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Design and Evaluation of Fexofenadine Orally Disintegrating Tablets for Rapid Dissolution

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Abstract:
This study aims to formulate and evaluate Fexofenadine Oral Disintegration Tablets (ODTs), focusing on overcoming patient compliance issues related to taste and swallowing difficulties, especially in elderly and pediatric patients. Fexofenadine, a first-line treatment for type 2 diabetes, is used to enhance rapid dissolution, absorption, and bioavailability. Objectives included preparing tablets using direct compression and evaluating formulations through in-vitro tests such as weight variation, thickness, hardness, friability, drug content, wetting time, dispersion time, disintegration time, and dissolution studies. FTIR spectral analysis confirmed the presence of principal peaks and interactions between drug and polymers. Results indicated a strong correlation (r=0.998) between Fexofenadine concentration and absorbance values. Tablets exhibited weight and thickness within pharmacopoeial limits, with hardness, friability, and drug content meeting acceptable standards. Wetting time and water absorption ratio varied among formulations, with Cross povidone and Croscarmellose sodium showing superior performance. Disintegration times ranged from 17.66±0.51 to 171.83±1.16 seconds, with tablet formulations containing Cross povidone or combinations of super disintegrants (CP + CCS, CP + SSG) demonstrating rapid disintegration. In-vitro dispersion and dissolution studies reaffirmed these findings, suggesting these ODT formulations can significantly improve patient adherence, providing a quick onset of action and enhanced drug bioavailability. Further studies are recommended to establish extended in-vivo performance and safety profiles, supporting the efficacy of Fexofenadine ODTs in clinical settings.

Keywords: Fexofenadine, Oral disintegration tablets (ODTs), direct compression technique, In-vitro evaluation, and Patient compliance

INTRODUCTION:

MOUTH DISSOLVING TABLETS (FDT):

Oral fast dissolving medicine delivery system (OFDDS) is one similar new approach to increase consumer acceptance by virtue of rapid-fire decomposition, tone- administration without water or chewing. Orally disintegrating tablets (ODT) are solid unit lozenge forms like conventional tablets, but are composed of super disintegrants, which help them to disintegrate the tablet fleetly in slaver without the need to take it water. Orally disintegrating tablets (ODT) aren't only indicated for people who have swallowing difficulties, but also are ideal for active people.

Oral administration is the most popular route about 50- 60 of total lozenge forms are administered due to ease of ingestion, pain avoidance, versatility(to accommodate colorful types of medicine campaigners), and most importantly patient compliance. Solid oral delivery systems don't bear sterile conditions and are thus less precious to manufacture. [1]

One important debit of solid lozenge forms is the difficulty in swallowing (dysphasia) or biting in some cases particularly pediatric and senior cases. [2]

The problem of swallowing is common miracle in senior case due to fear of choking, hand temblors, dysphasia and in children's due to underdeveloped muscular and nervous systems and in schizophrenic cases performing in poor compliance with oral tablet medicine remedy which leads to reduced overall remedy effectiveness. Difficulties in swallowing of tablet and capsule also do when water isn't available, in diarrhea, coughing during the common cold wave, antipathetic condition and bronchial infection. United States Food and medicine administration (FDA) defined ODT as "a solid lozenge form containing medicinal substance or active component which disintegrates fleetly generally within a matter of seconds when placed upon the lingo." Orally disintegrating tablets are also called as mouth-dissolving tablets, presto disintegrating tablets, quick dissolving tablets, orodispersible tablets, rapimelts, and pervious tablets, fast dissolving tablet. [3]

Lately European Pharmacopoeia also espoused the term ' orodispersible tablet' as a tablet that's to be placed in the mouth where it disperses fleetly before swallowing.(4)

Despite colorful languages used, orally disintegrating tablets are then to offer unique form of medicine delivery with numerous advantages over the conventional lozenge forms. "The US Food and Drug Administration's 2008 publication of guidance for orally disintegrating tablets".

Three main points stand out in the final regulations.

1. ODTs should have an In vitro decomposition time of roughly 30 seconds or lower (using United States Pharmacopeia decomposition test or original).
2. Generally, the ODT tablet weight shouldn't exceed 500 mg, although the concerted influence of tablet weight, size, and element solubility all factor into the adequacy of an ODT for both cases and controllers. The guidance serves to define the upper limits of the ODT category, but it does not supersede or replace the original regulatory definition mentioned. In other words, disintegration within a matter of seconds remains the target for an ODT. [5]

Ideal parcels of ODTs: [6, 7]

- Bear no H2O for oral administration, yet dissolve disperse/ disintegrate in mouth in a fraction of seconds.
- Have a pleasing mouth feel.
- Have a respectable taste masking property.
- Be harder and lower brickle.
- Leave little or no residue in mouth after intake. Exhibition low perceptivity to environmental conditions (temperature and moisture).
- Allow the manufacture of tablet using conventional processing and packaging accoutrements.

Advantages of ODTs [7, 8]

- Ease of Administration to the case that cannot swallow, similar as the senior, stroke victims, bedridden cases, patient affected by renal failure and case who refuse to swallow similar as pediatric, senior & psychiatric cases.

- No needs of water to swallow the lozenge form, which is largely accessible point for cases that are traveling and don't have immediate access to water.
- Some drugs are taken by the body from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is become high.
- Pre gastric immersion can affect in bettered bioavailability and as a result of reduced lozenge; ameliorate clinical performance through a reduction of unwanted goods.
- Good mouth feel property of ODTs helps to change the perception of drug as bitter lozenge particularly in pediatric case.

Disadvantages of ODTs: [9]

- ODT is hygroscopic in nature so must be keep by dry place, some time it possesses mouth feeling.
- cost- ferocious product process
- lack of physical resistance in standard fester packs
- Limited capability to incorporate advanced attention of active medicine.

Limitations of ODTs: [10]

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The drug may leave unpleasant odour and/or grittiness in mouth if not formulated correctly.

Challenges to develop ODTs: [4]

- Rapid disintegration of tablet
- Avoid increase in tablet size
- Have sufficient mechanical strength
- Little or no residue in mouth
- Protection from moisture.

Selection of drug candidates for ODTs: [11]

Several factors must be considered when opting medicine campaigners for delivery as FDT lozenge forms. The ultimate characteristics of a medicine for dissolution in the mouth and pre gastric immersion from ODTs include;

- incompletely non – ionized at oral depression's pH
- Medicines having capability to diffuse and partition into the epithelium of the upper GIT (log P> 1, or preferable> 2); and those suitable to percolate oral mucosal towel are considered ideal for FDT phrasings.
- Cases who coincidently take anticholinergic specifics may not be the stylish campaigners for these medicines
- Cases with Jorgen's pattern or blankness of the mouth due to dropped slaver product may not be good campaigners for FDT phrasings.
- Medicines which bear controlled or sustained release are infelicitous campaigners of fast dissolving oral lozenge forms.

