



Formulation and Evaluation of Moxifloxacin Hydrochloride Floating Tablet

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Article info

Received: 28/01/2020

Revised: 28/02/2020

Accepted: 24/03/2020

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Abstract

The tablet was prepared using appropriate procedure n equipments. and then Post Compression Studies was performed accordingly. The post compression studies included Hardness Thickness, Friability, Weight Variation, Floating Lag Time, Floating Time, and Drug Release.the results of our study clearly indicate that Weight Variation data of the prepared tablets indicated no significant difference in the weight of the individual tablet from the average value. Hardness of the prepared tablets was observed in range of 1.263 ± 0.07 to 1.184 ± 0.05 kg/cm². Thickness of all the tablets was found in the range of 4.16 ± 0.1 to 4.26 ± 0.04 mm. Friability was found below 1%. The floating lag time was found to be in range of 15-22 sec. Total Floating Time was found to be in range of 6-7 Hrs. Swelling Index was found to be between 78 to 124%. Drug Release of FT4 was found to be the good i.e. 94.524%. From results it concludes that the floating lag time increased as hardness increased and F4 had better controlled release than the other formulations. So, formulation F4 provides a better option for Controlled release action and improved bioavailability of Moxifloxacin Hydrochloride Hydrochloride. On the basis of present study it was concluded that floating tablets of Moxifloxacin Hydrochloride hydrochloride can increase the gastric residence time as well as bioavailability and thus better patient's compliance can be achieved.

Keywords: Floating Tablet, Moxifloxacin Hydrochloride, Gastro Retentive Drug Delivery System

Introduction

Gastro Retentive Drug Delivery Systems^[1-4]

The most important objectives of these new drug delivery systems are: First, it would be single dose, which releases the drug for prolonged time period. Second, it should deliver the active entity directly to where is supposed to act, thus, decreasing the side effects. To overcome the limitations of conventional drug delivery system, floating tablets have been developed. Drugs that have small absorption area gastrointestinal tract (GIT) will have less absorption. For such drugs, increasing the amount of time in the GIT offers

the advantages in increasing the gastric emptying time. To formulate a successful stomach specific or gastro retentive drug delivery system, several techniques are currently used such as hydro dynamically balanced systems (HBS) / floating drug delivery system.

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It has been frequently observed that the drugs that are easily absorbed from GI tract have short half lives and are eliminated quickly from the systemic circulation which leads to incomplete absorption of drugs from the upper part of the small intestine. to avoid the repeated dosing of a drug, there are now researches going on in order to develop a sustained release drug delivery systems

Controlled release drug delivery system is capable of achieving the benefits like maintenance of optimum therapeutic drug concentration in blood with predictable and reproducible release rates for extended time period; enhancement of activity of duration for short half life drugs; elimination of side effects; decreasing number of doses given; optimized therapy and better patient compliances.

