RESEARCH PAPER

Formulation Development And Optimization Of Fast Dissolving Tablet For Fexofenadine And Its Evaluation

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ABSTRACT

The composition and assessment of Fexofenadine's fast-dissolving tablets (FDTs), a second-generation antihistamine frequently used to treat allergic diseases such chronic urticaria and seasonal allergic rhinitis, are presented in this article. FDTs dissolve quickly in the oral cavity without the need for water, making them useful for individuals who have trouble swallowing pills. Despite its effectiveness, fexofenadine has a bitter taste, hence taste-masking ingredients must be included in the formulation. The study investigates how FDTs may improve bioavailability and lower first-pass metabolism by delivering a quicker beginning of action through absorption through the gastrointestinal system or oral mucosa. Microcrystalline cellulose (MCC), lactose, starch, acacia, and super disintegrants such sodium starch glycolate (SSG) and croscarmellose sodium (CCS) were used as excipients in the formulation process. The tablets were prepared by direct compression. A number of criteria, such as the produced tablets' physical appearance, hardness, friability, disintegration time, and dissolving rate, were assessed. Studies on in-vitro dissolution showed that Fexofenadine was released quickly, indicating the possibility of quicker therapeutic effects. In order to improve the therapeutic experience for patients with allergies, this research offers important insights into the development of FDTs for antihistamine medications.

Keywords: Fexofenadine, antihistamines, taste-masking compounds, bioavailability, fast-dissolving tablets (FDTs), and dissolution experiments

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INTRODUCTION:

These formulations improve the convenience of drug administration by dissolving quickly in the oral cavity and removing the need for water[1]. Because anti-histamines, like Fexofenadine, are widely used to treat allergic disorders like seasonal allergic rhinitis and chronic urticarial[2], they are excellent candidates for FDT formulations among the many therapeutic classes. Since the medicine is released directly into the mouth, taste-masking chemicals are frequently included in the formulation of FDTs to ensure palatability[3].This is especially crucial for medications that taste bitter or disagreeable. Since the medication can be taken and absorbed through the gastrointestinal tract or directly through the oral mucosa, one of the main benefits of FDTs is the possibility of a quicker beginning of

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action. Because of this, FDTs are perfect for drugs that need to have therapeutic effects quickly, like painkillers, anti-allergics, and agents that affect the central nervous system. Further more, FDTs can improve the bioavailability of some medications by preventing the liver's first-pass metabolism, which results in more effective drug delivery[4]. Mast cells and basophils store histamine, a biogenic amine. Histamine is released when an allergen enters the body, causing smooth muscle contraction, blood vessel dilatation, and inflammation of the mucous membranes. In order to stop histamine from producing these effects, antihistamines attach to histamine receptors. By preventing the effects of histamine, a substance released during allergic reactions, antihistamines are a class of medications used largely to treat allergic reactions. Immune reactions and the release of stomach acid are two physiological processes in which histamine is implicated. Excessive histamine release can result in symptoms including redness, swelling, itching, and mucus production[5]. The amino acid histidine is converted into the biogenic amine histamine. It regulates the release of stomach acid, modifies neurotransmission, and mediates allergy reactions, among other functions in the body[6]. Histamine interacts with particular receptors, including H1 Receptors, H2 Receptors, H3 Receptors, and H4 Receptors, to produce its effects[7]. The safety profile and effectiveness of fexofenadine, a second-generation non-sedative antihistamine, in reducing allergy symptoms are well-established. Its conventional tablet forms, however, could be problematic for people who have trouble swallowing or in circumstances where quick treatment is required[8- 11]. These problems might be resolved by creating a fast-dissolving pill for fexofenadine, which would provide a more practical and possibly quicker-acting dosage form The results of this study may offer important information about how FDTs for other antihistamine medications should be formulated, which could result in better treatment alternatives for allergy sufferers[12].

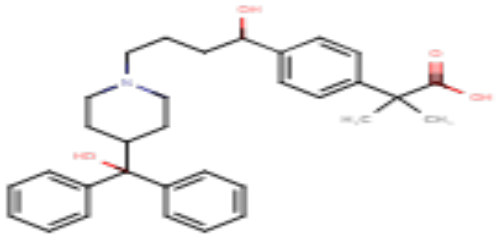

Fig no:1 Fexofenadine

MATERIALS AND METHODS

Materials

From SRL. Pvt. Ltd. in India, we acquired fexofenadine, microcrystalline cellulose, lactose, starch, acacia, crospovidone, sodium starch glycolate, and magnesium sterate.

