed further.

Table 5: Preliminary Characteristics of Formulations F1-F18.

Code & properties	Film property	Tack property	Ease of handling
F1	Poor	Non-tacky	Thick & brittle
F2	Poor	Non-tacky	Slightly thick & brittle
F3	Poor	Non-tacky	Slightly thick & brittle
F4	Poor	Non-tacky	Thin, brittle, difficult to peel
F5	Average	Non-tacky	Brittle
F6	Average	Non-tacky	Brittle, opaque
F7	Average	Non-tacky	Opaque, easy-peel
F8	Average	Tacky	Thick, easy peel
F9	Excellent	Non-tacky	Thin, easy for peel
F10	Good	Tacky	Thick, easy to peeling
F11	Excellent	Non-tacky	Thin, peeling is easy
F12	Good	Non-tacky	Thin, peeling was easy
F13	Poor	Non-tacky	Brittle
F14	Good	Non-tacky	Easy to peel
F15	Good	Non-tacky	Opaque, easy to peel
F16	Excellent	Non-tacky	Thin, peeling makes easy
F17	Excellent	Non-tacky	Thin, easy to peel
F18	Good	Non-tacky	Soft, thick, easy to peelability

In vitro quality control tests

Table 6: In Vitro quality control tests (mean±SD n=3).

CODE	Thickness (µm)	Weight variation (mg)	Folding Endurance (Count)	Surface pH	Content uniformity/ Assay (%)	In vitro Disintegration Time (sec)
F5	74±2	57.14±0.6	58±2	6.55±0.03	98.8±0.2	25±2
F6	75±1	52.22±0.1	54±2	6.74±0.01	92.44±0.46	24±2
F7	80±3	58.4±0.1	62±1	6.54±0.011	89.65±0.14	30±2
F8	82±2	60.2±0.1	64±4	6.6±0.02	95.5±0.2	22±2
F9	84±2	65.55±0.3	106±4	6.97±0.11	99.8±0.1	09±2
F10	88±1	62.55±0.1	70±1	6.88±0.01	98.7±0.8	18±2
F11	86±2	70.5±0.3	95±4	6.93±0.02	86.7±2.2	14±2
F12	80±1	71.5±0.5	86±3	6.89±0.010	97.32±0.3	20±2
F13	87±0	73.5±0.4	93±1	6.92±0.01	98.7±0.1	18±2
F14	91±1	79.2±0.3	96±2	6.95±0.01	98.7±1.6	23±2
F15	88±0	82.1±0.4	86±5	6.67±0.01	92.4±0.6	18±2
F16	85±2	80.2±0.3	90±2	6.93±0.02	96.7±2.2	15±2
F17	87±1	84.3±0.1	96±1	6.94±0.01	98.6±0.45	14±2
F18	88±1	86.0±0.3	98±1	6.89±0.03	97.7±0.55	18±2

The present invention identifies that the HPMC grades is one of the best water-soluble polymer and best used for the preparation of fast Release drug delivery systems, as the concentration of the HPMC increases the disintegration time decreases.

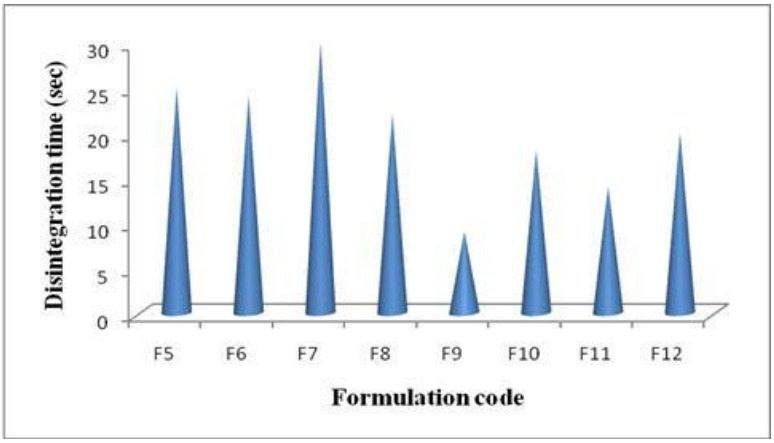

Figure 4: In vitro disintegrating time of HPMC E6 formulations.

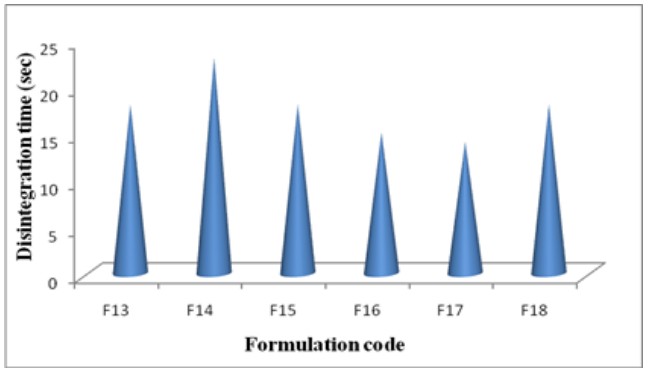

Figure 5: In vitro disintegration time of HPMC E15 formulations.

Tensile Strength & Percent Elongation

Tensile strength test was performed for selected formulations that are more like optimized formulation.

Table 7: Tensile Strength & Percent Elongation (mean±SD n=3).

FORMULATION CODE	TENSILE STRENGTH (g/cm2)	PERCENT ELONGATION(%)
F9	11.6±0.27	9.8±0.21
F11	9.6±0.91	8.2±0.16
F16	9.7±0.19	8.1±0.71
F17	10.7±0.31	9.3±0.50

In vitro dissolution studies

Table 8: Cumulative Percent Drug Release for HPMC E6 (mean ±SD n =3).

FORMULATION CODE TIME(MINUTES)	F5	F6	F7	F8
0	0	0	0	0
1	12.3±1.2	17.8±2.4	23.3±1.1	25.5±2.4
2	22.9±1.0	28.3±1.2	38.9±3.4	40.8±1.0
4	40.2±2.2	42.3±1.0	55.6±1.0	60.6±1.7
6	56.9±1.3	58.7±2.4	67.7±2.3	82.3±1.5
8	73.8±1.2	72.5±1.0	85.2±2.2	90.1±1.1
10	80.2±2.2	82.3±1.6	90.2±2.2	90.1±1.0

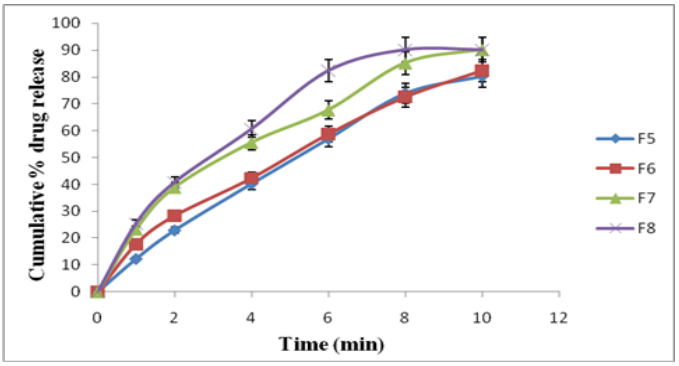

Figure 6: Cumulative Percent Drug Release for HPMC E6, F5-F8.

