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DEVELOPMENT AND IN-VITRO EVALUATION OF FLOATING TABLETS CONTAINING ITOPRIDE HYDROCHLORIDE

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ABSRACT

Itopride Hydrochloride is a gastroprokinetic drug, the site of achievement is abdomen; and the preparation pH ranges from 3.5-5.5. Floating tablets of itopride hydrochloride are considered to delay GIT abode time after oral administration, useful to achieve good flotation. Floating tablets were prepared by direct compression technique with hydrophilic polymer HPMC K4M and Carbopol 934P and Xanthan gum act as a release retarding material. Effervescent agent (Sodium bi carbonate, Citric acid) in unlike ratios to optimize their influence on drug release profile. Prepared formulations were evaluated by the physical categorization, assay, rigidity, friability, weight disparity and in vitro drug release. The outcome indicated that the formulation batch F_2 shows 98.20% optimum drug release profile in 12 hours and shows floating lag time within 1 minute. The positive outcomes of these studies indicate that the F_2 is the best formulation.

KEYWORDS:– Floating tablets, Itopride Hydrochloride, Xanthan gum, HPMC K4M, Carbopol 934, Floating lag time.

INTRODUCTION

Oral drug delivery is the mainly utilized route of organization among all the routes that have been explored for systemic delivery of drugs by pharmaceutical products of dissimilar dosage form. Oral route is considered mainly natural, complex, suitable and safe due to its ease of administration, patient acceptance and cost-effective developed process.

It is obvious from the recent scientific and patient literature that an improved interest in novel dosage forms that are retained in stomach for an expanded and predictable period of time exists today in educational and industrial research groups. One of the most reasonable approaches for achieving an extensive and conventional drug delivery in the GI tract is to control the gastric residence time (GRT), i.e. gastro retentive dosage form (GRDFs or GRDS). GRDFs expand considerably the period of time over which the drugs may be free. They not only prolong dosing intervals, but too increase patient compliance further than the level of obtainable controlled release dosage form.

FDDS offers fundamental advantages approximating they are a smaller amount prone to gastric emptying resulting in summary intra and inter subject variability in plasma drug levels, successful for delivery of drugs by thin absorption windows, reduced dosing and enhanced patient compliance, reduced Cmax and expanded drug levels above the smallest effective concentration and better safety profile for drugs with side effects linked with high Cmax.

Itopride has anticholinesterase (Ache) action as well as dopamine D2 receptor antagonistic action, accepted that M3 receptors exist on the smooth muscle layer every through the gut and acetylcholine (ACh) free from enteric nerve endings stimulates the contraction of smooth muscle through M3 receptors.

MATERIALS AND METHODS

Itopride hydrochloride is obtained by vasudha pharma, HPMC K4M are gifted by sotto chemie pvt.ltd, xanthan gum is gifted by asiamerica group, Sodium bicarbonate are gifted by GHCL Ltd, Citric acid is gifted by Kosher halal, carbopol 934P, Lactose, magnesium sterate, are procured by CDH (P) Ltd, New Delhi, India and Avicel were procured by international speciality product technologies limited, USA.

Equipments

UV spectrophotometer, Tapped density tester, moisture analyser balance, punching machine, hardness tester, electronic balance, friability tester, dissolution apparatus, Vernier caliper.

Methods

Tablets of Itopride HCl were composed by direct compression method, accurately weighed ingredients are passed through the sieve of # 40, and mix for 10 min blended in motor and

pestle uniformly, also passed through the sieve of # 60, compressed into tablets on a 12 station single much rotary tablet compression machine.

Ingredients used in floating tablets formulation

Table 1: Formulation ingredients for floating tablets.

