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DESIGN AND EVALUTION OF RIFAXIMIN EFFERVESCENT FLOATING TABLETS

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ABSTRACT

In the present research work effervescent floating of RFXMN (Rifaximin) by utilizing different polymers. At first systematic strategy improvement was accomplished for the medication atom. Assimilation maxima were resolved dependent on that alignment bend was created by utilizing various fixations. Gas creating specialist sodium bicarbonate was utilized. At that point the definition was created by utilizing various convergences of polymers of different polymers. The detailing mix was exposed to different preformulation thinks about; stream properties and every one of the plans were observed to be great demonstrating that the powder mix has great stream properties. Among every one of the details the F7 arranged by utilizing Guar gum 50mg created greatest medication discharge contrasted with different plans thus it was considered as the best formulation.

KEYWORDS: RFXMN, Guar gum.

INTRODUCTION

Gastric exhausting of dose structures is an incredibly factor procedure and capacity to drag out and control purging time is an important resource for measurements shapes, which live in the stomach for a more extended timeframe than customary dose frames. One of such challenges is the capacity to restrict the measurement structure in the ideal territory of the gastrointestinal tract. To beat this physiological issue, a few medication conveyance frameworks with delayed gastric maintenance time have been investigated. Endeavors are being made to build up a con-trolled sedate conveyance framework that can give therapeutically viable plasma medicate fixation levels for longer spans, along these lines diminishing the dosing recurrence and limiting vacillations in plasma tranquilize focus at consistent state by conveying drug in a controlled and reproducible way. Gastro retentive frameworks can stay in the gastric district for a few hours and consequently altogether draw out the gastric living arrangement time of medications. Drawn out gastric maintenance improves bioavailability decreases medication squander and improves. Solvency of medications that is less dissolvable in high pH condition. Gastric maintenance is to give new restorative potential outcomes and generous advantages from patients. In view of these methodologies, gliding drug conveyance frameworks is by all accounts the promising conveyance frameworks for control arrival of medications.

ADVANTAGES OF FDDS

- Floating dosage forms such as tablets or capsules will remains in the solution for prolonged time even at the alkaline pH of the intestine.
- FDDS are advantageous for drugs meant for local action in the stomach eg: Antacids.

DISADVANTAGES OF FDDS

- Floating systems are not feasible for those drugs that have solubility or stability problems in gastric fluids.

AIMS AND OBJECTIVES

Aim of the Work

Point of the investigation is to plan and assess RFXMN effervescent floating tablets utilizing various polymers in various proportions.

Objective of the Study

To plan and play out the different invitro assessment test parameters for RFXMN effervescent floating tablets, to enhance the centralization of different hydrophilic polymers and to translate the *in-vitro* disintegration information.

METHODOLOGY

Analytical method development

a) Determination of absorption maxima

b) Preparation calibration curve

100mg of RFXMN unadulterated medication was broken down in 100ml of 0.1N HCl (stock solution) 10ml of arrangement was taken and make up with100ml of 0.1N

HCl (100µg/ml).From this 10ml was taken and make up with 100 ml of 0.1N HCl (10µg/ml). The above arrangement was along these lines diluted with 0.1N HCl to acquire arrangement of dilutions Containing 0.1, 0.2, 0.3, 0.4, 0.5 and 0.6µg/ml of RFXMN per ml of arrangement. The absorbance of the above dilutions was estimated at 244 nm by utilizing UV-Spectrophotometer taking 0.1N HCl as clear. At that point a chart was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard bend was surveyed from the square of relationship coefficient (R2) which dictated by least-square direct relapse examination.

Drug – Excipient compatibility studies
Fourier Transform Infrared (FTIR) spectroscopy
Preformulation parameters
Angle of repose
Bulk density
Tapped density
Measures of powder compressibility
Formulation development of Tablets
Optimization of Sodium bicarbonate concentration
Table 1: Optimization of Sodium bicarbonate concentration.

S.No	Excipient Name (mg)	ERFXN1	ERFXN2	ERFXN3
1	RFXMN	200	200	200
2	Guar gum	50	50	50
4	NaHCO3	50	75	100
5	Mg.Stearate	5	5	5
5	Talc	5	5	5
7	MCC pH 102	Q.S	Q.S	Q.S
	Total weight	450	450	450

Formulation composition for floating tablets
Table 2: Formulation composition for floating tablets.