Equipments:

Electronic balance, punching machine, hardness tester, hot air oven, tablet dissolution and disintegration tester, UV spectrophotometer, and FT-IR spectrophotometer are among the tools utilized in the current study.

FORMULATION OF FAST DISSOLVING TABLETS:

Table no : 1 Qualitative and Quantitative Composition:

S. no	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Drug	120	120	120	120	120	120	120	120	120
2	MCC	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5
3	Lactose	66	61	56	66	61	56	66	61	56
4	Acacia	2	2	2	2	2	2	2	2	2
5	Starch	5	5	5	5	5	5	5	5	5
6	CCS	5	10	15	--	--	--	--	--	--
7	SSG	--	--	--	5	10	15	--	--	--
8	Crospovidone	--	--	--	--	--	--	5	10	15
9	Mg. sterate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Total	250	250	250	250	250	250	250	250	250

PROCEDURE

Drug: Fexofenadine Hydrochloride

This is the formulation's active pharmaceutical ingredient (API). An antihistamine used to treat allergies is fexofenadine HCl. Because of its rapid beginning of action, which is ideal for treating acute allergy symptoms, it is selected for FDTs.

WEIGHING OF INGREDIENTS:

An analytical balance is used to precisely weigh each ingredient, including excipients and Fexofenadine HCl. This step is essential to guaranteeing consistency in the formulation as a whole and the proper amount of the medication in each tablet.

DISPENSING:

Set aside specific, dry, and clean tools for each excipient, such as spoons, scoops, spatulas, and poly coverings. Prior to dispensing, adjust the weighing balance's bubble. In accordance with the bill of materials, dispense each excipient and API separately, and after correctly sealing, store them separately.

IDENTIFYING SIEVES AND THE PROCESS OF SIFTING OR CO-SIFTING:

- Co-sifting API and Acacia through 60# mesh
- MCC via 40# mesh
- Lactose was sieved using 40# mesh.
- CCS via 40# mesh
- Crossovididone via 40# mesh
- SSG via 40# mesh
- Start with 40# mesh.
- Sort magnesium stearate using 30#mesh.

BLENDING (OPTIMIZATION):

- Separate the filtered lactose into three halves.
- In the blender, add the first portion of lactose and the preloaded mix. Blend for five minutes at 10±1 rpm.
- Continue mixing for five minutes at 10±1 rpm after adding the second part of lactose to the previous step.
- After adding the third part of lactose, mix for a further fifteen minutes at 10±1 RPM. Note: In order to improve the process, samples were taken every five minutes to verify the consistency of the material.

COMPRESSION:

- Using the direct compression method, precisely weigh and sieve the medication (Fexofenadine HCl), as well as magnesium stearate and acacia, as well as fillers and Super disintegrants in different amounts.
- Mix the medication with fillers and one super disintegrant at a time, then add lubricant and acacia. Compress the powder into pills after the mixing is consistent.
- To compare the effectiveness of the formulations, assess the tablets' weight variation, hardness, friability, dissolving, and disintegration time.
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EVALUATION STUDIES:

PHYSICAL APPEARANCE:

The color, shape, dimension, smoothness, lack of chips or cracks, and other undesired features of the prepared tablets were examined.

HARDNESS:

A digital hardness tester was used to measure the hardness of 20 tablets, and the average hardness was computed and reported in N or kg/cm2.

THICKNESS:

Tablet thickness was measured using a vernier caliper. Ten tablets were measured for thickness in order to determine the average thickness.

FRIABILITY:

A Roche-style friabilator was used to hold the 6.5 g tablets. The device uses a plastic chamber that rotates at 25 rpm to drop the tablets from a height of 6 inches for 100 revolutions, subjecting them to the combined effects of shock and abrasion. The pre-weighed tablet sample was taken out, dusted, and weighed again after 100 revolutions. Friability as a percentage shouldn't exceed 1.0%.

DISINTEGRATION:

Six pills were subjected to the disintegration test utilizing a disintegration test instrument in 900 milliliters of DM water that was kept at 37 degrees Celsius. Over a distance of 5 to 6 cm, the device is permitted to move up and down at a frequency of 28 to 32 cycles per minute. The tablet remains 2.5 cm below the liquid's surface while it is moving upward and at least 2.5 cm from the bottom of the beaker when it is moving downhill. Every tablet's disintegration time was noted.