Table 9: Cumulative % Drug-Release for HPMC E6 (mean± SDn=3).

TIME(MINUTES)& FORMULATION CODE	F9	F10	F11	F12
0	0	0	0	0
1	27.3±1.6	24.35±1.24	30.1±1.2	42.5±2.3
2	43.9±2.3	35.8±1.62	42.5±1.23	63.5±1
4	65.05±2.5	53.55±2.27	63.6±2.35	78.9±0.22
6	88.5±1.7	73.4±3.2	81.1±1.22	85±1.22
8	97.8±1.34	95.8±2.5	94.5±2.4	94.1±0.34
10	98.6±2.55	95.6±2.0	96.6±2.33	95.2±2.4

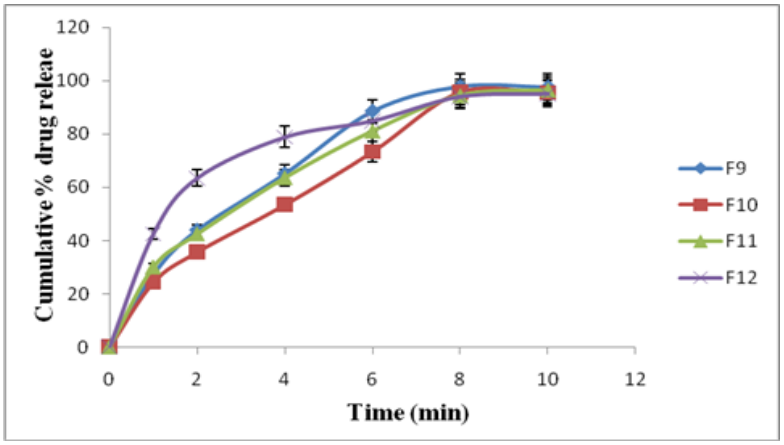

Figure 7: Cumulative % of Drug Release for HPMC E6,F9-F12(mean± SD n=3).

Table 10: Cumulative percentage Drug Release for HPMC E15(mean± SD n=3).

Time(Min) & Formulation Code	F13	F14	F15	F16	F17	F18
0	0	0	0	0	0	0
1	34.45±0.3	36.6±3.01	40.04±2.8	42.2±0.98	40.04±2.33	39.0±3.45
2	47.4±1.33	38.0±1.25	56.48±1.25	52.9±3.4	56.48±1.4	57.5±0.5
4	58.25±1.7	40.5±1.2	66.85±2.21	67.7±3.5	66.85±0.45	68.6±2.45
6	66.47±2.99	59.6±1.88	75.65±0.96	84.5±0.5	85.2±1.45	83.0±1.2
8	75.77±3.67	77.8±2.3	82.6±1.48	95.3±2.3	97.2±1.44	96.3±1.5
10	89.3±1.2	90.3±2.67	93.2±1.88	95.0±1.99	97.2±1.44	96.3±1.5

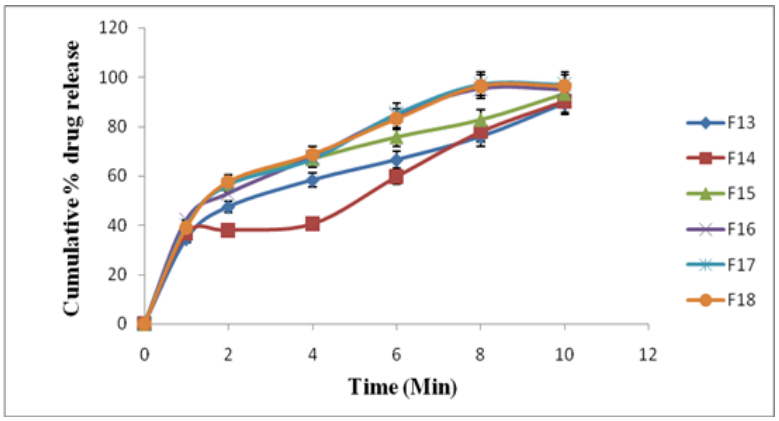

Figure 8: Cumulative Percent Drug Release for HPMC E15,F13- F18.

In vitro dissolution studies for the all formulated films were carried out byusing 900ml of phosphatebufferp H6.8 maintained 37±05°C 5ml at 50rpm speed. The aliquot was withdrawn at the specific time intervals, filtered through Whatman filter paper and analysed by spectrophotometer at 302 nm. The dissolution studies was studied in two different batches F5 to F12 and F13 to F18. As the concentration of HPMC concentration increases the percentage drug release was greater.

Comparison of optimized formulation with Marketed product From above studies F9was found optimum for formulation of Granisetron Hydrochloride FDOFs. Thus, cumulative drug release studies of F9 formulation was compared with the marketed product.

Table 11: Comparison of Cumulative Drug Release of F9 with Marketed Product.

Time(min) & Formulation code	1	2	4	6	8	10
F9	27.3±1.6	43.9±2.3	65.05±2.5	88.5±1.7	97.8±1.34	98.6±1.5
Marketed Product	20.8±0.5	35.5±1.2	48.0.5±1.0	61.0±0.5	70.8±1.4	78.5±2.22

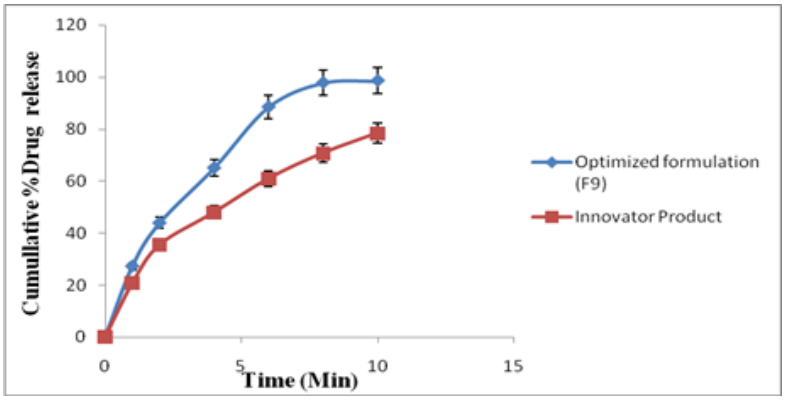

Figure 9: Comparison of Cumulative drug release of F9 with Marketed Product.