Formulation No.	RFXMN	Sodium CMC	Chitosan	Guar gum	$NaHCO_3$	Mg. Stearate	Talc	MCC pH 102
RFXN1	200	50	-----	-----	75	5	5	QS
RFXN2	200	75	-----	-----	75	5	5	QS
RFXN3	200	100	-----	-----	75	5	5	QS
RFXN4	200	-----	50	-----	75	5	5	QS
RFXN5	200	-----	75	-----	75	5	5	QS
RFXN6	200	-----	100	-----	75	5	5	QS
RFXN7	200	-----	-----	50	75	5	5	QS
RFXN8	200	-----	-----	75	75	5	5	QS
RFXN9	200	-----	-----	100	75	5	5	QS

All the quantities were in mg, Total weight is 450 mg.

Evaluation
Weight variation, hardness, thickness, friability and drug content.
In vitro Buoyancy studies:
In vitro drug release studies
Dissolution parameters:
Apparatus -- USP-II,
Paddle Method
Dissolution Medium -- 0.1 N HCl
RPM -- 75
Sampling intervals (hrs) -- 0.5,1,2,3,4,5,6,7,8,10,11,12
Temperature -- 37°c + 0.5°c

Release Rate Kinetics
Zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

RESULTS AND DISCUSSION

Analytical Method

Graphs of RFXMN was taken in Simulated Gastric fluid (pH 1.2) at 244 nm.

Table 3: Observations for graph of RFXMN in 0.1N HCl (244 nm).

Concentration	Absorbance
0	0
0.1	0.131
0.2	0.274
0.3	0.394
0.4	0.547
0.5	0.682
0.6	0.844

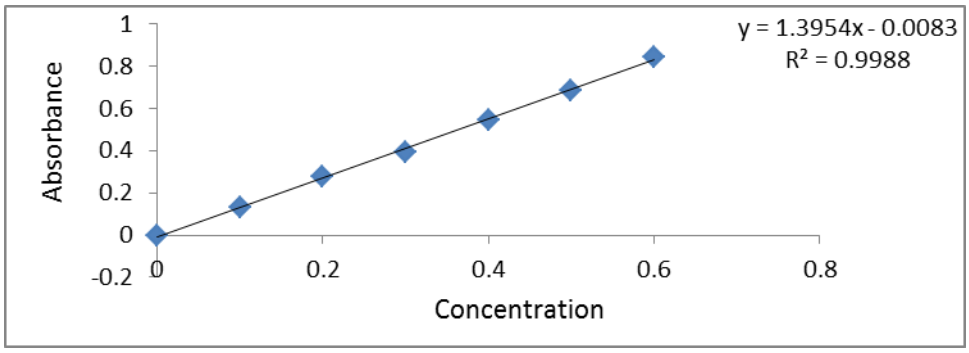


Figure 1: Standard graph of RFXMN in 0.1N HCl.

Table 4: Preformulation parameters of powder blend.

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
RFXN1	25.01	0.48	0.59	17.25	0.89
RFXN2	26.81	0.54	0.63	17.84	0.34
RFXN3	23.74	0.53	0.62	16.17	0.76
RFXN4	24.33	0.52	0.65	16.62	1.12
RFXN5	25.24	0.55	0.68	17.97	1.76
RFXN6	24.12	0.57	0.67	16.62	1.45
RFXN7	28.08	0.55	0.53	17.47	0.38
RFXN8	27.12	0.49	0.58	16.92	1.19
RFXN9	29.45	0.59	0.70	17.81	1.87

Quality Control Parameters For tablets

Tablet quality control tests such as weight variation, hardness, and friability, thickness, and drug release studies in different media were performed on the tablets.

Table 5: Quality control parameters for tablets.