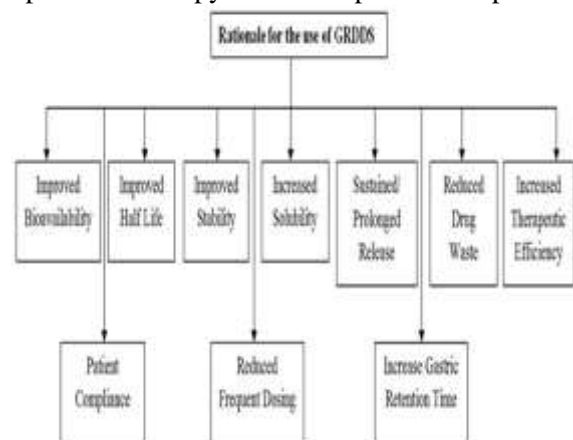


Fig. 1: Rationale for the Use of GRDDS

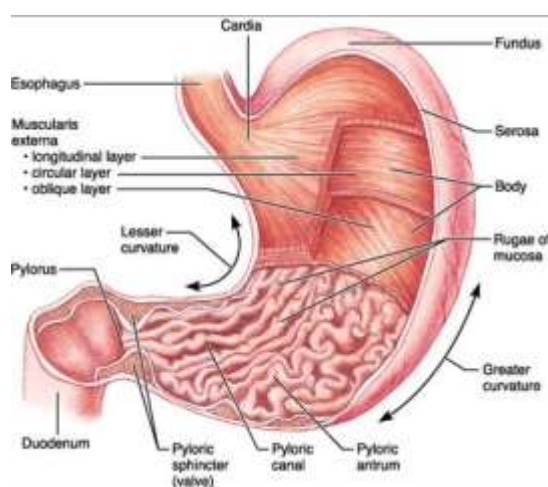


Fig. 2: Anatomy of Stomach

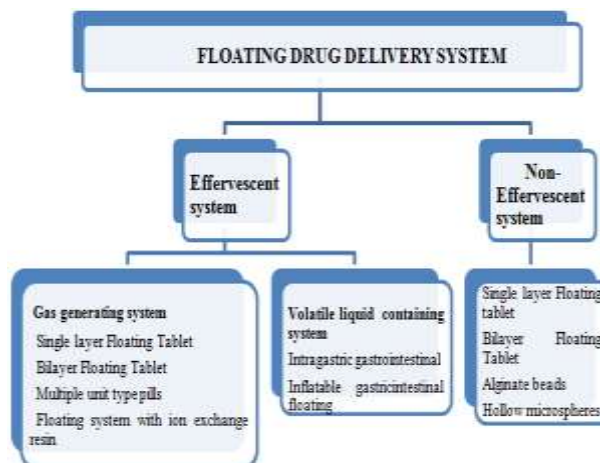


Fig. 3: Classification of Floating Drug Delivery Systems

Material and Methods

Following Drugs & materials are used in this method; Moxifloxacin Hydrochloride I.P, Poly Vinyl Pyrrolidone K 30, Hydroxy propyl methyl cellulose, Sodium bicarbonate, Citric acid.

Formulation of Floating Tablet:

- Weighed quantity of Moxifloxacin Hydrochloride, HPMC, sodium bicarbonate, citric acid and MCC were taken according the formulae F1, F2, F3 and F4 (Table) and sifted separately through mesh #44.
- These materials were mixed in separate pestle mortar and were granulated by a solution of PVP k30 and isopropyl alcohol.
- The granulated material was dried in a hot air oven at 40 – 45 degree Celsius.
- The dried granules were sifted through mesh #30.
- To these granules, weighed quantity of talc and magnesium stearate were added and mixed.
- The blends were taken for compression activity on compression machine. The tablets were compressed for formulae F1, F2, F3 and F4.

Ingredients	FT1	FT2	FT3	FT4
Moxifloxacin Hydrochloride	250 mg	250 mg	250 mg	250 mg
HPMC	70 mg	80 mg	90 mg	100 mg
Sod. Bicarbonate	100 mg	100 mg	100 mg	100 mg

Citric acid	40 mg	30 mg	20 mg	10 mg
MCC	15 mg	15 mg	15 mg	15 mg
PVP K30	20 mg	20 mg	20 mg	20 mg
Magnesium stearate	5 mg	5 mg	5 mg	5 mg
Talc	5 mg	5 mg	5 mg	5 mg
IPA	q.s	q.s	q.s	q.s

Ethanol	Soluble
Chloroform	Insoluble

Results and Discussion

Organoleptic Properties

The samples of Moxifloxacin Hydrochloride were identified for colour, odour and taste which were found to be same as that of standard parameters.

Table 1: Organoleptic properties of Moxifloxacin Hydrochloride Melting Point

The melting point of Moxifloxacin Hydrochloride

S.NO	Parameters	Sample
1	Colour	Slightly yellowish white
2	Odour	Odourless

I.P was found to be 324 ° C and the drug was found to be in the pure form.

Table 2: Melting point of Moxifloxacin Hydrochloride I.P.

Range	Melting point
324 - 325 °C	324 °C

Solubility Studies:

The solubility of the drug sample was determined by accurately weight 10 mg of Moxifloxacin Hydrochloride I.P was added in 6 test tubes and was added in aqueous and non aqueous solvents and solution was kept for 24 hrs and then samples were analyzed by U.V visible spectrophotometry and were found to be soluble in polar and were found to be insoluble in non polar solvents.