Release Order Kinetics models of Optimized Formulation(F9) of Granisetron HCl

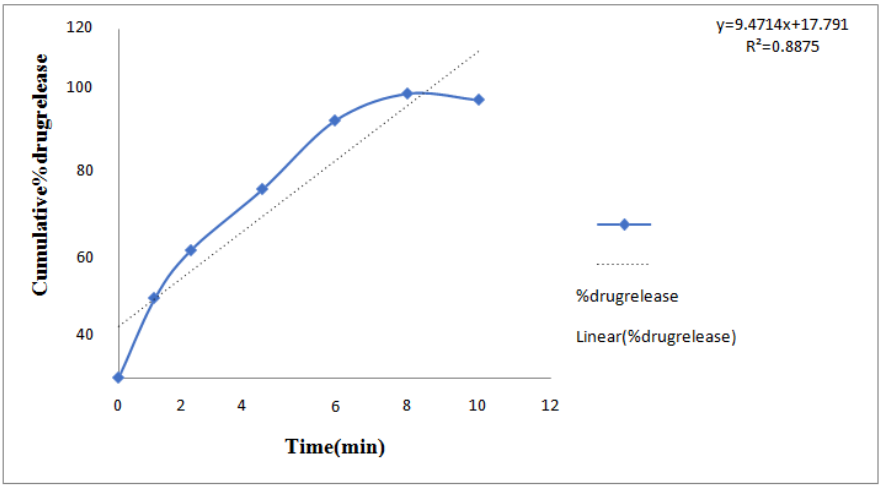

Figure 10: Zero order of Optimized Formulation (F9).

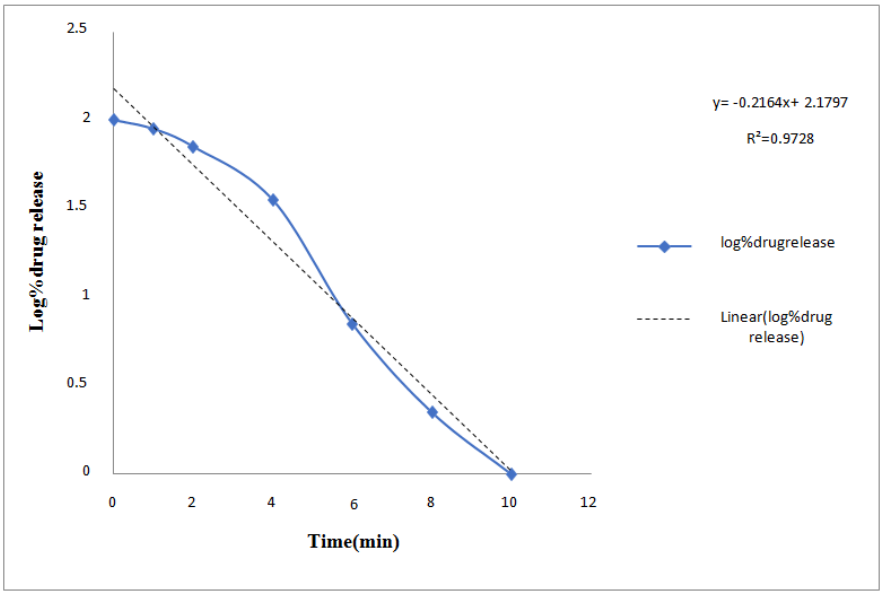

Figure 11: First order of Optimized Formulation (F9).

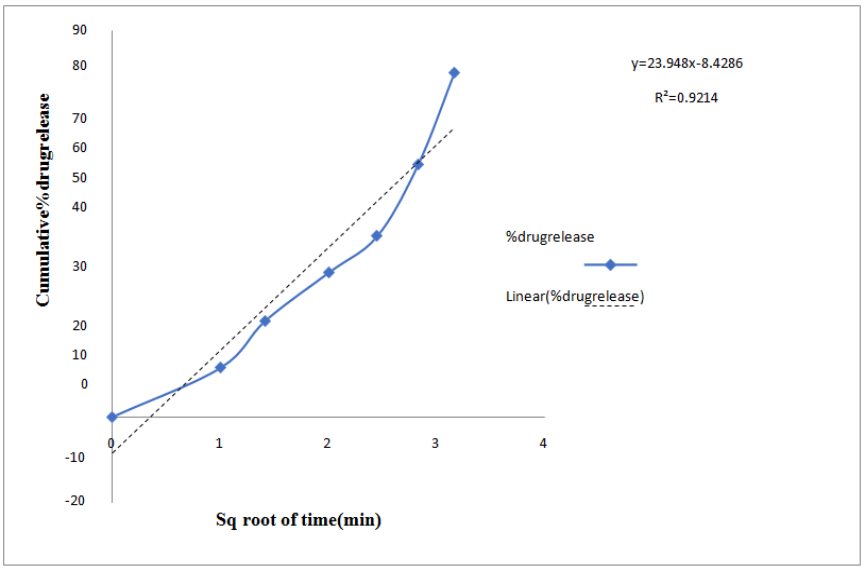

Figure 12: Higuchi plot of Optimized Formulation (F9).

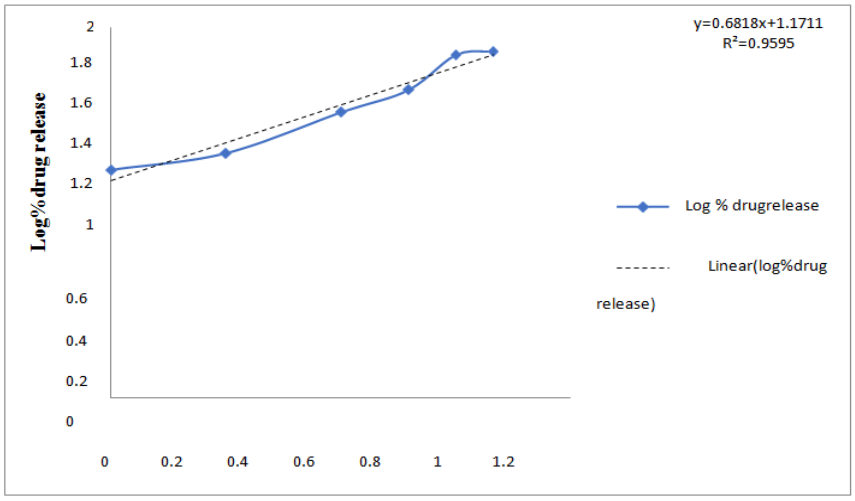

Figure 13: Korsmeyer–Peppas plot of Optimized Formulation (F9).