Selection of Super disintegrant: [6]

- Although super disintegrant primarily affect the rate of decomposition, but when used at high situations they can also affect mouth sense, tablet hardness and frangibility.
- Hence, colorful ideal factors to be considered while opting applicable super disintegrant for a particular expression should:
- Produce rapid-fire decomposition (hydrophilic) when tablet meets slaver in the mouth.

- Be compactable enough to produce lower-brickle tablets.
- Produce good mouth feel to the case. Therefore, small flyspeck size is preferred to achieve patient compliance.

Expression aspects in developing ODTs: [4]

Orally disintegrating tablets are formulated by exercising several processes, which differ in their methodologies and odts formed vary in colorful parcels similar as

1. Mechanical strength of tablets
2. Taste and mouth feel
3. Swallow capability
4. medicine dissolution in slaver
5. Bioavailability and Stability

TECHNIQUES IN PREPARATION OF ORALLY DISINTEGRATING DRUG DELIVERY SYSTEM: [12, 7]

Disintegrant Addition: Involves the addition of super disintegrants in optimum attention to the expression to achieve rapid-fire decomposition/ dissolution. For e.g. MCC and sodium bounce glycolate are used in expression of Efavirenz, Crystalline cellulose (Avicel PH- 102) and low substituted HPEC used in oxybutinin and pirenzepine expression. Crospovidone used in galanthamine HBr. Crospovidone (3%w/w) and cross carmellose Na (5%w/w) used in prochlorperazine maleate expression.

Characteristics: similar analogous to conventional tablets with advanced % of disintegrants, lower hardness and advanced % of friability.

Freeze Drying or Lyophilization: The medicine is dissolved or dispersed in a waterless result of a carrier. The admixture is poured into the wells of the preformed fester packs. The servers holding the fester packs are passed through liquid nitrogen indurating lair to indurate the medicine result. Also the frozen fester packs are placed in refrigerated closets to continue the snap drying. Eventually the pocks are packaged and packed.

Characteristics: The medications are largely pervious, have high specific face area, dissolve fleetly and eventually show bettered immersion and bioavailability.

Cure incorporated- undoable 400 mg

Water answerable medicine lading- 60 mg

Moulding: Water-answerable constituents with a hydro alcoholic detergent are used and are moldered into tablets under pressure lower than that used in conventional tablet contraction. Characteristics moldered tablets are veritably lower compact than compressed tablet pervious structure that enhances decomposition/ dissolution and eventually immersion increased.

Sublimation: Inert solid constituents that volatilize fleetly like urea, camphor ammonium carbonate, ammonium bicarbonate, and hexamethylenetetramine were added to the other tablet constituents and the admixture is compressed into tablets. The unpredictable accoutrements were also removed via sublimation, which generates pervious structure.

Characteristics: pervious structure that enhances dissolution by using unpredictable material or solvent e.g. cyclohexane, benzene etc.

Spray-Drying: Drying By hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium bounce glycolate or crosscarmellose sodium as disintegrating agent and an acidic material(e.g. citric acid) and/ or alkali material(e.g. Sodium bicarbonate) to enhance decomposition/

dissolution.

Characteristics Prepared tablet disintegrates within 20 seconds when immersed in an waterless medium.

Mass Extrusion: Involves softening the active mix using the solvent admixture of water answerable polyethylene glycol, methanol and expatriation of softened mass through the extruder or syringe to get a spherical shape of the product into indeed parts using heated blade to form tablets.

Characteristics: The dried product can be used to cover grains of bitter tasting medicines and thereby making their bitter taste. [16]

Direct compression: Conventional outfit, generally available excipients and a limited number of processing way are involved in direct contraction.

Characteristics: It's utmost cost effective tablet manufacturing fashion.

Cotton candy process: Involves the conformation of matrix of polysaccharides by contemporaneous action of flash melting and spinning. This delicacy floss matrix is also mulled and blended with active constituents and excipients after re-crystallization and latterly compressed to FDT.

Characteristics: It can accommodate high boluses of medicine and offers bettered mechanical strength. [17]

Compaction:

a) Melt granulation**:** Prepared by incorporating a hydrophilic waxy binder (super polystate) cut-6-stearate. Good polystate not only acts as binder and increase physical resistance of drug and also provides the disintegration of drug.

Characteristics: It melts in the mouth and solubilizes fleetly leaving no residue.

b) Phase- transition process: Prepared by compressing greasepaint containing two sugar alcohols with high and low melting points and posterior heating at a temperature between their melting points. The tablet hardness was increased after hotting process due to increase of inter flyspeck bond convinced by phase transition of lower melting point sugar alcohol

Characteristics: The comity increased and so sufficient hardness gained by the expression.

Nanonization: Involves size reduction of medicine to nanosize by mulling the medicine using a personal wet- milling fashion. The nanocrystals of the medicine are stabilized against agglomeration by face adsorption on named stabilizers, which are also incorporated into ODTs.

Characteristics: It's used for inadequately water answerable medicines. It leads to advanced bioavailability and reduction in cure, cost effective manufacturing process, conventional packaging due to exceptional continuity and wide range of boluses (up to 200 mg of medicine per unit).

Fast Dissolving Films: Involves size reduction of medicine to nanosize by mulling the medicine using a personal wet- milling fashion. The nanocrystals of the medicine are stabilized against agglomeration by face adsorption on named stabilizers, which are also incorporated into ODTs.

Characteristics: It's used for inadequately water answerable medicines. It leads to advanced bioavailability and reduction in cure, cost effective manufacturing process, conventional packaging due to exceptional continuity and wide range of boluses (up to 200 mg of medicine per unit).

Phase transition process: The combination of low and high melting point sugar alcohols, as well as a phase transition in the manufacturing process, is important for making orally disintegrating tablets without any special outfit. Then, tablets produced by compressing the greasepaint containing two sugar alcohols of high and low melting point and latterly hotting at temperature between their dual melting points. ODT's were produced by compressing greasepaint containing erythritol (melting point: 122^0C) and xylitol (melting point 93 - 95^0C) and then heating at about 93^0C for 15min. After hotting

The median severance size of the tablets was increased and tablet hardness was also increased. The increase of tablet hardness with heating and storehouse did n't depend on the crystal clear state of the lower melting point of the sugar alcohol. Before heating process, tablet didn't have sufficient hardness because of low comity but after heating, increase in inter particular cling or binding face area occurs which also increased tablet hardness.

Melt granulation: Melt granulation fashion is a process by which pharmaceutical maquillages are efficiently rolled by a meltable binder. The advantage of this fashion compared to a conventional granulation is that no water or organic detergents is demanded. Because there's no drying step, the process is lower time consuming and uses lower energy than wet granulation. It's a useful fashion to enhance the dissolution rate of inadequately water-answerable medicines, similar as griseofulvin.