Formulation code	Weight variation(mg)	Hardness(kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)	Floating lag time (min)
RFXN1	452.53	3.05	0.55	3.3	99.45	4.3
RFXN2	452.49	3.23	0.49	2.6	99.56	4.5
RFXN3	449.65	3.45	0.51	2.8	99.67	4.6
RFXN4	456.68	3.58	0.45	2.5	99.82	4.2
RFXN5	442.46	3.42	0.59	2.8	99.19	4.7
RFXN6	459.72	3.29	0.62	2.3	98.67	4.1
RFXN7	455.35	3.17	0.73	2.9	98.89	4.0
RFXN8	452.23	3.32	0.48	2.2	99.38	4.4
RFXN9	447.23	3.59	0.58	2.7	99.43	4.8

***In-Vitro* Drug Release Studies**

Table 6: Dissolution Data of RFXMN Tablets.

Time(Hrs)	RFXN1	RFXN2	RFXN3	RFXN4	RFXN5	RFXN6	RFXN7	RFXN8	RFXN9
0	0	0	0	0	0	0	0	0	0
0.5	6.72	5.16	6.15	7.78	9.61	7.19	6.15	9.36	12.39
1	14.51	17.75	14.44	13.44	12.65	16.61	10.18	22.41	29.76
2	19.03	24.73	19.46	26.68	23.42	24.17	17.26	36.59	37.48
3	27.13	28.45	24.44	32.65	28.79	29.61	29.55	39.65	45.79
4	34.16	33.64	28.17	39.46	39.64	34.55	37.47	40.74	49.54
5	39.95	44.38	38.75	41.34	42.97	42.18	46.29	44.27	54.82
6	44.94	48.19	43.76	46.69	49.69	49.19	55.75	49.75	59.68
7	49.16	53.76	49.85	49.49	56.61	53.77	58.37	50.87	66.03
8	55.33	59.77	54.25	56.65	62.78	59.15	65.74	53.33	73.76
9	58.96	65.85	59.43	58.67	77.56	64.15	78.68	57.67	76.53
10	65.83	78.38	65.36	63.59	81.07	69.13	83.56	63.43	78.56
11	68.75	84.17	68.44	76.36	85.66	72.15	92.16	71.05	85.62
12	79.23	88.26	78.43	79.85	90.08	86.85	98.07	79.37	89.57

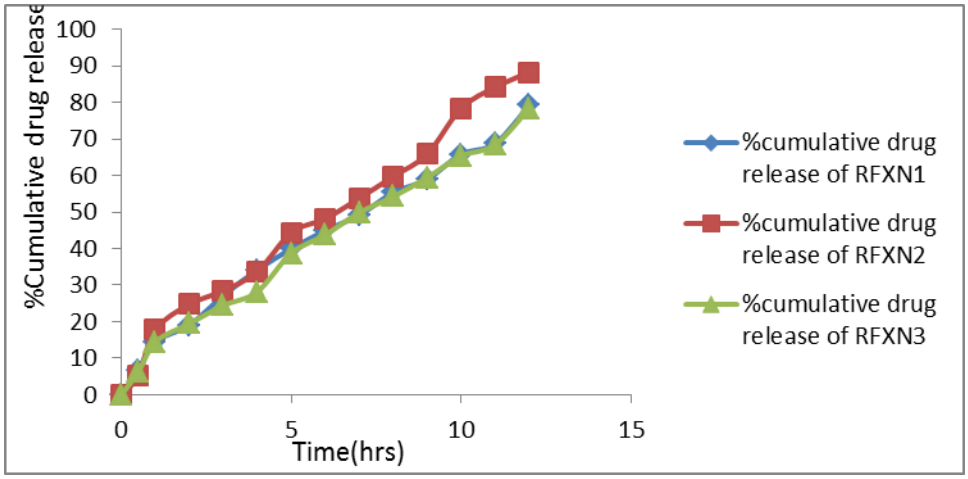


Figure 2: Dissolution profiles of formulations RFXN1-RFXN3.