S. No.	Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4(mg)	F5(mg)	F6(mg)
1	Itopride hydrocholride	100	100	100	100	100	100
2	HPMC K4M	40	50	60	70	75	80
3	Xanthan gum	40	50	60	70	75	80
4	Carbopol 934P	40	50	60	70	75	80
5	Sodium bi carbonate	70	70	70	70	70	70
6	Citric acid	30	30	30	30	30	30
7	Lactose	195	165	135	105	90	75
8	Avicel	20	20	20	20	20	20
9	Magnesium Stearate	15	15	15	15	15	15
10	Total	550mg	550mg	550mg	550mg	550mg	550mg

Pre compression parameter (Evaluation of blend)

- **The angle of repose of drug:** A powder funnel was adjusted with tripod stand and clamp in such a manner that lower part was 8cm above the surface. 3gm of the powder taken and opening of funnel wad (3.96mm) blocked with thumb powder put into the funnel. Subsequently, the thumb removed and the blend was allowed to pour through opening and fall on the surface. The width and height of the heap were measured.
- **Bulk density of drug:** 3gm powder pour into a 10ml graduated measuring cylinder and its volume was measured as it was.
- **Tapped density of drug:** Placing 3gm of powder into 10ml graduated measuring cylinder and start mechanical tapping apparatus.
- **Carr's index:** This value was calculated according to the formula –
  (Tapped density –Bulk density / Tapped density) x 100
- **Hausner's ratio:** The hausner's ratio is to check the flow property of powder.
- **The % moisture content of drug:** The % moisture contents of blend was determined using moisture analyzer balance.

Post-compression parameters

***In-vitro* floating study**

The time taken by tablet to float after placing in 900ml, Gastric Fluid without pepsin, at pH 1.2, temperature 37±0.5ºC, basket rotation at 50 rpm.

Water uptake study (determination of swelling index)

Weighed One tablet placed in a beaker containing 100 ml of 0.1N HCl, After each hour, removed from beaker and weighed do again up to 8 hrs, the % weight gain by the tablet was calculated.

Swelling index = (Wt – Wo) / Wo X 100

RESULT AND DISCUSSION

UV spectroscopic study of Itopride HCl

Table 2: UV spectroscopic study of Itopride HCl at λmax 262 nm.

S. No.	Concentration	Absorbance
1	5	0.046
2	10	0.135
3	15	0.304
4	20	0.465
5	25	0.619
6	30	0.826

Calibration curve of Itopride HCl

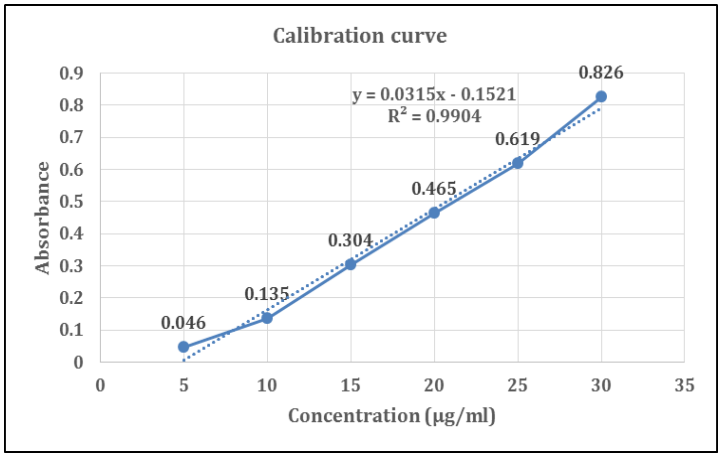

Fig. 1: Calibration curve of Itopride HCl at λmax 262 nm.

FTIR study of itopride hydrochloride

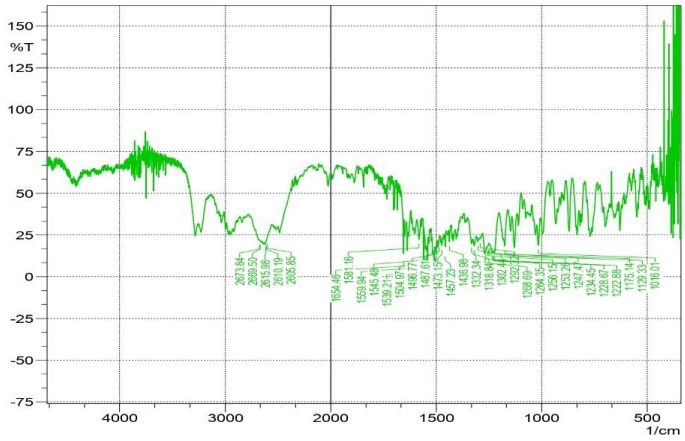

Fig. 2: FTIR Spectra of Itopride HCl.

Evaluation of blend

The angle of repose, bulk density, tapped density, Hausner's ratio, Carr's index was given the following table no. 3-

Table 3: Evaluation Parameters and Their values.