Effervescent method: Orodispersible tablets are also prepared by bouncy system by mixing sodium bicarbonate and tartaric acid of attention 12% (w/w) along with super disintegrants like pregelatinized bounce, sodium bounce glycolate, cross povidone, and croscarmellose. First, sodium bicarbonate and tartaric acid were preheated at a temperature of 80° c to remove absorbed/ residual humidity and completely mixed in the motor. Eventually, the composites are compressed in the punch.

The major advantages of this system are its well established, easy to apply and mask the bitter taste of the medicine. The bouncy system is generally composed of a dry acid and dry base which when reply grease a mild bouncy action when the tablet contact with slaver.

The bouncy response accelerates the decomposition of tablet through the release of carbon dioxide, water and swab. Due to the elaboration of Carbon dioxide, the bitter taste of the medicine is also masked and an affable mouth feel is felt. The major downsides of these styles includes chemical stability for which controlled moisture conditions needed and storehouse conditions like temperature and hygroscopicity. [7, 13]

ROLE OF SUPER DISINTEGRANTS IN ODT [7]

The introductory approach in development of ODTs is use of disintegrant. Disintegrant plays an important part in the decomposition and dissolution of ODT. It's essential to choose a suitable disintegrant, in an optimum attention so as to insure quick decomposition and high dissolution rates. Disintegrant give quick decomposition due to concerted effect of swelling and water immersion by the expression. Because of swelling of perfect disintegrant, the bathe face of the carrier hypes; this increases the wet capability and dispersability of the system, therefore increasing the decomposition and dissolution. Care should be taken to taken while obtaining attention of the super disintegrant. Super disintegrants are named according to critical attention of disintegrant. Below this attention, the tablet decomposition time is equally commensurable to the attention of the super disintegrant, whereas if attention of super disintegrant is above critical attention, the decomposition time remains nearly constant or indeed increases.

Common disintegrants used in this expression are croscarmellose sodium(Vivasol, Ac - Di - Sol), crospovidone (Polyplasdone), carmellose (NS - 300), carmellose calcium (ECG - 505), sodium bounce glycolate(SSG) etc. lately many ion exchange resins(e.g. Indion 414) are set up to have super - disintegrant property and are extensively used in pharmaceutical assiduity.

List of Super disintegrants: [10]

Super disintegrants	Example	Mechanism of action	Special comment
Croscarmellose, Ac-Di-Sol, Nymce ZXS, Primellose, Solutab, Vivasol, L-HPC	Crosslinked Cellulose	Swells 4-8 folds in < 10 seconds. Swelling and wicking both.	Swells in two dimensions. Direct compression or granulation Starch free.
Crosspovidone, crosspovidon M, Kollidon, Polyplasdone	Crosslinked PVP	Swells very little and returns to original size after compression but act by capillary action	Water insoluble and spongy in nature so getporous tablet
Sodium starch, glycolate, explotab, Primogel	Crosslinked Starch	Swells 7-12 folds in <30 seconds	Swells in three Dimensions and high level serve as sustain release matrix
Alginic acid NF, Satialgin	Crosslinked alginic acid	Rapid swelling in aqueous medium or wicking action	Promote disintegration in dry granulation.
Soy polysaccharides, Emcosoy	Natural super Disintegrant		Does not contain any starch or sugar. Used in nutritional products
Calcium silicate		Wicking action	Highly porous, Optimum concentration is between 20-40%

Table No: 1 List of Super disintegrants

PREFORMULATION STUDIES:

It's the first step in rational development of lozenge forms of medicine substance. Pre expression testing is defined as disquisition of physical and chemical parcels of a medicine substance alone and when combined with excipients. It gives information demanded to define the nature of the medicine substance and give frame work for the medicine combination with pharmaceutical excipients in the lozenge form.

Bulk Density (Db) [14]

It's the rate of total mass of greasepaint to the bulk volume of greasepaint. It was measured by pouring the weight greasepaint (passed through standard sieve # 20) into a measuring cylinder and initial weight was noted. This starting volume is called the bulk volume. From this the bulk density is calculated based on the formula mentioned down. It's expressed in g/ ml and is given by

Db = M/ Vb

Where, M is the mass of powder, Vb is the bulk volume of the powder.

Tapped Density (Dt) [15]

It's the rate of total mass of the greasepaint to the tapped volume of the greasepaint. Volume was measured by tapping the greasepaint for 750 times and the tapped volume was noted if the difference between these two volumes is lower than 2%. Still, tapping is continued for 1250 times and tapped volume was noted, if it's further than 2%. Tapping was continued until the difference between consecutive volumes is lower than 2 % (in a bulk viscosity outfit). It's expressed in g/ml and is given by

Dt = M / Vt

Where, M is the mass of powder, Vt is the tapped volume of the powder.

Carr's index (or) % compressibility

It indicates grease paint in flow parcels. It's expressed in chance and is give

carr's Index I=Dt-DbDt×100

Where, Dt is the tapped density of the powder,

Db is the bulk density of the powder

% Compressibility	Flowability
5-12	Excellent
12-16	Good
18-21	Fair passable
23-35	Poor
33-38	Very Poor
>40	Very very poor

Table No: 2 Relationship between % compressibility and flowability

Hausner ratio

Hausner rate is a circular indicator of ease of greasepaint inflow. It's calculated by the following formula:

Hausner ratio=Dt/Db

Where, Dt is the tapped density, Db is the bulk density.

Lower hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25).

Angle of Repose

The disunion forces in loose greasepaint can be measured by the angle of repose. It's a reflective of the inflow parcels of the greasepaint. It's defined as maximum angle possible between the face of the pile of greasepaint and the vertical aeroplane

tan (θ) = h / r

θ = tan-1 (h / r)

Where, θ is the angle of repose,

h is the height in cms, r is the radius in cms.

Angle of Repose	Flow
<25	Excellent
25-30	Good
30-40	Passable

>40	Very poor

Table No: 3 of Repose as an Indication of Powder Flow Properties

RESULT AND DISCUSSION

The present logical system adhered Beer's law in the attention range of 5 – 30 µg/ ml and is suitable for the estimation of Fexofenadine form different results. The correlation measure(r) value for the direct retrogression equation was set up to be 0.998, indicating a positive correlation between the attention of Fexofenadine and its corresponding absorbance values.

Evaluation of orally disintegration tablet formulations

Different quality control tests were performed for all the ODT phrasings to check whether these have met the specifications given in USP along with other In vitro tests like wetting down time and water immersion rate.

Assay

20 tablets were aimlessly named, counted and finely pulverized; greasepaint fellow to one tablet was added to 100 ml of pH 6.8 phosphate buffer in a conical beaker. Conical steins were placed on a rotary shaker overnight. An aliquote of result was centrifuged and supernatant was filtered through 0.22 µ sludge. Absorbance of the redounded supernatant result was measured using U.V Visible spectrophotometer at a wavelength of 412nm against pH 6.8 phosphate buffer as blank. Attentions were calculated with the help of standard graph and total quantum present in the expression was calculated.