IN-VITRO DISSOLUTION STUDIES:

PROCEDURE:

MAKING A BUFFER SOLUTION WITH A PH OF 3.5:

The Phosphate Buffer Monobasic potassium phosphate and phosphoric acid are combined to create a buffer solution with a pH of 3.5. By keeping the pH constant during the dissolving process, this buffer will give the drug release a steady environment.[13]

CONDITIONS AND DISSOLUTION EQUIPMENT:

USP Paddle Apparatus 2: For tablets, the USP Apparatus 2 is frequently utilized. In order to replicate body temperature, the dissolving media is kept at 37 ± 0.5°C. The speed at which the paddle rotates is set at 50 rpm. Dissolution Medium Volume: For dissolution tests, 900 milliliters of the buffer solution are utilized.[14]

SAMPLE COLLECTION AND ANALYSIS:

- **Sampling Intervals**: At specified intervals, such as 5, 10, 15, 30, 45, and 60 minutes, take samples of the dissolving medium.
- **Sample Filtration:** Prior to analysis, filter the samples to get rid of any particles that haven't dissolved.
- **Analysis Method:** Use UV-Visible Spectrophotometry to measure the concentration of Fexofenadine in the samples. The absorbance is typically measured at around 220 nm, where Fexofenadine shows strong absorbance.[15]

DETERMINATION OF SHORT TIME STABILITY STUDIES:

In order to determine stability, tablets are loaded under Accelerated Stability Conditions (40°C/75% relative humidity). It is taken and evaluated for pH, assay, RS, uniformity, water content, and description after a

predetermined amount of time (one month). The batch will pass the test only if all of these parameters are compared to the original sample and verified to be in compliance with the specifications.

RESULT AND DISCUSSION:

PHYSICAL CHARACTERIZATION AND DRUG IDENTIFICATION:

The first step in identifying a pharmacological substance is to look at its organoleptic properties. It aids in determining whether a medicine can be formulated into the desired dosage form. Additionally, this aids in evaluating patient acceptability criteria like color, nature, taste, and odor, all of which eventually improve patient compliance. Pale white in color Nature: Powder

Table no: 2 Solubility Studies

S.no	Medium	Mean Solubility (mg/mL) ± SD
1	Water	1.7 mg/mL
2	Phosphate buffer pH 3.5	2.5 mg/mL
3	Ethanol	0.1 mg/mL

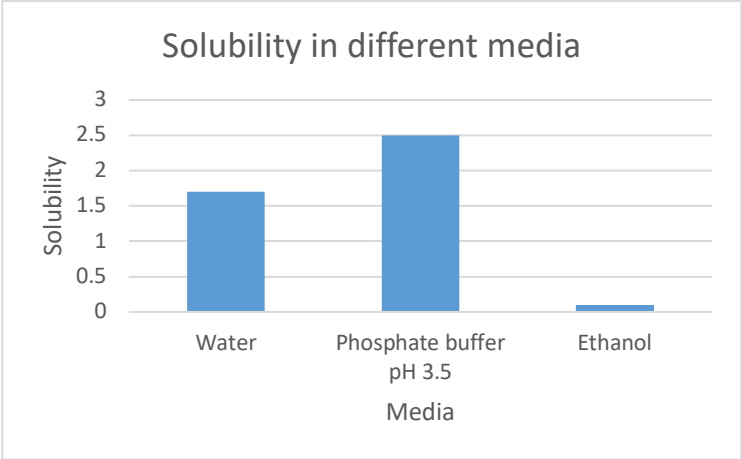

Fig no 2: Solubility in different media

DISCUSSION:

The medication was tested in a range of solvents, including buffers with varying pH values. According to the findings, fexofenadine HCl was poorly soluble in water but more soluble in acidic buffers, especially at lower pH values. Since solubility is essential to both dissolution and bioavailability, this property is critical for creating fast-dissolving tablets. Important information regarding the choice of excipients and formulation optimization to guarantee quick and effective drug release was supplied by the solubility data.