S. No.	Parameters	F1	F2	F3	F4	F5	F6
1	Bulk density	0.370	0.353	0.384	0.390	0.32	0.406
2	Tapped density	0.525	0.515	0.580	0.570	0.570	0.550
3	Hausner's ratio	1.40	1.44	1.50	1.42	1.32	1.34
4	Carr's index	29.50	30.26	34.40	31.18	26.20	26.70
5	Angle of repose	22.78	31.50	22.70	24.80	22.30	7.75

Evaluation of tablets

The formulation weight deviation, (width and lenth), diameter, hardness, friability, and percentage API content were given.

Table 4: Evaluation parameters with values.

S. No.	Parameters	F1	F2	F3	F4	F5	F6
1	Weight variation	0.536+-7.76	0.512 +7.64	0.412+ 6.43	0.410-6.34		0.320-6.213
2	Thickness	1.67	1.66	1.68	1.69	1.68	1.67
3	Diameter	3.2 mm	2.9mm	2.7 mm	2.8mm	2.98	2.30mm
4	Hardness	2.9±0.3	3±0.5	2.8±0.5	2.8±0.5	2.8±0.5	2.8±0.5
5	Friability	0.4%	0.5%	0.7%	0.9%	0.6%	0.4%
6	% drug content	98.2%	91.1%	99.2%	99%	99.9%	98.%

***In-vitro* dissolution test**

Itopride HCl floating tablet dissolving investigation utilising USP type 1 dissolution equipment which is shown in table 6.5.1

Table 5: All formulations percentage drug release with time.

Time	F1	F2	F3	F4	F5	F6
0.5	5.15	3.26	4.58	8.45	2.70	3.2
1	10.52	8.25	7.26	17.60	4.80	7.00
2	20.08	15.5	12.75	19.30	11.82	12.45
3	26.85	25.85	18.30	22.14	17.40	18.50
4	32.78	30.02	25.80	28.2	24.52	23.20
5	34.10	37.36	30.55	33.90	29.52	29.80
6	48.53	54.20	40.03	45.22	42.5	39.30
7	57.44	59.22	50.01	49.60	45.11	46.52
8	64.11	68.93	54.40	58.60	59.55	63.24
9	78.8	75.20	62.85	69.95	68.60	70.60
10	80.01	80.64	70.75	78.58	77.60	79.60
11	91.18	93.75	80.72	84.01	84.20	84.60
12	95.30	98.20	90.45	91.60	89.40	90.25

The Floating tablet of F2 formulation of Itopride HCl was given maximum release.

Cumulative % drug release study from all formulations (F1-F6)

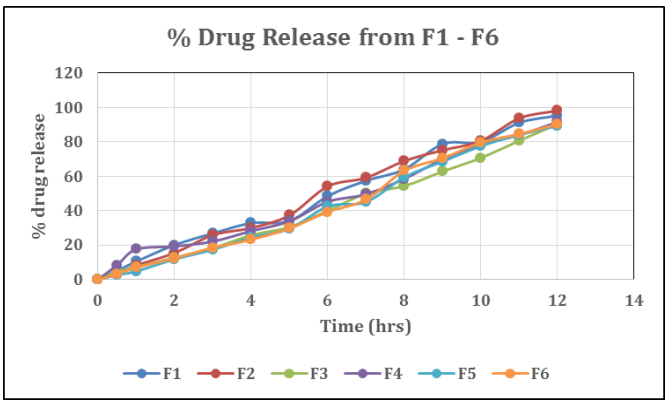

Fig. 3: Cumulative % drug release from all formulations (F1-F6).

Fig. 4: Dissolution Study of prepared floating tablets.