Formulae of Fexofenadine ODTs prepared by direct compression method with various super disintegrants:

Ingredients	**Super disintegrants concentration (%) of Crosspovidone/ Croscarmellose Sodium/ Sodium Starch Glycolate**			
	3%	6%	9%	12%
Fexofenadine	30	30	30	30
Super disintegrants	3	6	9	12
Avicel PH 102	44	41	38	35
Pearlitol SD200	10	10	10	10
Sodium saccharin	10	10	10	10
Orange flavor	2	2	2	2
Sodium stearyl fumerate	0.5	0.5	0.5	0.5
Talc	0.5	0.5	0.5	0.5
Total weight (mg)	100	100	100	100

Table No: 4 Formulae of Fexofenadine ODTs prepared by direct compression method with various super disintegrants

Preformulation characteristics of Fexofenadine ODTs

Formulation	Bulk density (g/cc)	Tapped Density (g/cc)	Hausner ratio	Compressibility index (%)	Angle of repose (ɵ)
F1	0.435	0.522	1.20	16.66	32.67
F2	0.429	0.518	1.20	17.18	29.08
F3	0.430	0.524	1.21	17.18	29.08
F4	0.432	0.528	1.22	18.18	30.64
F5	0.428	0.518	1.21	17.37	30.64
F6	0.420	0.510	1.21	17.64	31.05
F7	0.416	0.509	1.22	18.27	32.54
F8	0.417	0.515	1.23	19.02	29.67
F9	0.425	0.515	1.21	17.47	31.85
F10	0.421	0.509	1.20	17.28	29.56
F11	0.419	0.515	1.22	18.64	30.17
F12	0.415	0.512	1.23	18.94	32.08

Table No: 5 Preformulation characteristics of Fexofenadine ODTs

Tabletting characteristics of Fexofenadine ODTs

Formulation	Weight (mg)	Drug content (%)	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)
F1	99.9±0.70	98.96±0.47	3.05±0.13	0.48	2.84±0.032
F2	99.52±0.85	99±0.65	3.10±0.15	0.53	2.85±0.028
F3	98.9±0.52	99.11±0.52	2.95±0.08	0.44	2.86±0.024
F4	100.2±1.17	99.15±0.60	2.95±0.10	0.57	2.86±0.051
F5	99.0±0.49	99.2±0.4	3.08±0.12	0.43	2.88±0.048
F6	98.8±0.58	98.85±0.58	3.11±0.14	0.56	2.90±0.052
F7	99.3±0.54	99.31±0.24	2.92±0.08	0.53	2.92±0.038
F8	100.4±1.0	98.96±0.28	3.0±0.09	0.45	2.91±0.042
F9	99.6±0.95	99.3±0.38	2.9±0.07	0.6	2.90±0.040
F10	99.2±0.97	99.36±0.29	3.05±0.08	0.49	2.89±0.042
F11	99.4±0.86	98.75±0.40	3.05±0.09	0.53	2.89±0.034
F12	98.5±0.42	99.21±0.38	2.93±0.08	0.58	2.87±0.031

Table No: 6 Tabletting characteristics of Fexofenadine ODTs

Graphical representation of friability of Fexofenadine ODTs prepared by varying concentrations of super disintegrants

Formulation	Wetting time (Sec)	In vitro dispersion time (sec)	Disintegration time (sec)	Water absorption ratio (%)
F1	24.86±0.98	221.33±1.03	117.5±1.37	58.45
F2	21.16±0.75	181.5±1.04	96.16±0.75	59.25

F3	14.66±0.51	75±0.89	56.50±1.64	58.9
F4	**11.66±0.51**	**54±0.63**	**27.83±1.16**	**60.65**
F5	57.33±0.81	245.5±1.04	167.83±1.94	59.88
F6	22.33±1.36	215.5±0.54	98±0.63	61.48
F7	28±1.09	178.83±1.16	73.16±1.47	59.55
F8	19.66±0.81	126.66±0.81	36.66±1.21	60.01
F9	38.33±0.81	260.83±1.47	173.83±1.16	64.37
F10	28.33±0.81	226.33±0.81	153.00±0.89	67.54
F11	27.66±0.81	186.83±0.75	81.5±1.04	65.50
F12	36.84±1.16	156.5±0.83	42.66±1.75	65.89

Table No: 7 Graphical representation of friability of Fexofenadine ODTs prepared by varying concentrations of super disintegrants

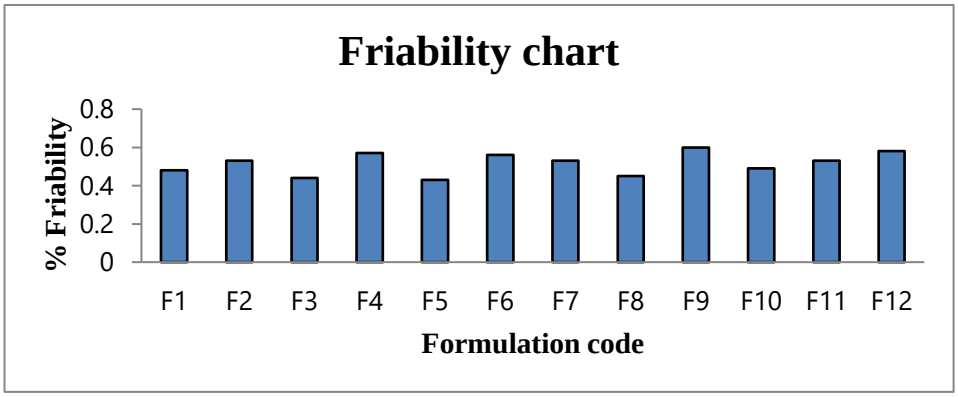

Figure 1: Graphical representation of friability of Fexofenadine ODTs prepared by varying concentrations of super disintegrants

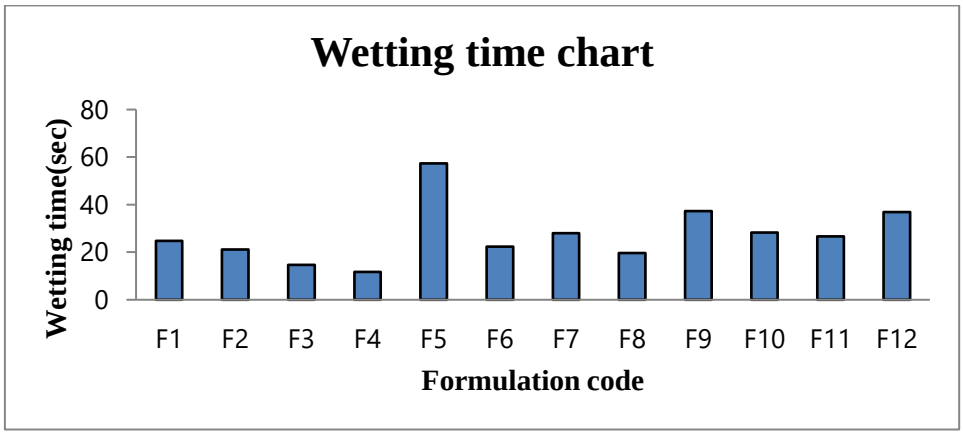

Figure 2: Graphical representation of wetting time of Fexofenadine ODTs prepared by varying concentrations of super disintegrants