Kinetics models of Marketed Product

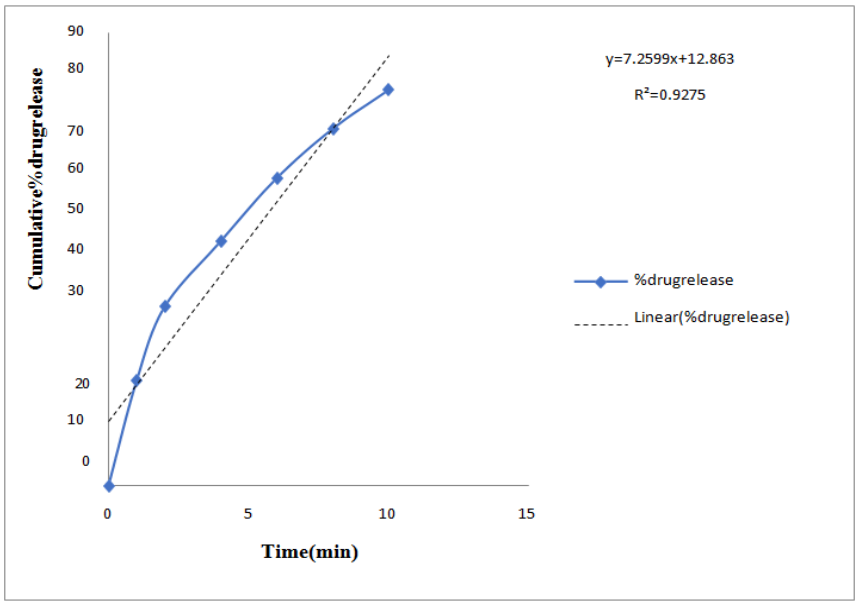

Figure 14: Zero order plot of Marketed Product.

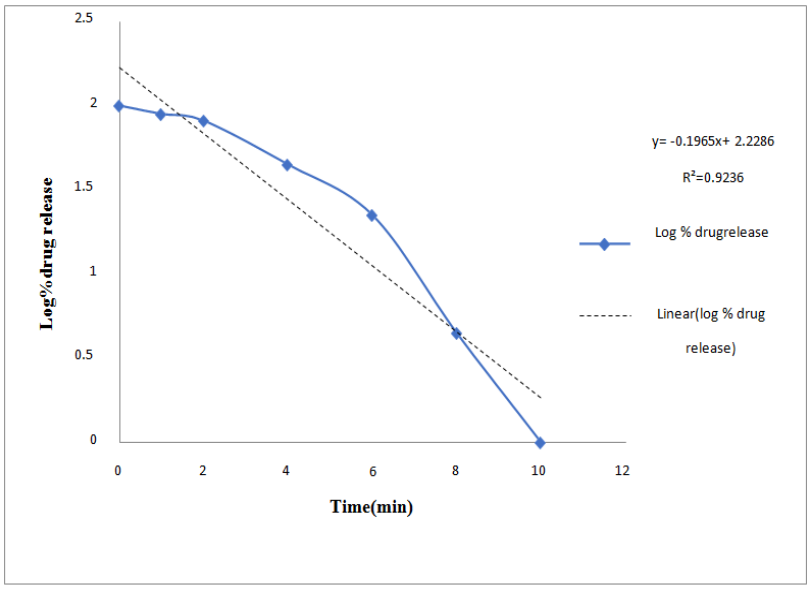

Figure 15: First order plot of Marketed Product.

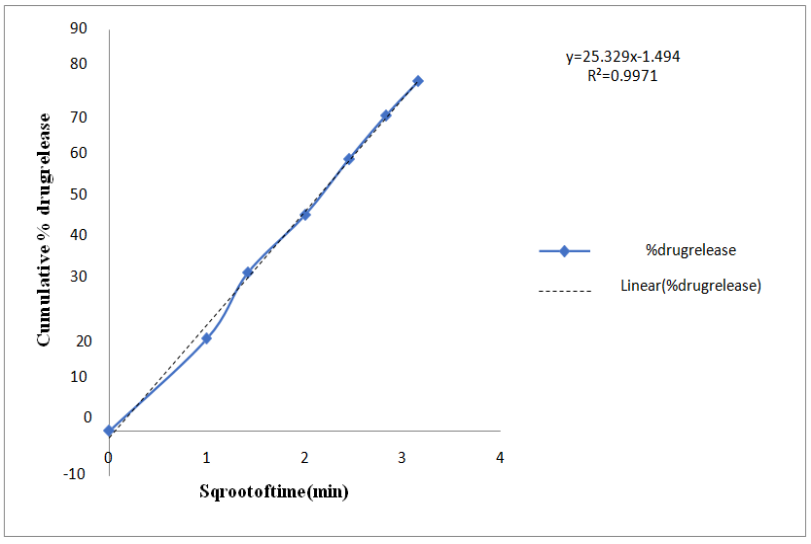

Figure 16: Higuchi plot of Marketed Product.

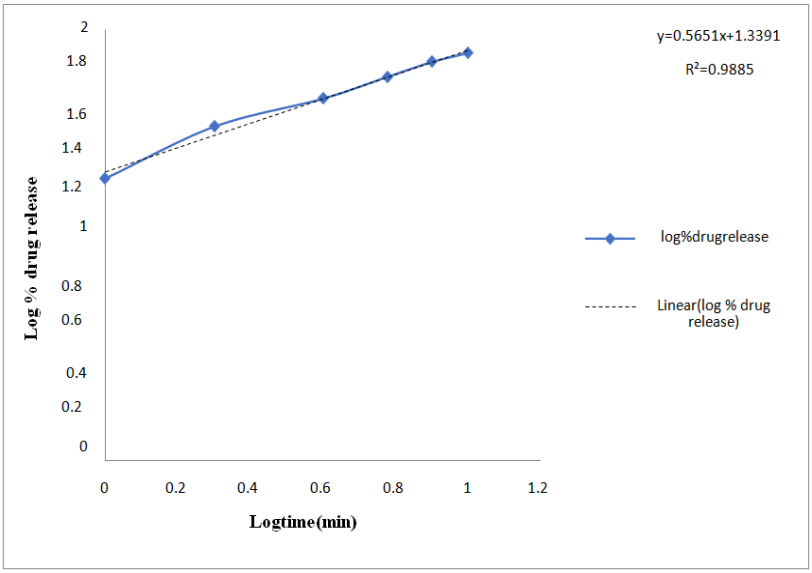

Figure 17: Korsmeyer–Peppas plot of Marketed Product.