Table 3: Solubility Profile of Moxifloxacin Hydrochloride I.P In Aqueous And Non Aqueous Solvents

Solvent	Solubility
Dimethyl Sulphoxide	Soluble
Methanol	Soluble

UV Visible Spectroscopy Studies:

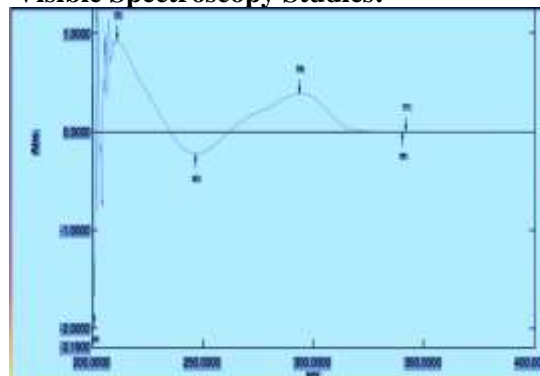


Fig. 3: Determination of Absorption Maxima of Moxifloxacin Hydrochloride in DMSO At 282 nm.

Table 4: Spectrophotometric Data for Standard Curve of Moxifloxacin Hydrochloride (DMSO)

S.No.	Conc. (µg/ml)	Absorbance at λ _{max} 282 nm
1	10	0.049
2	20	0.162
3	30	0.247
4	40	0.316
5	50	0.399
6	60	0.428

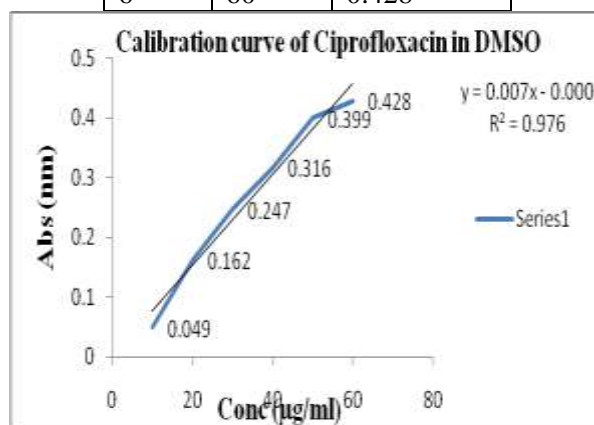


Fig. 4: Standard Curve of Moxifloxacin Hydrochloride in DMSO at 282 nm

Absorption maximum was determined by using solution of Moxifloxacin Hydrochloride in DMSO the observed maximum wavelength (λ_{max}) was 282 nm in DMSO.

**Drug –excipients interaction studies:
Fourier Transform Infrared Spectroscopy (FTIR)
studies**

The characteristics peaks were determined by FTIR spectra, which show purity of drug. If sample does not contain characteristics peaks of compound than it shows the impurity of sample.

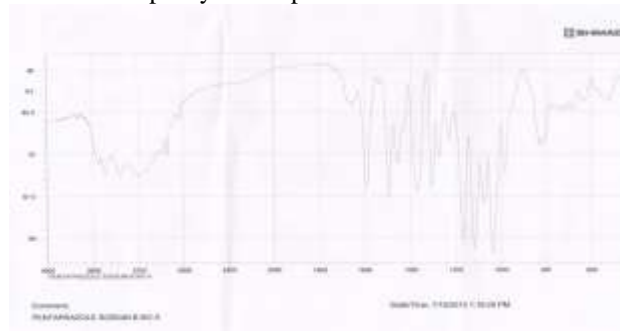


Fig. 5: FTIR Spectra of Moxifloxacin Hydrochloride

Table 5: Characteristics Peak of FTIR Spectra of Moxifloxacin Hydrochloride

S.No.	Functional Group	Standard Peak	Sample Peaks
1	OH Stretching vibration	3403.99	3400.33
2	C-H, Ar-H Stretching	2921.94	2922.94
3	C-O Stretching Vibration	1724.95	1724.00
4	N-H Bending	1628.81	1628.80
5	C-O Bending	1473.82	1472.69
6	O-H Bending	1268.42	1269.41

FTIR show characteristic peaks of drug which was similar to that of standard. It was the test for identification of drug. This test confirms the presence of various groups in the sample and confirms that it was Moxifloxacin Hydrochloride.