UV- SPECTRA ANALYSIS:

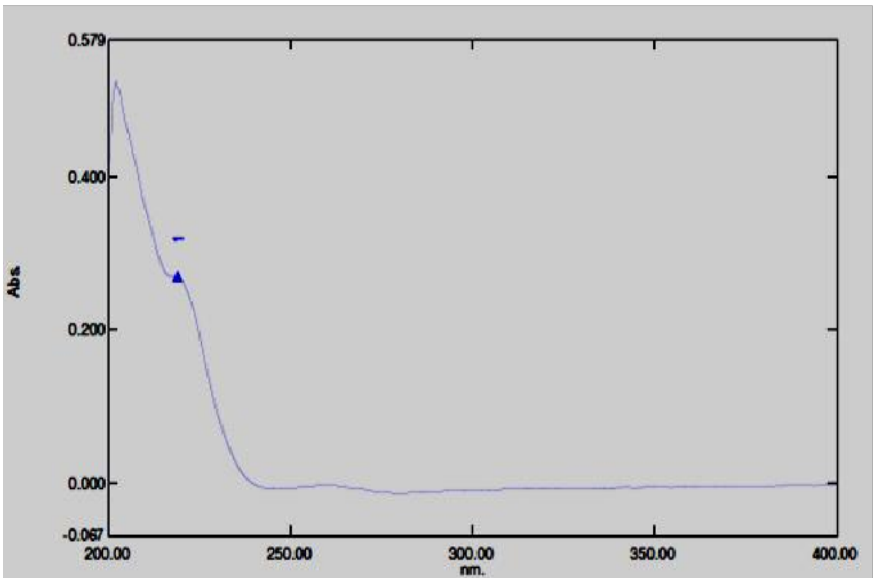

Fig no 3: UV- Spectra analysis

DISCUSSION:

The UV spectra analysis of Fexofenadine HCl revealed a maximum absorbance (λmax) at 220 nm, indicating the presence of specific chromophores within the drug structure. The analysis was performed in a pH 3.5 buffer, ensuring solubility and stability. A calibration curve confirmed linearity following Beer-Lambert's law, validating the method's accuracy for quantifying Fexofenadine HCl in formulations. No shifts in λmax were observed, confirming the drug's stability during the analysis.

IR- SPECTRA ANALYSIS:

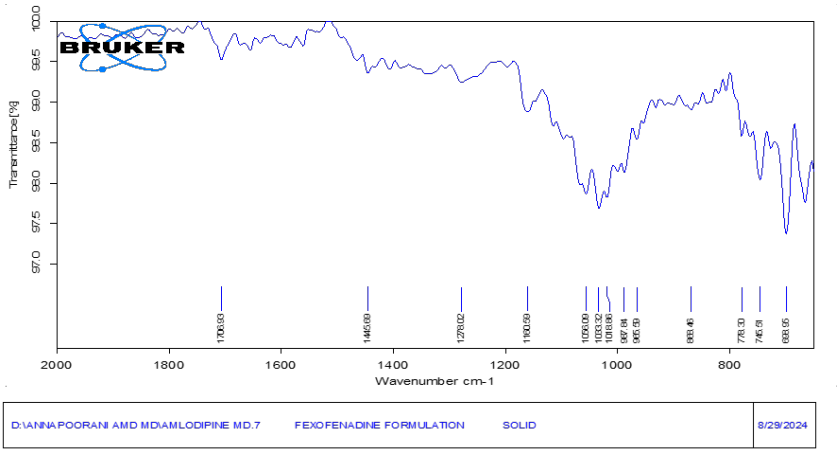

Fig no 4: IR- Spectra analysis

DISCUSSION:

To verify Fexofenadine HCl's chemical integrity and compatibility with formulation excipients, an FTIR spectra analysis was performed. No anomalies or unexpected peaks were visible in the collected spectra, indicating that the medication remained stable. Furthermore, no chemical alterations or interactions were detected, guaranteeing that Fexofenadine HCl was unaltered during the formulation procedure.

COMPATIBILITY STUDIES

Table no: 3 Physical Compatibility studies

S.NO	Description and condition								
	Drug & Excipient	Initial	Room temperature			45°C ± / 75% ± 5% RH (in days)		
			10	20	30	10	20	30
1	Drug + MCC	Pale White	NC	NC	NC	NC	NC	NC
2	Durg + Lactose	Pale White	NC	NC	NC	NC	NC	NC
3	Durg + Starch	Pale White	NC	NC	NC	NC	NC	NC
4	Durg + Acacia	Pale White	NC	NC	NC	NC	NC	NC
5	Durg + Crospovidone	Pale White	NC	NC	NC	NC	NC	NC
6	Durg + CCS	Pale White	NC	NC	NC	NC	NC	NC/
7	Durg + SSG	Pale White	NC	NC	NC	NC	NC	NC
8	Durg + Mg. Sterate	Pale White	NC	NC	NC	NC	NC	NC
9	Drug + All Excipients	Pale White	NC	NC	NC	NC	NC	NC