Drug excipients interactions studies by FTIR SPECTROSCOPY

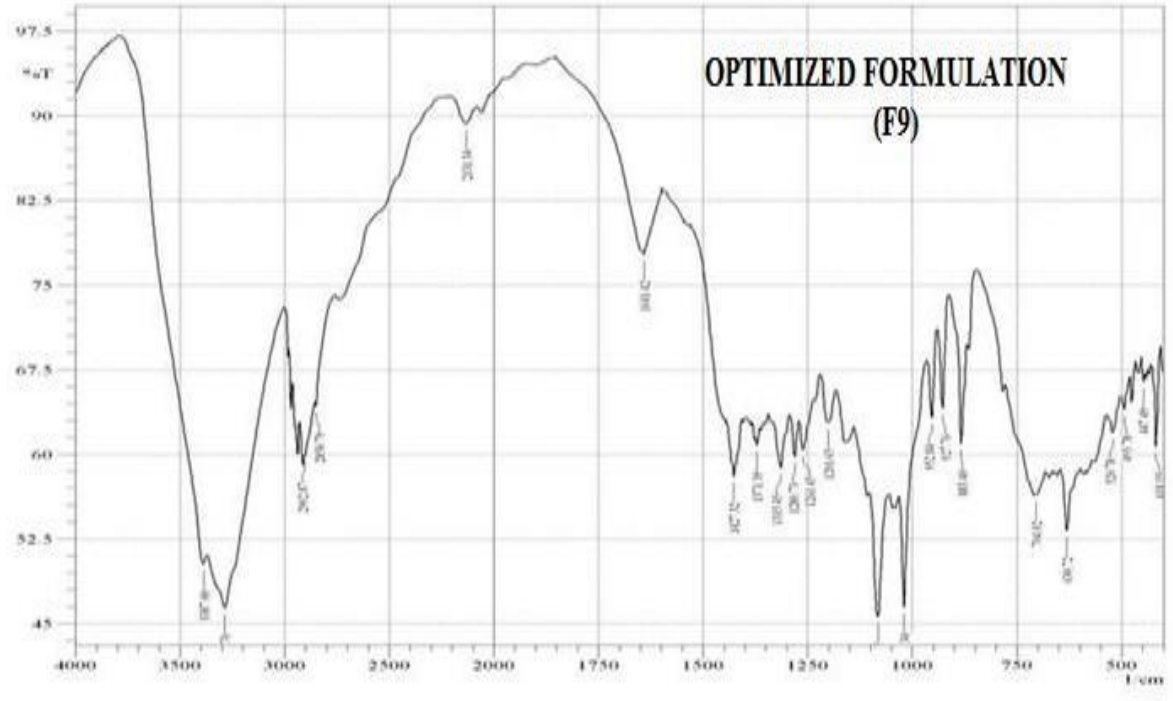

Figure 18: FTIR Spectroscopy of Granisetron Hcl Pure Drug.

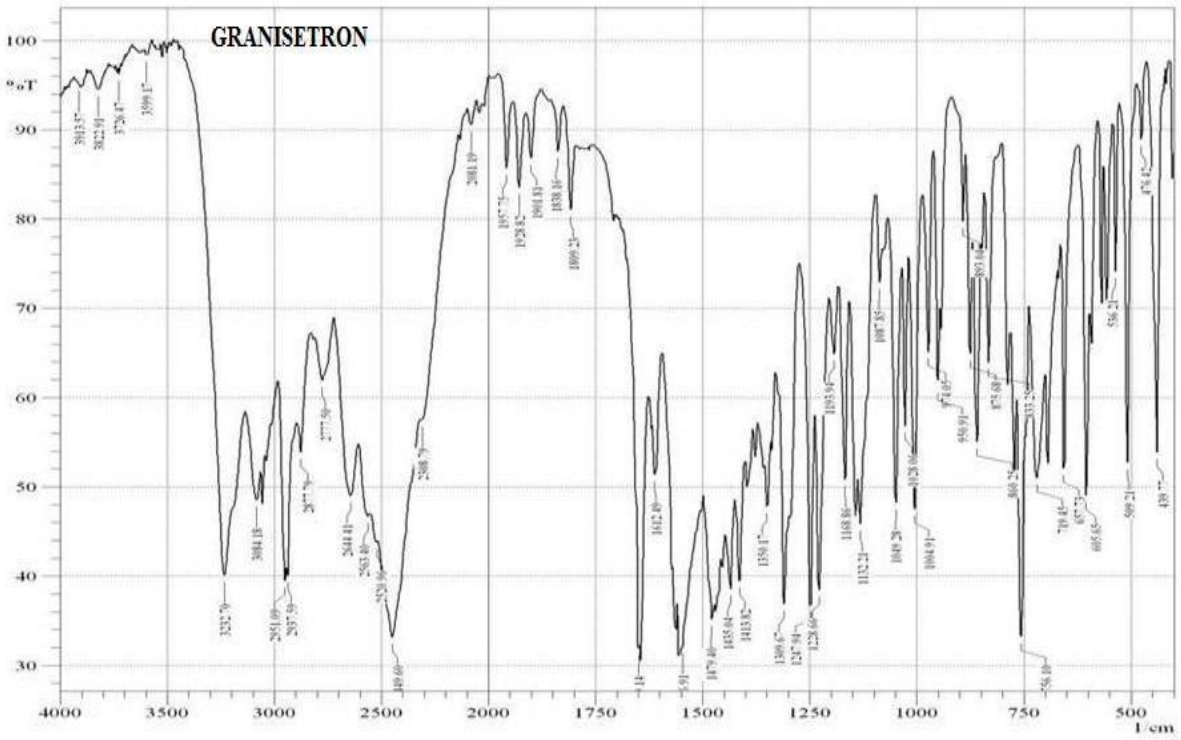

Figure 19: FTIR Spectroscopy of Granisetron Hcl Formulation F9.

Interpretation of FTIR data

The FTIR Spectra of pure Granisetron Hydrochloride displayed bandat 3400cm-1duetoC-Hstretch, at 1673cm-1dueto C=Ostretching at 1550 due to hetero cyclic C=C stretching. The spectra also showed bands at 1253 due to C-N stretching at 1612 due to N-H stretching. The FTIR spectrum of film containing Granisetron Hydrochloride such as bands at 3392 cm-1due to C-H stretch, at 1677 cm-1due to C=O stretching at 1560 due to hetero cyclic C=C stretching, at 1260 due to C-N stretching, at 1617 due to N-H stretching. Thus, the presence of characteristic absorption bands of Granisetron Hydrochloride and the film containing Granisetron Hydrochloride suggest that there is no interaction takes place between the drug and excipients used in the formulation.

Drug excipients compatibility studies by DSC

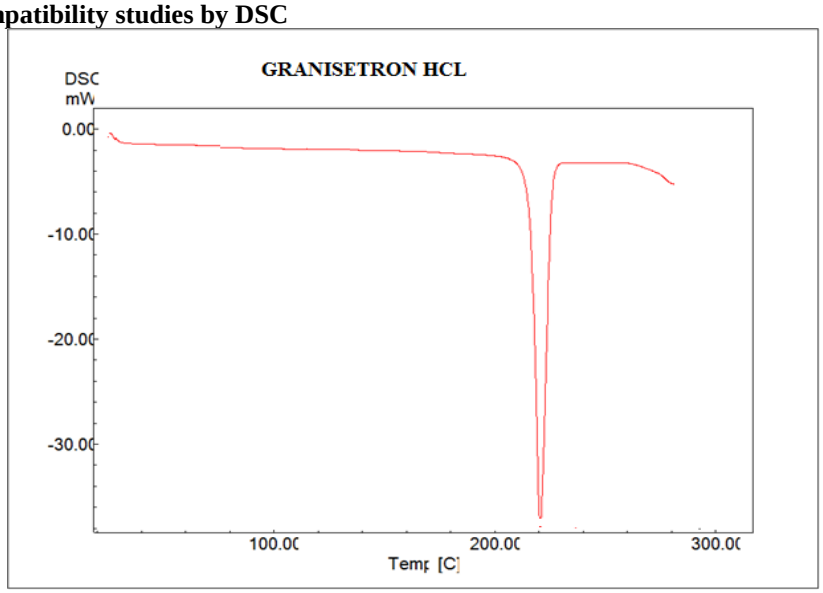

Figure 20: DSC of Granisetron Hydrochloride.