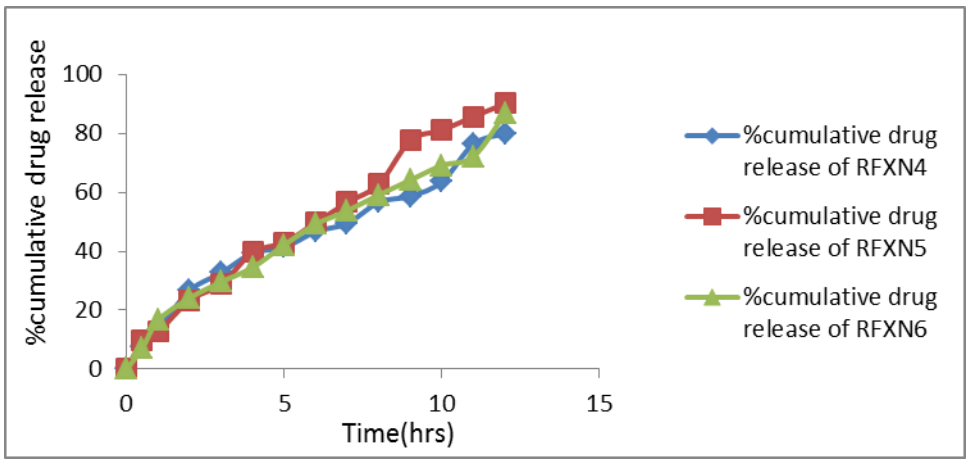


Figure 3: Dissolution profiles of formulations RFXN4-RFXN6.

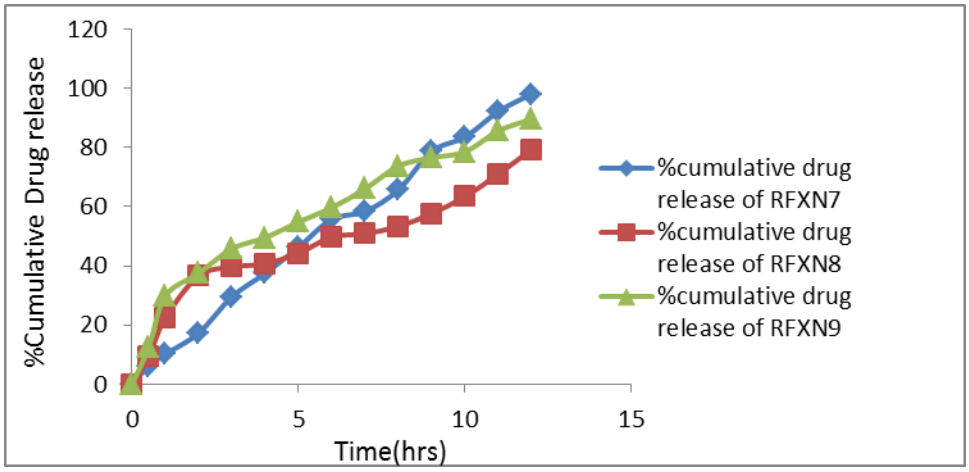


Figure 4: Dissolution profiles of formulations RFXN7-RFXN9.

From the dissolution data it was evident that RFXN8 formulation is the optimized.

Application of Release Rate Kinetics

zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Table 7: Release Kinetics Data of optimized formulation RFXN10.

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG(%) RELEASE	LOG (T)	LOG (%) REMAIN
0	0	0			2.000
6.15	0.5	0.458	0.789	1.987	1.972
10.18	1	1.000	1.008	0.000	1.953
17.26	2				
29.55	3	1.732	1.471	0.477	1.848
37.47	4	2.000	1.574	0.602	1.796
46.29	5	2.236	1.665	0.699	1.730
55.75	6	2.449	1.746	0.778	1.646
58.37	7	2.646	1.766	0.845	1.619
65.74	8	2.828	1.818	0.903	1.535
78.68	9	3.000	1.896	0.954	1.329
83.56	10	3.162	1.922	1.000	1.216
92.16	11	3.317	1.965	1.041	0.894
98.07	12	3.317	1.821	1.350	1.162

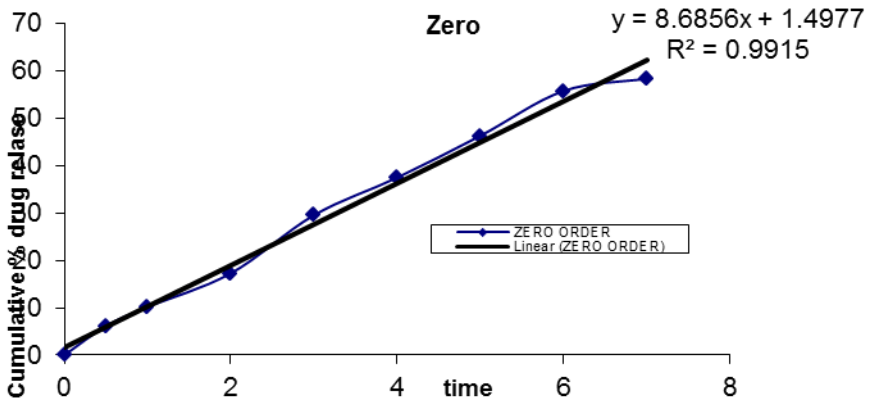


Fig 5: Zero order release kinetics graph.