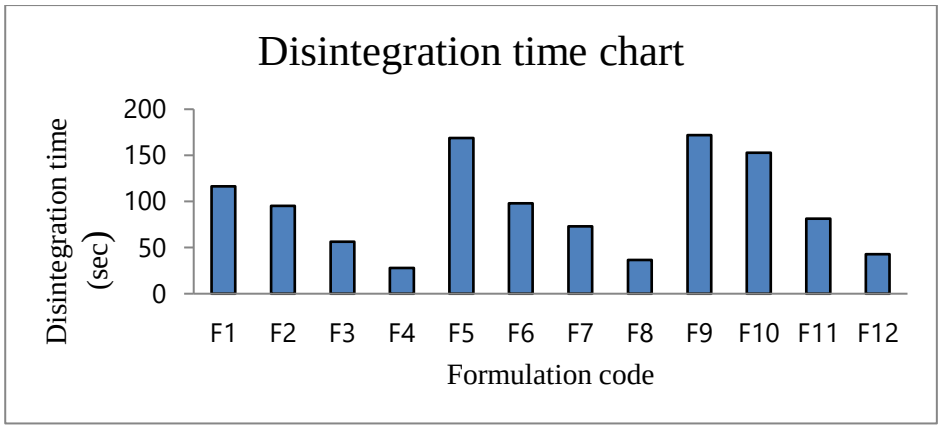

Figure 3: Graphical representation of disintegration times of Fexofenadine ODTs prepared by varying concentrations of super disintegrants

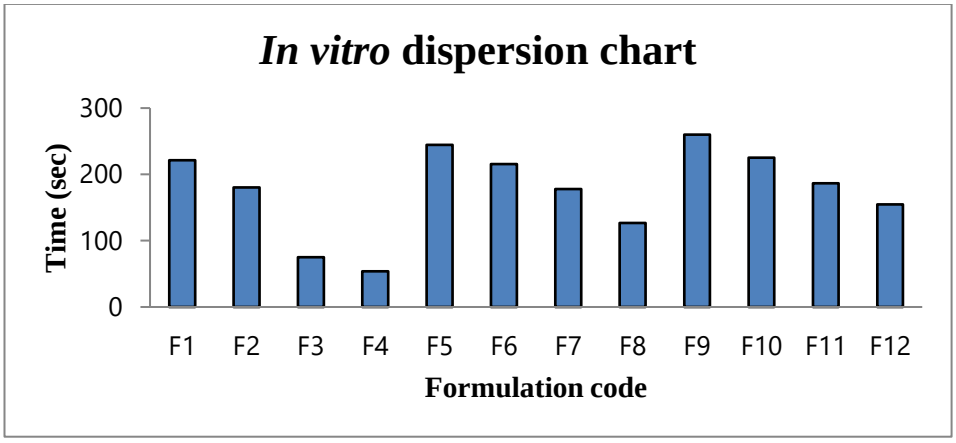

Figure 4: Graphical representation in vitro dispersion times of Fexofenadine ODTs prepared by varying concentrations of super disintegrants

Cumulative percent Fexofenadine released from ODTs containing varying concentrations of different super disintegrants

Cumulative percent (±S.D.) drug released						
Time (min)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
2	27.35±0.28	22.35±0.52	20.46±0.2	28.31±0.2	18.35±0.34	15.43±0.30
4	40.33±0.28	34.36±0.28	29.28±0.19	41.33±0.24	25.5±0.28	23.43±0.32
6	55.46±0.31	45.31±0.27	42.35±0.25	59.33±0.26	37.36±0.25	37.36±0.26
8	69.46±0.27	62.35±0.25	61.31±0.23	73.48±0.34	57.41±0.23	54.38±0.26
10	74.38±0.27	75.48±0.30	76.4±0.36	86.38±0.34	64.55±0.28	67.38±0.37
15	83.35±0.20	87.4±0.31	82.53±0.30	98.6±0.29	72.48±0.35	75.46±0.26
20	94.45±0.30	96.31±0.29	97.31±0.20	98.89±0.32	80.45±0.28	82.31±0.23
25	94.89±0.24	95.57±0.28	97.65±0.28	98.95±0.24	86.5±0.26	87.48±0.24
30	95.78±0.27	96.85±0.32	97.96±0.25	98.99±0.23	89.53±0.19	92.36±0.25

Cumulative percent (±S.D.) drug released						
Time (min)	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
2	22.33±0.25	14.38±0.31	19.33±0.20	23.43±0.16	18.48±0.33	19.4±0.32
4	33.36±0.31	22.1±0.59	29.36±0.32	35.31±0.27	27.18±0.18	27.41±0.26
6	45.46±0.26	36.43±0.30	36.45±0.25	47.36±0.29	34.43±0.23	35.28±0.29
8	62.43±0.23	55.46±0.30	49.43±0.26	53.5±0.34	45.61±0.17	52.43±0.26
10	70.28±0.20	62.46±0.25	56.48±0.26	64.45±0.30	52.41±0.36	65.41±0.33
15	78.41±0.26	75.58±0.27	68.46±0.32	72.6±0.27	61.25±0.55	78.45±0.35
20	86.28±0.24	80.4±0.26	74.58±0.27	79.41±0.14	70.46±0.21	84.51±0.24
25	90.28±0.17	83.48±0.30	78.43±0.27	84.45±0.28	75.41±0.24	88.36±0.18
30	94.46±0.25	95.43±0.19	85.4±0.22	88.45±0.18	90.4±0.33	92.38±0.19

Table No: 8 Cumulative percent Fexofenadine released from ODTs containing varying concentrations of different super disintegrants

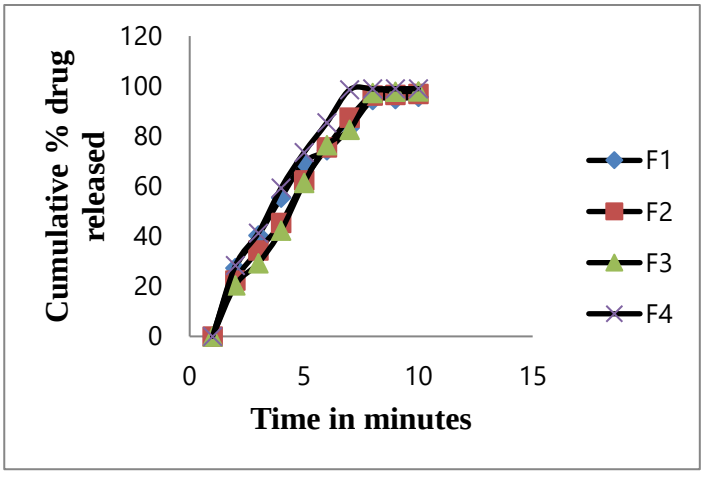

Figure No: 5 Graphical representations of Cumulative percent Fexofenadine released from ODTs containing varying concentrations of cross povidone