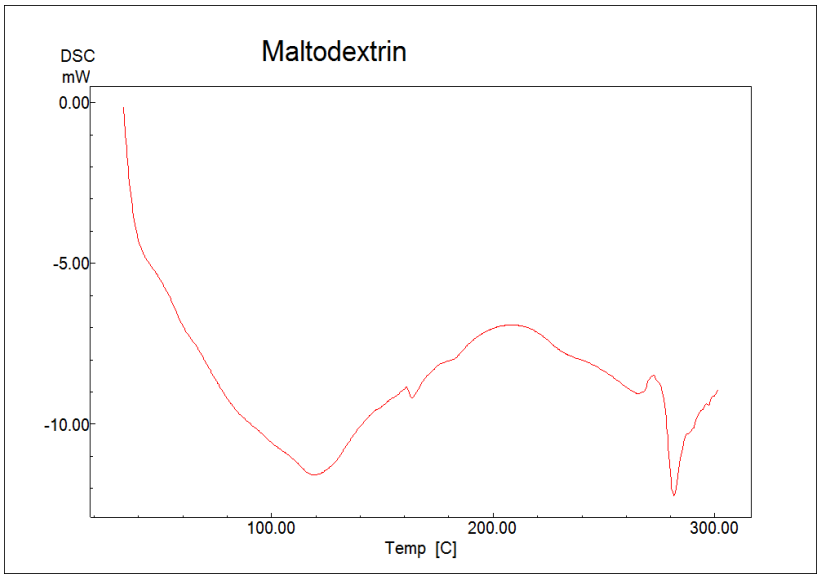

Figure 21: DSC of Maltodextrin.

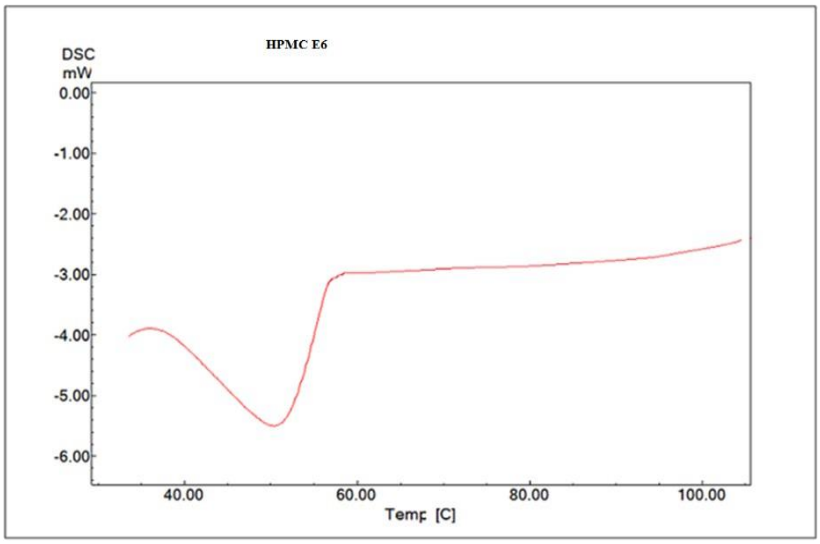

Figure 22: DSC of HPMC E6.

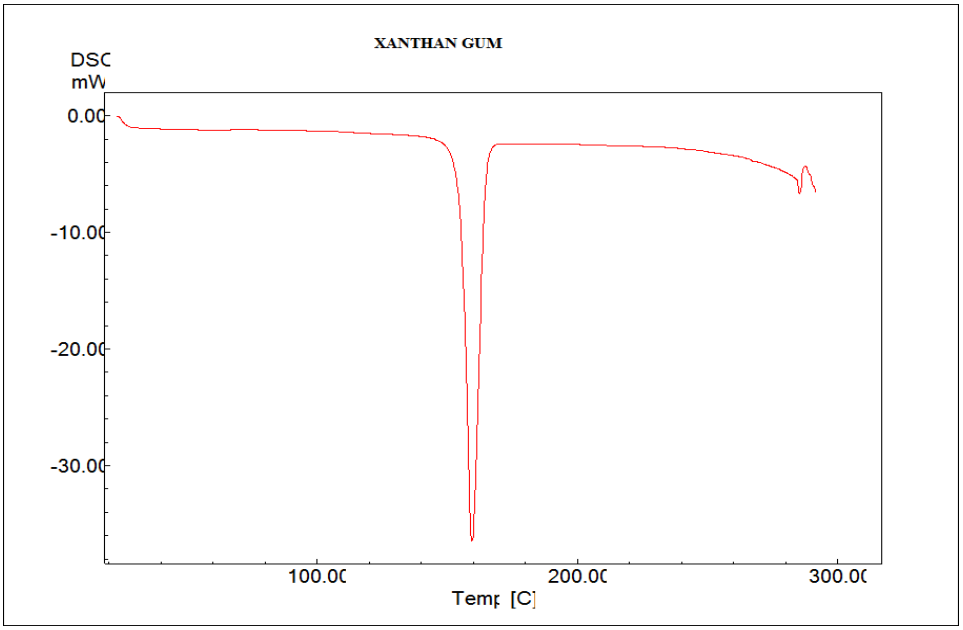

Figure 23: DSC of Xanthangum.

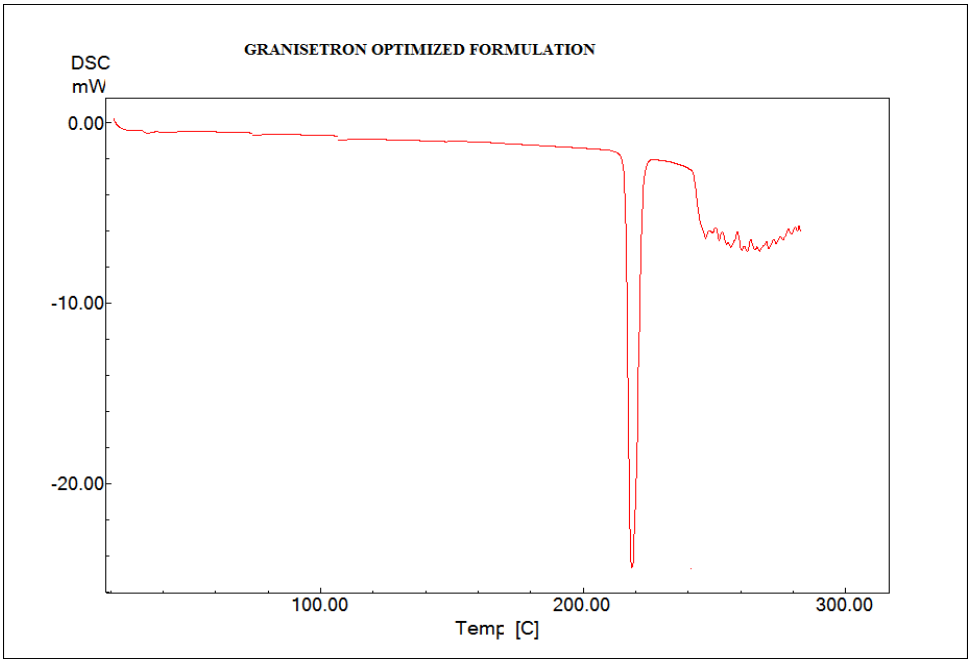

Figure 24: DSC of Granisetron Hydrochloride Formulation F9.