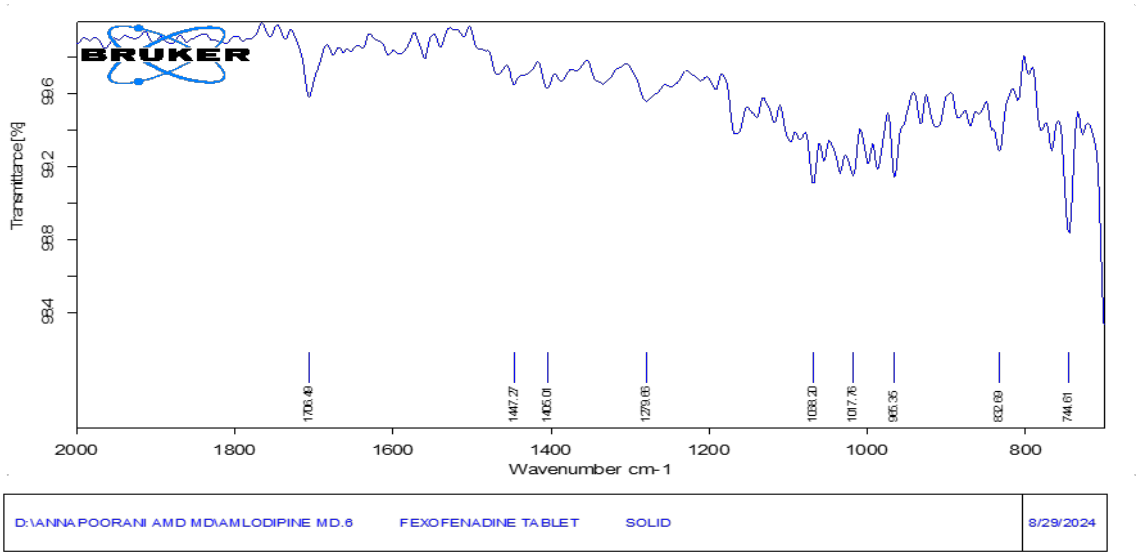

Fig no 5: Drug + All Excipients

CHEMICAL COMPATIBILITY STUDIES

DISCUSSION:

Throughout the trial, there were no discernible changes in the pale white physical appearance of any mixture, including the medicine with individual excipients (MCC, Lactose, Starch, Acacia, Crospovidone, CCS, SSG, Magnesium Stearate) and the combined excipients. This suggests that there are no physical incompatibilities. The drug's chemical stability with the excipients was confirmed by FTIR chemical compatibility testing, which revealed no new peaks or shifts. This ensured that there was no degradation or interaction that could affect the drug's effectiveness.

PREFORMULATION STUDIES RESULT:

Table no: 4 Flow and consolidation properties:

S.No	Parameters	Mean (±SD)	Flow
1.	Angle of Repose	33.1	Good
2.	Bulk density	0.431 g/ml	
3.	Tapped Density	0.51 g/ml	
4.	Compressibility Index*	12.85	
5.	Hausner's ratio**	1.15	

Table no 5: Limit of flow characters

Flow Character	Compressibility Index (%)*	Hausner's ratio**
Excellent	≤10	1.00-1.11
Good	11-15	1.12-1.18
Fair	16-25	1.19-1.34
Poor	26-31	1.35-1.45
Very poor	32-37	1.46-1.59
Extremely poor	>38	>1.60

DISCUSSION:

To determine if the Fexofenadine HCl powder was suitable for tablet compression, its flow and consolidation characteristics were examined. An adequate angle of repose suggested that the powder had good flowability. Furthermore, the formulation's good compressibility characteristics were indicated by the bulk and tapped density tests. The powder blend's suitability for direct compression was further validated by the compressibility index and Hausner's ratio, which makes it effective for tablet production.