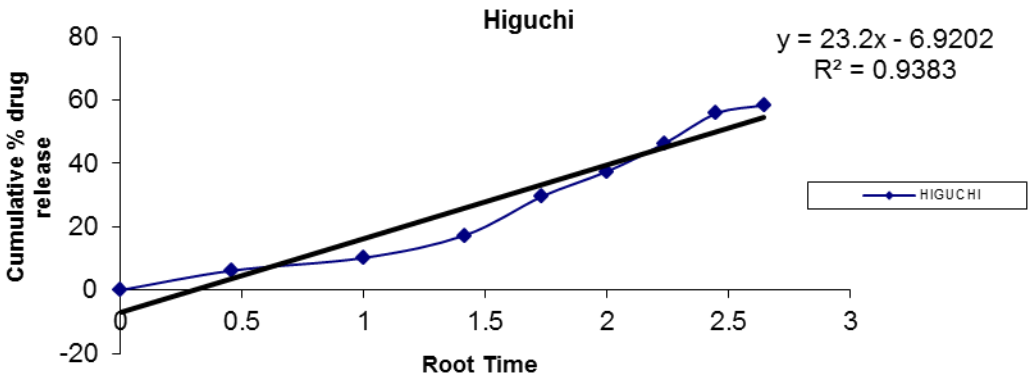


Fig 6: Higuchi release kinetics graph.

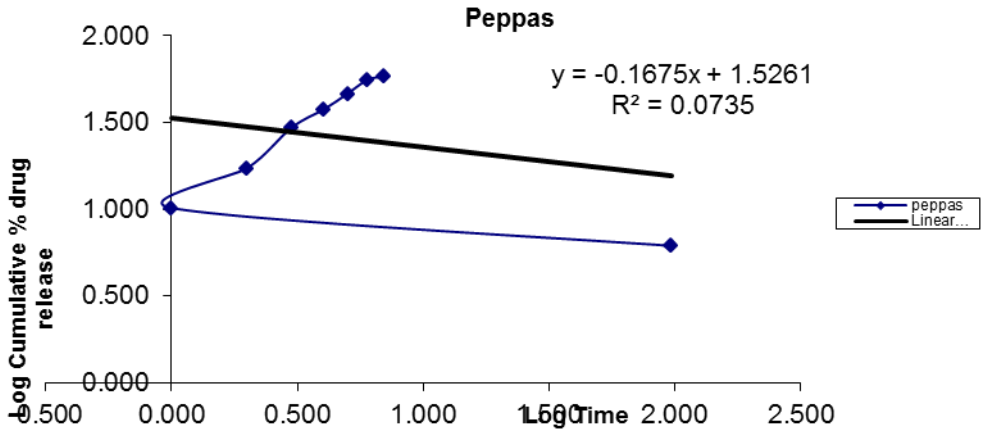


Fig 7: Karr's mayers peppas graph.