Interpretation of DSC Data

DSC results revealed that pure drug Granisetron Hydrochloride had MP 219, Maltodextrin had MP 110, HPMC E6 had 50, Xanthan gum had 130 & Optimised formula F9 with HPMC & Maltodextrin had MP 220.

No significant change is observed in melting endotherm of drug in optimised formulation indicating that there is no interaction between drug & other excipients used in formulation.

Melting points from DSC data

Table 12: Melting points from DSC Data.

INGREDIENT	MELTINGPOINT(°C)
GRANISETRON	219
MALTODEXTRIN	110
HPMCE6	50
XANTHANGUM	130
GRANISETRON OPTIMIZEDFORMULATION(F9)	220

Accelerated stability studies

Short term stability studies were carried out for optimized formulation F9 for a dated of 2 months at 40ºc/75%RH–accelerated stability testing according to ICH guide lines & films were found to be stable & acceptable. At25ºc/60%RH-long term stability testing according to ICH guidelines, films were found stable& acceptable. The films were evaluated for disintegrating time which is critical for drug release from formulation, percent drug content/ assay & transparency to know if any amount of drug or excipient has degraded over a period of time.

Stability Studies for optimized formulation

Optimized formulation was selected for stability studies on the basis of high cumulative % drug release. Stability studies were conducted for 3 months according to ICH guidelines. From these results it was concluded that optimized formulation is stable and retained their original properties with minor differences which depicted in the table.

Table 13: Table: Physico-chemical characteristics of optimized formulation stored at 40 ±2ºC /75 ±5%RH.

Retest-Time For Optimized formulation	Time of disintegration (sec)	Drug percent Content / Assay (%)	Drug In-vitro release profile(%)	Transparency
0days	09+2	99.8+0.1	98.6±1.5	Transparent
30days	10+8	99.06+0.14	97.5±1.4	Transparent
60days	11+6	98.06+0.12	96.8±1.09	Transparent
90days	11+2	97.54+0.26	96.1±1.13	Transparent

Pharmacokinetic study

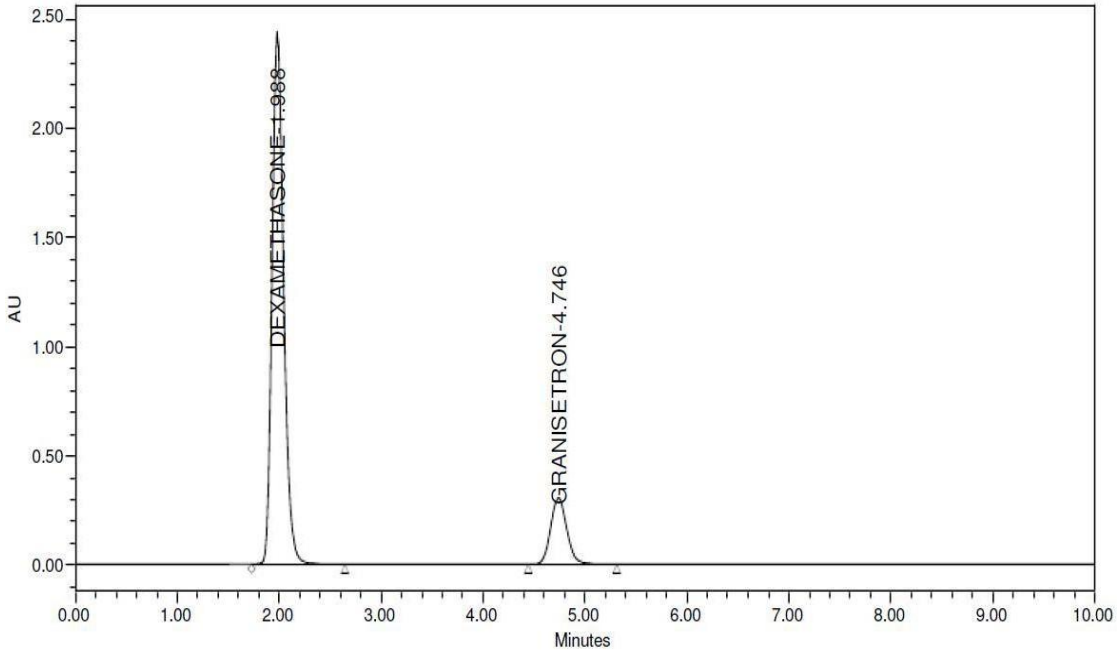

Figure 25: HPLC Chromatogram of Granisetron Hydrochloride.

Table 14: Standard calibration curve of Granisetron Hydrochloride (HPLC).

Concentrations (ng/ml)	Area
0	0
10	3440.424
20	6880.848
30	10321.27
40	13661.7
50	17202.12
60	20542.54
70	24042.97
80	27823.39
90	30963.82
100	34404.24

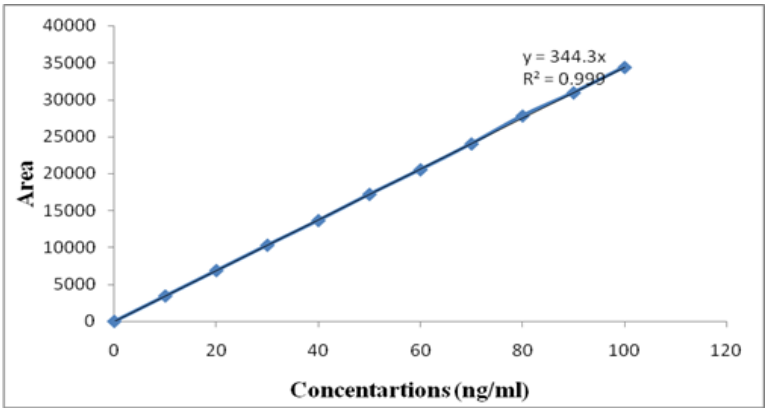

Figure 26: Standard calibration curve of Granisetron Hydrochloride.

Table 15: Plasma concentrations at different time intervals.