Table 6: Precompression Studies of Moxifloxacin Hydrochloride Tablets

Formulation Codes	Parameters				
	Bulk Density (g/cc)	Tapped Density (g/cc)	Hausner's Ratio	Compressibility Index (%)	Angle of Repose (°)
FT1	0.914	1.085	1.18	15.76	25.15
FT2	0.928	1.049	1.13	11.53	23.43
FT3	0.899	1.053	1.17	14.78	24.80
FT4	0.920	1.056	1.14	12.87	24.35

Table 7: Evaluation Test for Floating Tablets

Evaluation Test/Formulation Code	FT1	FT2	FT3	FT4
Hardness (kg cm ⁻²) ±SD	1.346±0.06	1.184±0.05	1.560±0.06	1.263±0.07
Thickness ±SD	4.26±0.04	4.23±0.05	4.16±0.1	4.25±0.05
Friability (%)±SD	0.3±0.04	0.5±0.02	0.5±0.1	0.2±0.08
Weight Variation (mg) ±SD	495±3.12	498±2.94	504±2.70	502±3.52
Floating Lag Time (sec)	22	20	18	13
Floating Time (hrs)	6	6.3	6.5	7

±SD= Standard Deviation

Table 8: Swelling Index for Floating Tablets

Time in hour	Formulation Swelling index (%)			
	FT1	FT2	FT3	FT4
1	40	54	44	50
2	46	60	57	55
3	54	63	75	65
4	65	68	84	78
5	73	74	96	82
6	78	82	124	90

Table 9: Drug Release Profile of Floating Tablets

S. No.	Time (hr.)	% Cumulative amt. of drug released (F1)	% Cumulative amt. of drug released (F2)	% Cumulative amt. of drug released (F3)	% Cumulative amt. of drug released (F4)
1	0	0	0	0	0
2	1	5.586	3.896	5.954	7.794
3	2	12.998	9.778	14.024	19.08
4	3	22.084	18.088	22.858	30.814
5	4	32.286	29.102	33.6	47.05
6	5	44.568	44.77	50.994	67.264
7	6	59.954	61.274	70.944	94.524

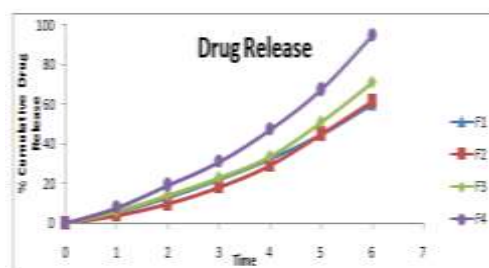


Fig. 6: In-vitro drug release profile of Moxifloxacin Hydrochloride Tablets for various tablet formulation (FT1 to FT4)

Dissolution was carried out in USP apparatus 2, paddle type, six bucket dissolution apparatus. Formulated (F1, F2, F3 and F4) tablets were fixed with sinkers and put in the buckets of the dissolution apparatus filled with 0.1 N HCl upto 900 ml maintained at a temperature of 37± 0.5 ° C and paddle rotation speed at 50 rpm. Samples were withdrawn at time points of 1, 2, 3, 4, 5 and 6 hrs and analyzed in UV- spectrophotometer

(Schimadzu UV-1800) at lambda max of 282 nm. The values of absorbance obtained were used to calculate the amount of drug release.

Release Kinetics for Optimized Formulation (FT4): Zero Order Release Kinetics, First Order Release Kinetics, Higuchi Model Release Kinetics, Korsmeyer Pappas Release Kinetics
 For Calculation release kinetics, a Plot is made between **Percentage Cumulative Drug Released Vs. Time**. The Higuchi model and Korsmeyer Peppas model were found to be best fitted release kinetic model as their Regression Coefficient (R^2) were found to be in the range for the Drug Release of Moxifloxacin Hydrochloride Floating Tablet.

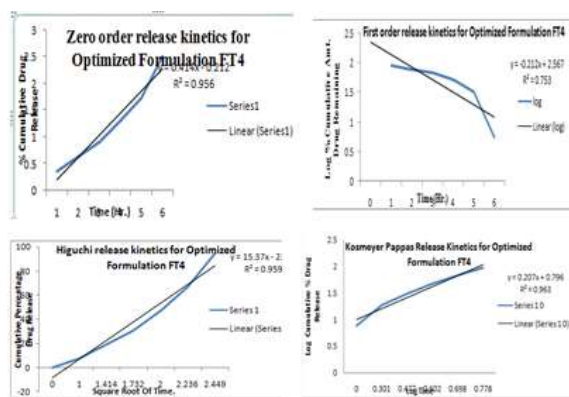


Fig. 7: Release kinetics of Moxifloxacin Hydrochloride Tablets for various tablet formulation (FT4)

Table 10: Release Kinetic models for Moxifloxacin Hydrochloride Floating Tablets

Formulation Code.	Regression Coefficient. (R^2)			
	Zero Order.	First Order.	Korsmeyer Peppas Model.	Higuchi Model.
FT4	0.956	0.753	0.963	0.959



Fig. 8: Moxifloxacin Hydrochloride Floating Tablet.