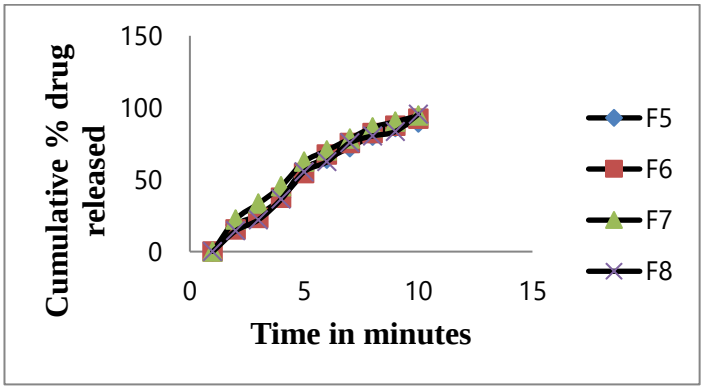

Figure No: 6 Graphical representations of Cumulative percent Fexofenadine released from ODTs containing varying concentrations of croscarmellose sodium

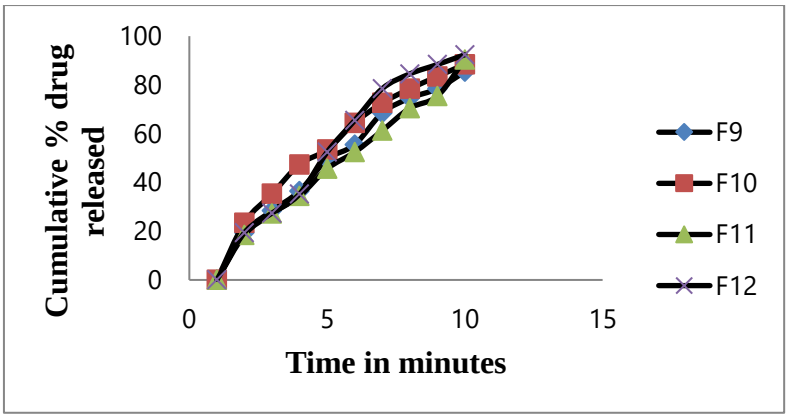

Figure No: 7 Graphical representations of Cumulative percent Fexofenadine released from ODTs containing varying concentrations of sodium starch glycolate.

Formulae of Fexofenadine ODTs prepared with combination of super disintegrants

Ingredients	CP + CCS				CP + SSG			
	6%	8%	10%	12%	6%	8%	10%	12%
Fexofenadine	30	30	30	30	30	30	30	30
Super disintegrants	6	8	10	12	36	48	60	72
Avicel PH 102	41	39	37	35	41	39	37	35
Pearlitol SD200	10	10	10	10	10	10	10	10
Sodium saccharine	10	10	10	10	10	10	10	10
Orange flavor	2	2	2	2	2	2	2	2
Sodium stearyl fumerate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Talc	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Total weight (mg)	100	100	100	100	100	100	100	100

Note: CP – Crosspovidone, CCS – Croscarmellose Sodium, SSG – Sodium Starch Glycolate.

Table No: 9 Formulae of Fexofenadine ODTs prepared with combination of super disintegrants.

Preformulation characteristics of Fexofenadine ODTs prepared with combination of super disintegrants

Formulation	Bulk density (g/cc)	Tapped density (g/cc)	Hausner ratio	Compressibilty index (%)	Angle of repose (ɵ)
F13	0.420	0.520	1.23	19.23	29.67
F14	0.423	0.512	1.21	17.38	29.54

F15	0.435	0.520	1.20	16.34	31.76
F16	0.422	0.512	1.21	17.57	32.04
F17	0.425	0.523	1.23	18.73	30.56
F18	0.434	0.528	1.21	17.49	31.23
F19	0.426	0.512	1.20	16.79	29.52
F20	0.420	0.519	1.23	19.07	29.32

Table No: 10 Preformulation characteristics of Fexofenadine ODTs prepared with combination of super disintegrants

Tabletting characteristics of Fexofenadine ODTs prepared with combination of super disintegrants

Formulation	Weight (mg)	Drug content (%)	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)
F13	100.3±1.18	98.56±0.49	3.19±0.05	0.47	2.86±0.034
F14	99.3±0.53	98.61±0.60	3.16±0.04	0.52	2.86±0.023
F15	100.1±0.75	98.99±0.56	3.10±0.10	0.63	2.87±0.044
F16	100.3±0.86	99.03±0.58	3.05±0.09	0.58	2.89±0.051
F17	99.1±0.84	97.75±0.69	3.15±0.04	0.58	2.85±0.029
F18	98.8±0.56	98.76±0.56	2.92±0.08	0.53	2.88±0.046
F19	99.6±0.60	99.08±0.29	3.00±0.09	0.51	2.86±0.025
F20	100.0±0.75	98.86±0.39	3.12±0.12	0.55	2.84±0.034

Table No: 11 Tabletting characteristics of Fexofenadine ODTs prepared with combination of super disintegrants

Formulation	Wetting time (sec)	*In vitro* dispersion time (sec)	Disintegration time (sec)	Water absorption ratio (%)
F13	19.33±0.51	91.66±1.21	82.5±1.04	59.49
F14	14.33±0.51	49.33±1.03	46±0.89	56.59
F15	**11.16±0.75**	**30.66±0.81**	**17.66±0.51**	**57.08**
F16	13.5±0.54	35.16±0.75	20.33±0.81	58.72
F17	19.1±0.75	97.83±0.40	86.16±0.75	57.95
F18	14.83±0.75	54.16±1.72	47.5±1.04	60
F19	11.5±0.54	46.66±0.81	24.66±0.51	61.50
F20	13±0.89	43.83±0.75	20.83±1.16	58.24

Table No: 12 Friability of Fexofenadine ODTs prepared by varying concentrations of combination of super disintegrants

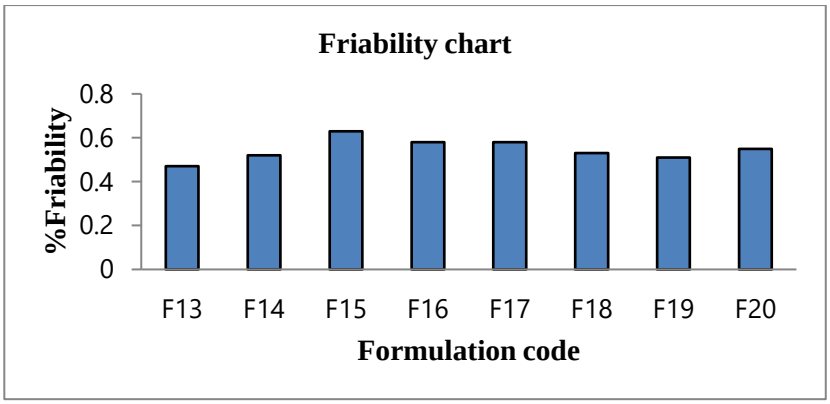

Figure No: 8: Graphical representation of friability of Fexofenadine ODTs prepared by varying concentrations of combination of superdisintegrants