Time(hrs)	Optimized(best) formulation(F9)(ng/ml)	Marketed Product (ng/ml)
0	0±0	0±0
0.25	0.12±0.1	0±0
0.5	0.458±0.1	0.15±0.1
1	0.325±0.4	0.343±0.1
1.5	0.254±0.2	0.324±0.2
2	0.194±0.4	0.292±0.1
2.5	0.122±0.5	0.255±0.2
3	0.115±0.5	0.209±0.1
4	0.1±0.1	0.154±0.1
5	0±0	0.135±0.1
6	0±0	0.114±0.4
8	0±0	0.09±0.1
12	0±0	0±0
16	0±0	0±0
24	0±0	0±0

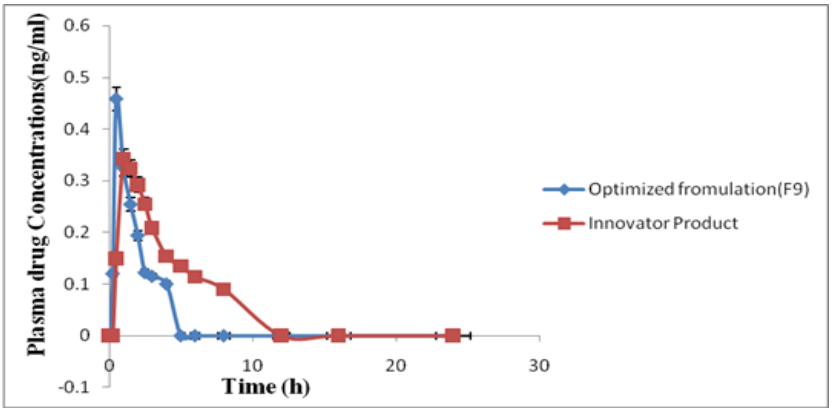

Figure 27: Plasma concentrations at different time intervals.

Table 16: Comparison of pharmacokinetic parameters of Granisetron Hcl between film and Marketed Product in Rabbits (mean ± SD, n = 6).

Parameters	Optimized formulation	Innovator
Cmax(ng/ml)	0.498±0.41	0.343±0.154
AUC0-t(ngh/ml)	1.688±0.741	1.547±0.156
t½(hrs)	1.4531±0.5191	2.3646±0.012
AUC0-∞(ngh /ml)	1.9467±0.142	1.911±0.123
Kel(h-1)	1.0361±0.181	1.496±0.931
Tmax(hr)	0.501±0.54	1.04±0.144

Pharmacokinetic parameters comparison for Granisetron Hydrochloride optimized film and Marketed Product

The mean Granisetron Hydrochloride plasma concentrations - time profiles for the prepared Granisetron Hydrochloride film and innovator ares how in Table. The bioavailability parameters for the both test film and reference standard are summarized in Table. Mean time to reach peak drug concentration (Tmax) was 0.50±0.5h and 1.0±0.1h for the optimized and commercial formulations, respectively, while mean maximum drug concentration (Cmax) was 0.498±0.4ng/ml and 0.343±0.1ng/ml, respectively. Cmax was significantly increased when compared with marketed product. The statistical comparison of tmax, AUC0–∞ and AUC0–t indicated no significant difference between the two treatments, based on the statistical inferences it was concluded that the two formulations exhibited comparable plasma level time profiles as per the dosage forms, Both the formulations shown immediate release.

IN VITRO- IN VIVO CORRELATION STUDIES

Table 17: In vitro & In vivo details of GRANISETRON HCl optimized formulation of mouth dissolving film (F9).

Time (min)	% Fraction of drug dissolved (F9)	Plasma drug concentration (ng/ml)(F9)
0	0	0
1	27.3	0.06
2	43.9	0.13
4	65.05	0.23
6	88.5	0.31
8	97.8	0.38
10	98.6	0.44

IVIVC for Granisetron HCl was evaluated by plotting mean plasma drug concentration (PDC) versus mean percentage of drug dissolved (FD). data were evaluated using linear regression analysis, & validity of correlation model was also determined by calculating internal prediction error between observed & predicted plasma drug concentration & extent of Granisetron HCl absorption. An excellent correlation (r2=0.99689) between FA & FD, slope value was very near to unit (0.93502) was observed.

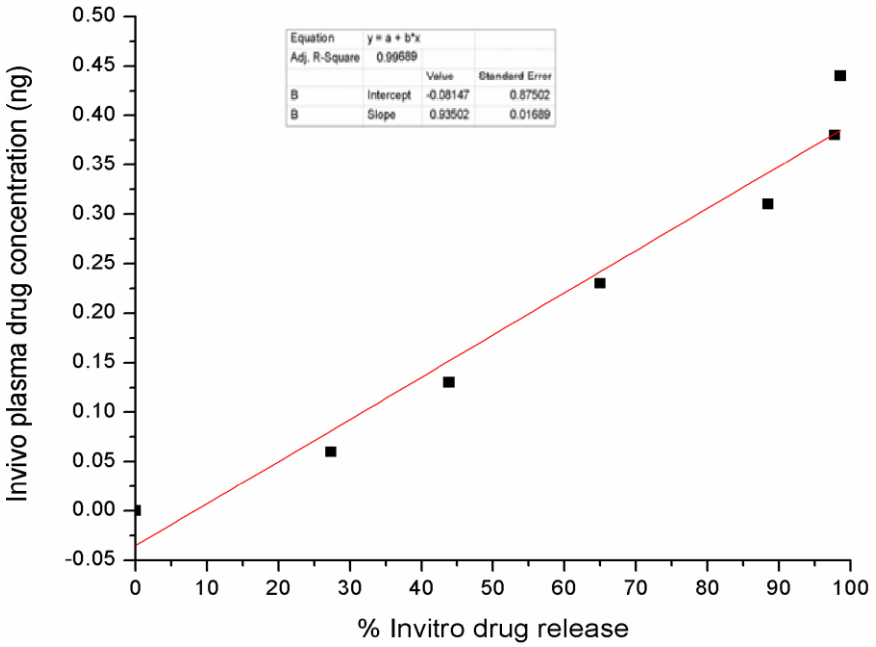

Fig. 28: In vitro-In vivo correlation models, regression plots of mean Plasma drug concentration (PDC) versus fraction of drug dissolved(FD)of Granisetron HCl optimized formulation of mouth dissolving film (F9).

CONCLUSION

Fast dissolving Oral film of Granisetron Hydrochloride was formulated by using solvent casting method with different concentrations of HPMC-E3, E6 and E15. Film forming property of various grades of HPMC was investigated based on preliminary characteristics of various batches of FDOFs. Formulations with HPMC E3 were not evaluated for other physical parameters due to their poor film forming ability, tack property and ease of handling or peeling. The bitter taste of the drug was

masked by Aspartame and Vanilla flavour. Formulations with HPMC E6 and E15 were evaluated for their physical characteristics, thickness, folding endurance, tensile strength, disintegration time, drug content uniformity and drug release characteristics. Dissolution studies were performed for FDOFs excluding batches that showed poor film forming property. Among the prepared formulations F9 showed minimum disintegration time 12 sec. Formulation F9 released 97.8% of drug within 8 min when compared to the other formulations. Based on the physicochemical properties like tensile strength, folding endurance, thickness, disintegration results and dissolution studies, it was concluded that F9 finalized as optimized formulation. DSC and FTIR data revealed that no interactions takes place between the drug and polymers used in the optimized formulation. The *in vitro* dissolution profiles of marketed product and optimized formulation was compared and found to be the drug.

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