PHYSICAL AND CHEMICAL EVALUATION STUDIES

Table no 6: In-process Parameters

Formulation Code	Average weight (mg) (±7.5 %)	Thickness (mm) (±0.3mm)	Hardness (N)	Friability % NMT 1.0 %	DT
F1	250.8	3.11	22	0.37	2'99"

F2	250.5	3.09	23	0.29	2'77"
F3	251.2	3.08	23	0.21	2'41"
F4	251.8	3.12	25	0.31	3'03"
F5	250.6	3.11	24	0.51	2'87"
F6	250	3.12	22	0.45	2'27"
F7	251.5	3.15	23	0.29	2'97"
F8	252.3	3.07	24	0.32	2'37"
F9	250.4	3.15	22	0.24	2'17"

DISCUSSION:

A number of physical characteristics, including average weight, thickness, hardness, friability, and disintegration time (DT), were assessed for the manufactured Fexofenadine HCl tablets. Every formulation fell within the permissible ranges for hardness, thickness, and weight fluctuation. Good mechanical integrity was indicated by the tablets' friability, which was likewise much below the permitted limit. F9 stood out as the best-performing formulation because it showed the quickest disintegration time among the formulations, which makes it ideal for attaining rapid drug release.

Table no :7 In- vitro drug release studies for fexofenadine Hcl.

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	24.5	29.5	30.1	26.6	32.5	38.9	25.3	32.6	35.5
10	45.6	48.6	50.2	47.6	47.5	51.6	44.5	47.2	51.6
15	55.6	60.2	64.6	53.5	60.4	67.9	54.6	61.6	68.9
30	70.5	72.3	75.3	70.4	73.5	79.5	72.2	77.4	79.8
45	78.5	88.2	89.5	81.6	85.6	88.6	81.6	87.3	89.6
60	92.5	94.5	96.5	92.5	95.7	97.5	93.5	95.6	98.3

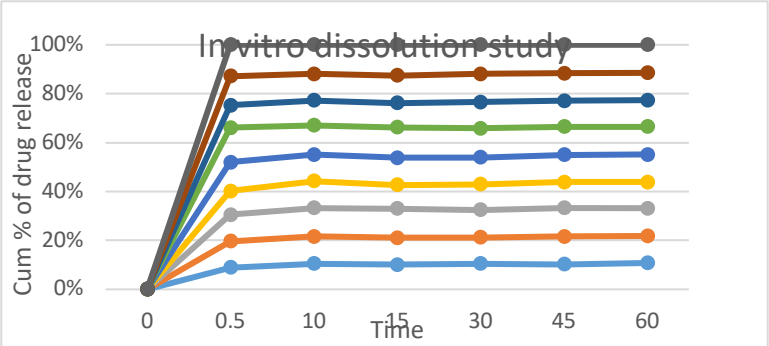

Fig no 6: In-vitro dissolution study

DISCUSSION:

To evaluate the release profile of Fexofenadine HCl tablets in a pH 3.5 buffer solution, dissolution tests were carried out. The formulation with the highest crospovidone content, F, performed the best out of the nine. Rapid drug release was indicated by its highest dissolving rate and fastest disintegration. In comparison to the other formulations, this demonstrates that F9 satisfies the requirements for fast-dissolving tablets, guaranteeing a speedier therapeutic action and better bioavailability.

DETERMINATION OF SHORT TIME STABILITY STUDIES AS PER THE ICH GUIDELINES

After a month of stability testing, the samples were examined to look for any changes in the drug's chemical and physical characteristics.

Table no :8 Short-term Stability Study

S. No	Tests	Initial	1 Month (40±2°C/75±5% RH)

1	Description	Pale white colour	Pale white colour
2	Hardness	22	21
3	Friability	0.24	0.26
4	Disintegration	2'17"	2'19"
5	Dissolution (% Drug Release)	95%	91%

According to the analysis, all of the parameters are stable and within the range, and no notable alterations were noticed.

DISCUSSION:

The short-term stability studies conducted at 40±2°C/75±5% RH for one month, the formulation remained stable with only slight variations in key parameters. The physical appearance of the tablets remained unchanged, and the hardness and friability showed minimal differences over time. The disintegration time was consistent, maintaining the fast-dissolving characteristic of the tablets. There was a slight reduction in the drug release rate during dissolution testing, but it remained within acceptable limits for efficacy. Overall, the formulation demonstrated good stability under accelerated conditions in compliance with ICH Guidelines**.**

CONCLUSION:

Direct compression is an effective and successful method for creating fast-dissolving tablets of the anti-histamine drug fexofenadine utilizing a superdisintegrant. The crospovidone formulation F9 tablets disintegrate the fastest. Using the solid dispersion method, the study demonstrates that Fexofenadine HCL dissolves quickly in tablets. By adding superdisintegrants, the direct compression approach can significantly increase the pace at which fexofenadine Hcl disintegrates. When compared to other formulations, the tablet containing crospovidone is exhibiting good results.

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