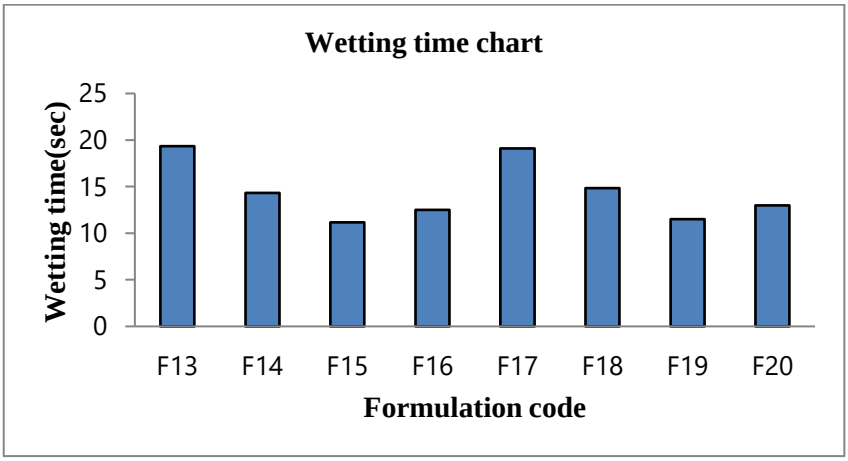

Figure No: 9 Graphical representation of witting time of Fexofenadine ODTs prepared by varying concentrations of combination of super disintegrants

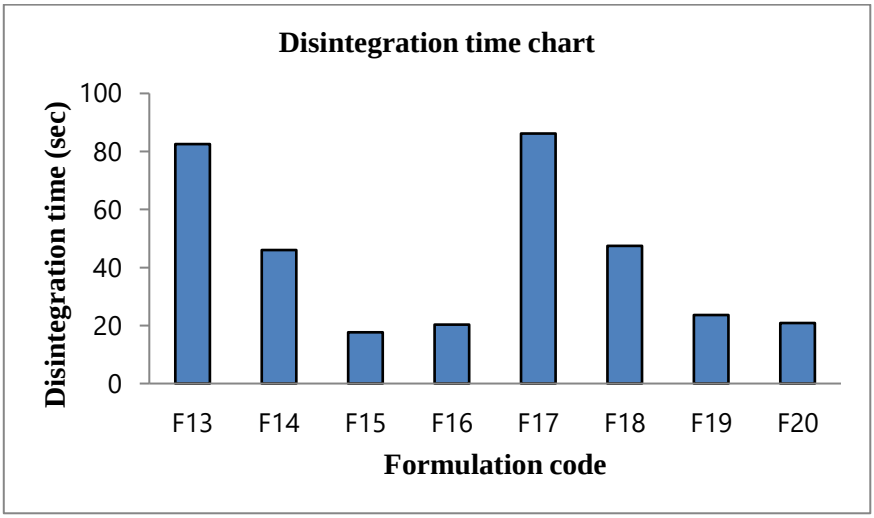

Figure No: 10 Graphical representations of disintegration times of Fexofenadine ODTs prepared by varying concentrations of combination of super disintegrants

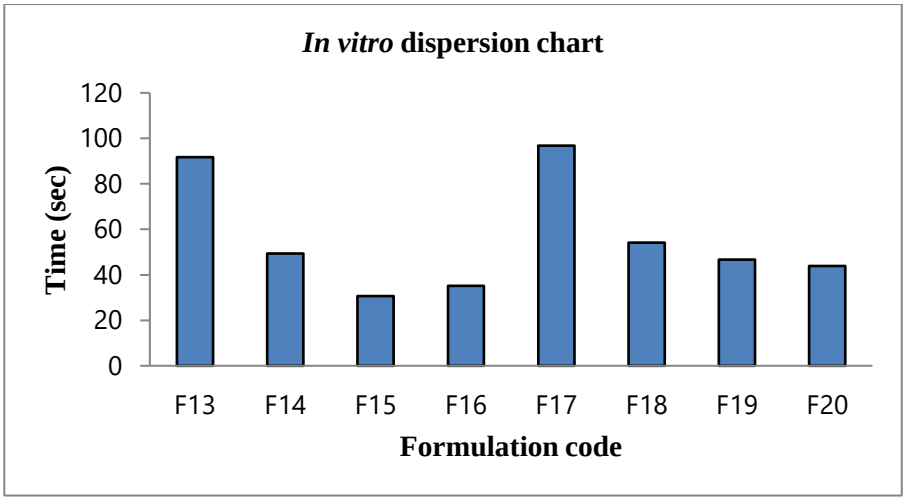

Figure No: 11 Graphical representations of *in vitro* dispersion times of Fexofenadine ODTs prepared by varying concentrations of combination of super disintegrants

Cumulative percent Fexofenadine released from ODTs prepared by varying concentrations of combination of super disintegrants

Cumulative percent (±S.D.) drug released				
Time (min)	**F13**	**F14**	**F15**	**F16**
2	17.41±0.26	26.21±0.17	25.43±0.29	21.4±0.24
4	25.43±0.25	33.38±0.21	37.41±0.31	31.43±0.33
6	37.43±0.33	45.31±0.27	51.36±0.28	41.25±0.18
8	54.45±0.26	60.25±0.15	68.35±0.31	65.45±0.28
10	66.43±0.24	75.31±0.29	78.35±0.28	71.53±0.26
15	78.45±0.24	87.48±0.24	89.4±0.2	79.46±0.22
20	83.45±0.24	89.31±0.17	93.38±0.24	84.53±0.25
25	85.35±0.25	97.52±0.19	99.87±0.18	89.55±0.16
30	94.5±0.21	------	------	96.38±0.24

Cumulative percent (±S.D.) drug released				
Time (min)	**F17**	**F18**	**F19**	**F20**
2	13.48±0.27	24.55±0.32	24.35±0.30	26.3±0.28
4	25.35±0.30	35.3±0.28	31.41±0.25	38.3±0.28
6	33.4±0.20	42.4±0.31	43.53±0.21	38.3±0.28
8	51.38±0.18	54.38±0.27	57.43±0.33	61.48±0.21
10	61.4±0.30	65.43±0.35	70.53±0.24	69.35±0.28
15	75.55±0.32	76.5±0.28	77.48±0.34	76.51±0.17
20	77.43±0.29	82.45±0.30	85.38±0.23	82.48±0.24
25	83.45±0.18	87.5±0.26	91.45±0.18	84.45±0.27
30	88.56±0.21	92.5±0.14	96.48±0.18	95.51±0.19