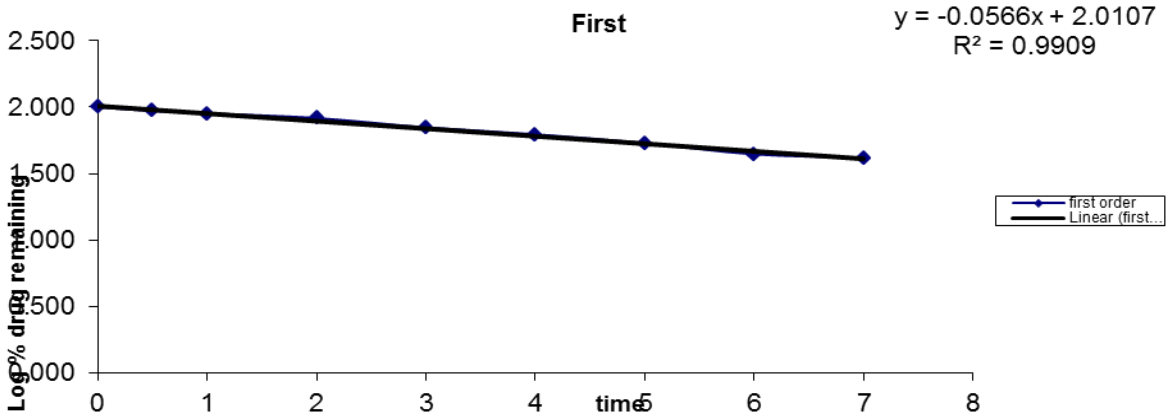


Fig 8: First order release kinetics graph.

Fourier Transform-Infrared Spectroscopy

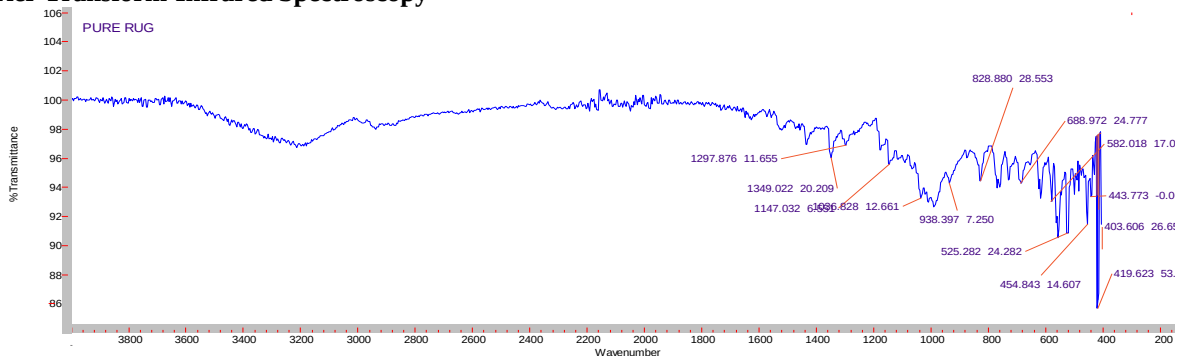
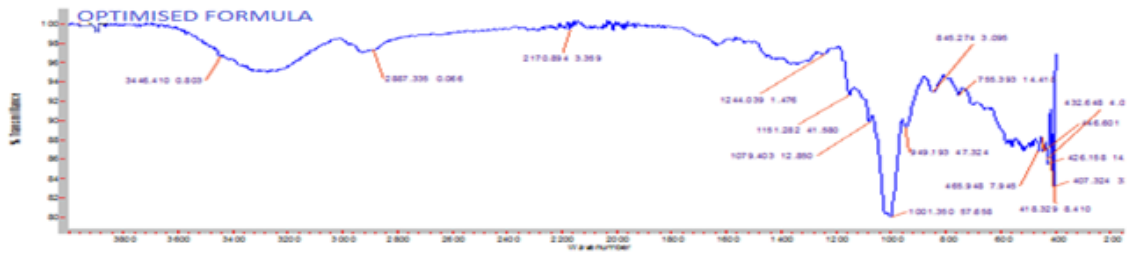


Figure 9: FT-TR Spectrum of RFXMN pure drug.



Figuren 10: FT-IR Spectrum of Optimized Formulation.

CONCLUSION

In the present research work effervescent floating of RFXMN by utilizing different polymers. At first systematic strategy improvement was accomplished for the medication atom. Assimilation a maximum was resolved dependent on that alignment bend was created by utilizing various fixations. Gas creating specialist sodium bicarbonate was utilized. At that point the definition was created by utilizing various convergences of polymers of different polymers. The detailing mix was exposed to different preformulation thinks about; stream properties and every one of the plans were observed to be great demonstrating that the powder mix has great stream properties. Among every one of the details the F7 arranged by utilizing Guar gum 50mg created greatest medication discharge contrasted with different plans thus it was considered as the best formulation.

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