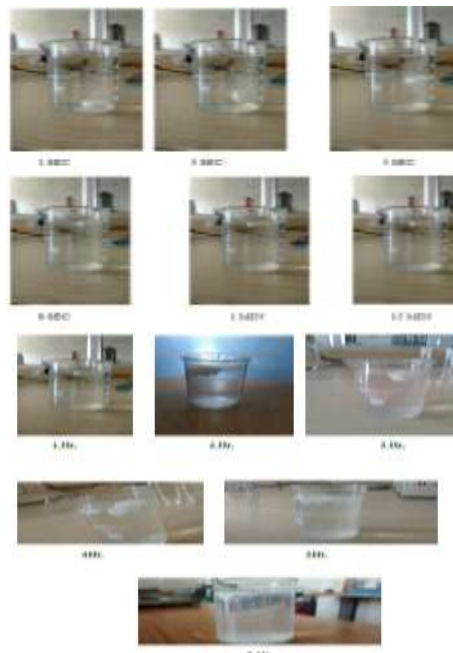


Fig. 9: Pictures showing Floating Time of Tablet

Conclusion

The Main objective of the study was to prepare and evaluate Moxifloxacin Hydrochloride floating tablet. An attempt was made to prepare. Drug Moxifloxacin Hydrochloride was selected after looking in various research studies of Floating Tablet. First organoleptic properties of drug was studied .Then Melting point of the drug was identified by Capillary method and it was found to be 324°C. Solubility of Moxifloxacin Hydrochloride as determined in various aqueous and non-aqueous solvents. The drug was found to be soluble in DMSO, Ethanol and Methanol and Insoluble in chloroform. Calibration curve of the drug were prepared in DMSO with the help of UV spectrophotometer. The method used for the estimation of drug followed Beer Lambert’s law in the concentration range 2 to 20 µg/ml with good accuracy, which is evident from regression coefficient obtained for each calibration curve. Drug Excipients Studies was determined by infrared absorption Spectrophotometry. The characteristics peaks were determined by FTIR spectra, which show purity of drug. FTIR show characteristic peaks of drug which was similar to that of standard. It was the test for identification of drug. This test confirms the presence of various groups in the sample and confirms that it was Moxifloxacin Hydrochloride. A new formula was developed using factorial design n the various sub formulas was prepared accordingly. Then the Precompression Studies which included Bulk Density, Tapped Density, Hausner’s Ratio,

Compressibility Index, Angle of Repose was then studied accordingly and data was obtained which is given in detail in project.

The tablet was prepared using appropriate procedure n equipments. and then Post Compression Studies was performed accordingly. The post compression studies included Hardness Thickness, Friability, Weight Variation, Floating Lag Time, Floating Time, Drug Release.

The results of our study clearly indicate that Weight Variation data of the prepared tablets indicated no significant difference in the weight of the individual tablet from the average value. Hardness of the prepared tablets was observed in range of 1.263 ± 0.07 to 1.184 ± 0.05 kg/cm². Thickness of all the tablets was found in the range of 4.16 ± 0.1 to 4.26 ± 0.04 mm. Friability was found below 1%. The floating lag time was found to be in range of 15-22 sec.

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From results it concludes that the floating lag time increased as hardness increased and F4 had better controlled release than the other formulations. So, formulation F4 provides a better option for Controlled release action and improved bioavailability of Moxifloxacin Hydrochloride Hydrochloride.

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Cite this article as:

Agrawal R., Choukse R., Gupta D.K and Patel R. (2020). Formulation and Evaluation of Moxifloxacin Hydrochloride Floating Tablet, *Int. J. of Pharm. & Life Sci.*, 11(3): 6510-6515.

Source of Support: Nil

Conflict of Interest: Not declared

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