Table No: 13 Cumulative percent Fexofenadine released from ODTs prepared by varying concentrations of combination of superdisintegrants

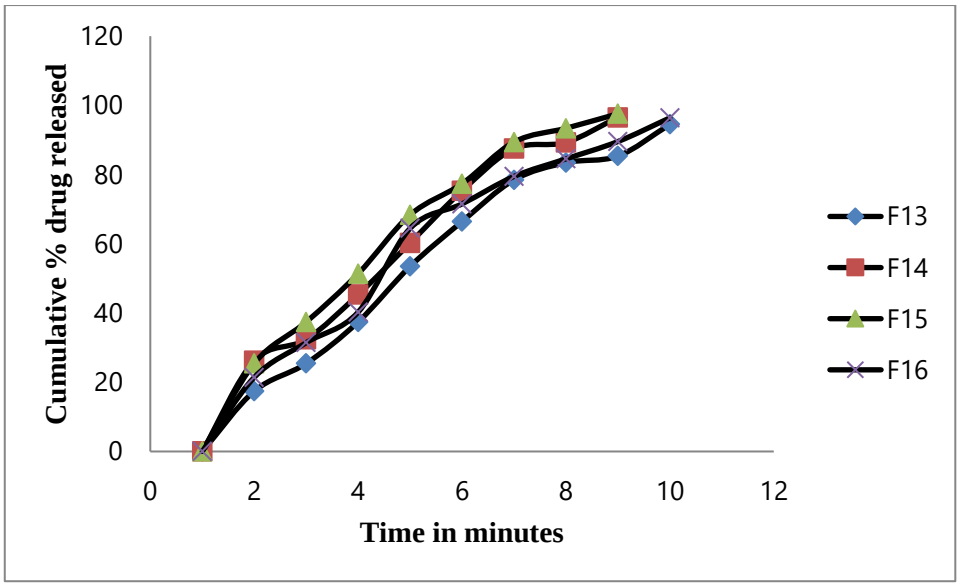

Figure No: 12 Graphical representations of Cumulative percent Fexofenadine released from ODTs containing varying concentrations of CP + CCS

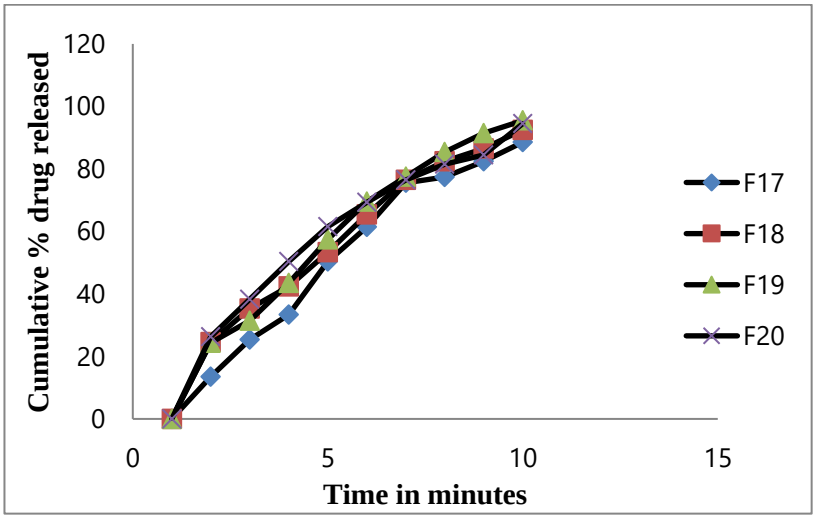

Figure No: 13 Graphical representation of Cumulative percent lisinopril released from ODTs containing varying concentrations of CP + SSG

FTIR studies:

FTIR gamuts of IR diapason of pure Fexofenadine, croscarmellose sodium, cross povidone, sodium bounce glycolate and combination thereof were recorded on Perkin Elmer spectrophotometer. The reviews were estimated for presence of top peaks of medicine, shifting and masking of medicine peaks due to presence of polymer. The FT – IR gamut's of pure fexofenadine.

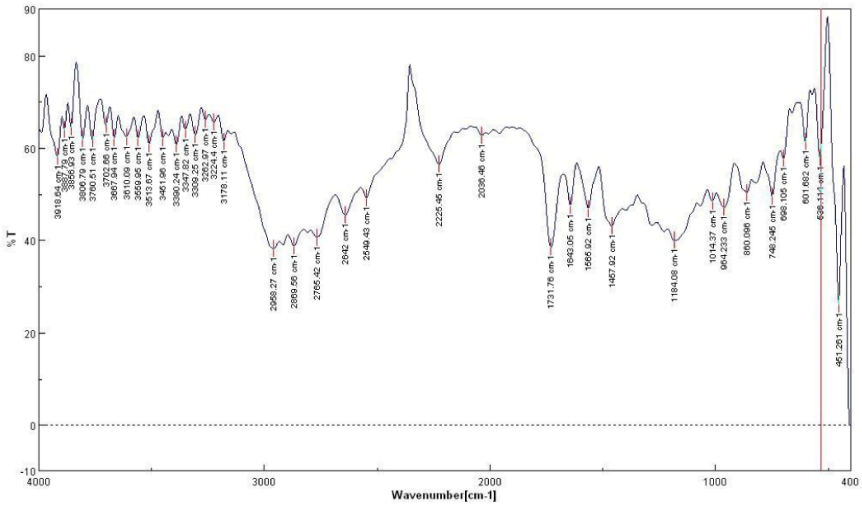

Figure No: 14 FTIR spectra of Fexofenadine

The Fourier transfigures infrared spectroscopy studies were carried out for pure medicine along with excipients. The results are epitomized are follows. The below peaks are considered as characteristic peaks of Fexofenadine. These peaks weren't affected and prominently observed in IR gamuts of medicine and excipients. This indicates there's no commerce between medicine and excipients.

Conclusion:

The study aimed to design oral disintegrating Fexofenadine tablets and flicks that disintegrate in slaver within seconds. Tablets were prepared using colorful disintegrants (Crosspovidone, Croscarmellose sodium, Sodium bounce glycolate) and other complements via direct contraction. Out of 20 phrasings, the bone with a combination of Cross povidone and Croscarmellose sodium (F15) showed the stylish performance with a decomposition time of17.66±0.51 seconds and 99.87±0.18% medicine release within 25 twinkles. The use of water-answerable excipients, like Pearlitol SD 200 and Avicel 102, contributed to the effectiveness of the tablets.

Oral disintegrating flicks were prepared using different grades of Hydroxy Propyl Methyl Cellulose (HPMC). The combination of Cross povidone and Croscarmellose sodium in expression F15 was concluded to be the superior choice.

This expression is salutary for pediatric and senior cases, icing better compliance and ease of use.

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