Floating lag time study of prepared formulations

S. no.	Formulation	Time
1	F1	1 min 10 sec
2	**F2**	**1 min**
3	F3	1 min 21 sec
4	F4	2min 20 sec
5	F5	1min 30 sec
6	F6	1min 17 sec

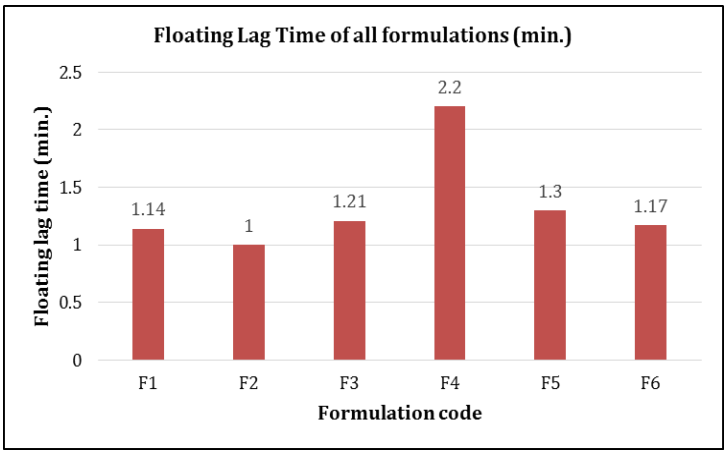

Fig. 5: Floating lag time of all batches.

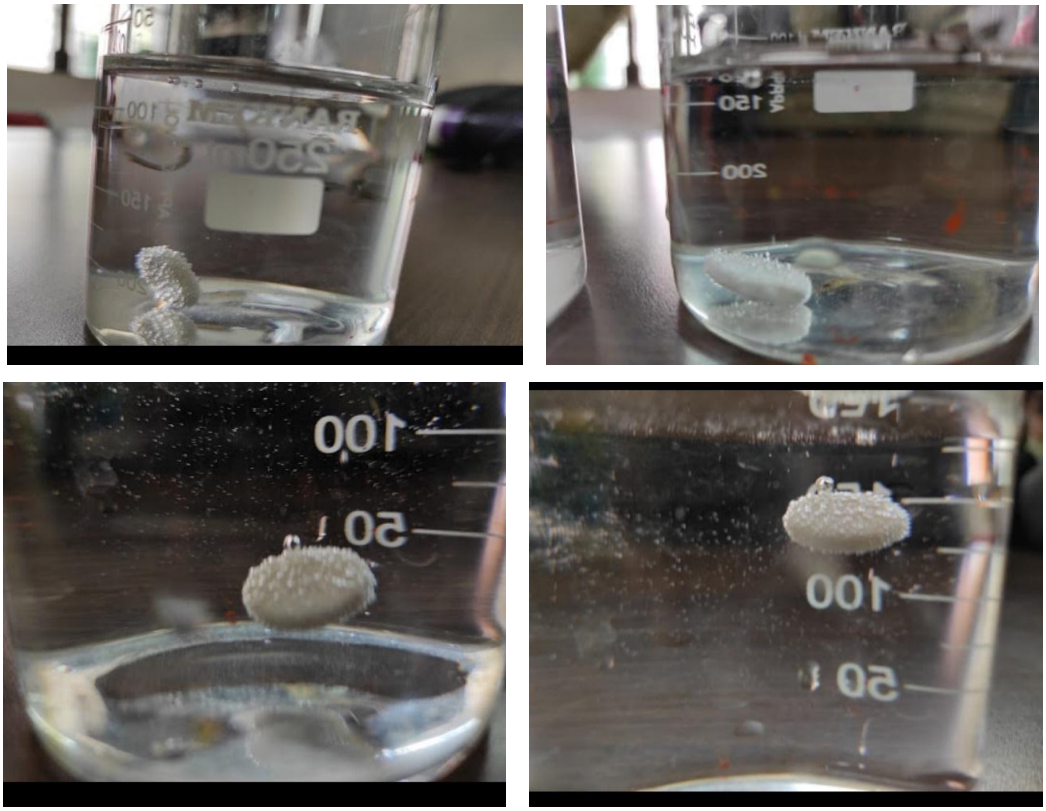

Fig. 6: Floating lag time study of the prepared formulations.

CONCLUSION

Itopride hydrochloride floating tablets were made utilising the direct compression method with the following formulation parameters: weight deviation, hardness, thickness, friability, preparation release, and floating lag time. There are six different itopride HCl floating tablet formulations: F1, F2, F3, F4, F5, and F6. Formulation F2 exhibits a therapeutic drug release profile of floating tablets with a longer duration and a prolong drug release time of 12 hours, which makes it more effective. The intended drug release profile of > 98.20 percent has been met by F2 after 12 hours. F2 will be used for more product development research.

Conflict of interest

The authors declared no conflict of interest.

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