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FORMULATION AND EVALUATION OF FAST DISINTEGRATING VITAMIN C TABLETS TO IMPROVE BIOAVAILABILITY

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ABSTRACT

Ascorbic acid or vitamin C, is a water-soluble vitamin with significant immunomodulatory and antioxidant properties. However, its chemical instability and dose-dependent, saturable intestinal absorption may limit its oral bioavailability. In addition to requiring water for administration, conventional tablets may disintegrate more slowly, making them less convenient and delaying the release of medication, particularly in patients who are dysphagic, elderly, or paediatric. Mouth dissolving tablets are the most important and advised method of drug delivery because they are easier for patients to access and tolerate, which dissolves and breaks in the mouth in a matter of minutes thanks to the action of super disintegrating agents that maximise the formulation's pore structure. The goal of this study was to create an ascorbic acid tablet that dissolves in the mouth. The dry granulation method was used to prepare tablets containing the drug and excipients. To do this, excipients were combined in different ways. The optimal formulation was optimised by examining the effects of various combinations. Using FTIR spectrum analysis, drug-excipient interaction investigations were conducted. The tablets hardness, dissolving parameters, wetting time, and

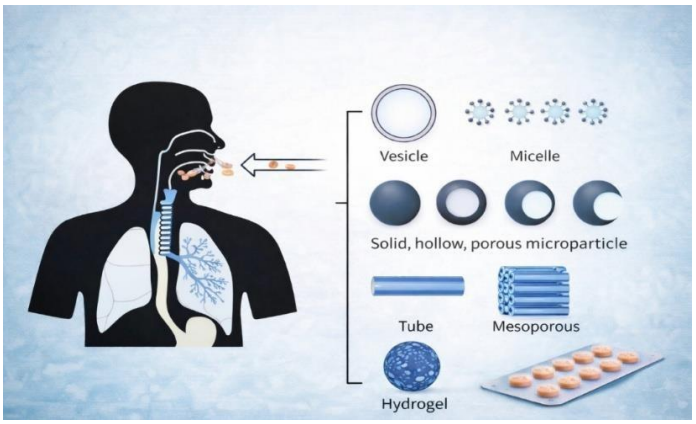
disintegration time were assessed. Soluble starch, sodium starch glycolate, and tablets were found to meet all evaluation criteria and were therefore chosen as the optimal formulation. Stability testing was performed on the optimised formulation in order to predict the shelf life. Super disintegrants and inactive chemicals play a significant role in increasing the drug's bioavailability and accelerating its release in the oral cavity. According to the study's findings, fast- disintegrating vitamin C tablets are a viable dose form that offers improved patient compliance, a quick onset of action, and maybe enhanced bioavailability, making them appropriate for both routine supplementation and populations with swallowing issues.

KEYWORDS: Ascorbic acid, oral drug delivery system, Fast disintegrating tablet, Dissolution rate, Improved bioavailability and Patient compliance.

INTRODUCTION

Vitamin C, often known as ascorbic acid, is a water-soluble vitamin. They are frequently used to prevent scurvy. Additionally, they stop chemicals inside the body from oxidising. They therefore function as powerful antioxidants. Oranges, lemons, and citrus fruits are natural sources of vitamin C. Collagen fibres are produced by ascorbic acid. Vitamin C has strong antimicrobial, immunostimulant, and anti-inflammatory properties. It is a strong antioxidant and a cofactor for enzymes that control genes. The activity of T and B cells was improved by ascorbic acid. Corn or wheat is the last raw material used to produce vitamin C (ascorbic acid). Specialised companies transform these ingredients from starch to glucose and finally to sorbitol. We use a number of biotechnical, chemical processing, and purification procedures to create the pure final products from sorbitol. The empirical formula is C6 H8 O6, and the molecular weight is 176.13.

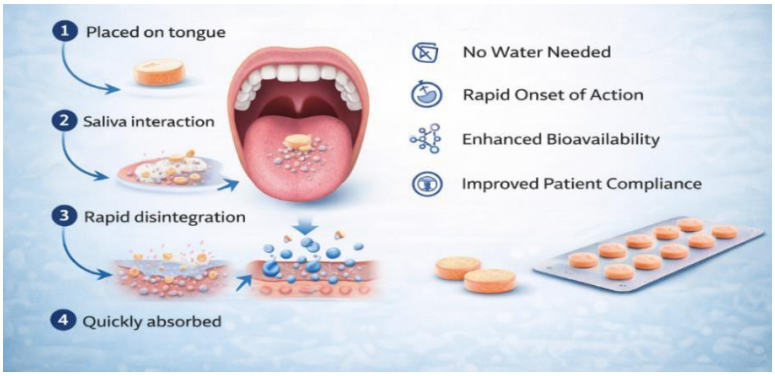
ORAL DRUG DELIVERY



Due to its ease of use, non-invasiveness, affordability, and high patient compliance, oral medication delivery is the most popular and practical method for delivering therapeutic drugs. Among the different kinds of oral dosage systems, tablets remain the most extensively used because they offer accurate dosing, stability, and convenience of large-scale manufacture. However, the physicochemical properties of the medication, the formulation design, and the intended therapeutic goal all have a significant role in an oral tablet's effectiveness.

Ascorbic acid, also known as vitamin C, is a water-soluble vitamin that is vital for many physiological functions, such as the production of collagen, the healing of wounds, the immune system, and the avoidance of oxidative stress. Regular dietary intake or supplementation is required since the human body cannot produce or store large levels of vitamin C. Oral tablets give a stable and controlled technique of maintaining adequate vitamin C levels in the body, ensuring consistent bioavailability. Because vitamin C is extremely prone to oxidation when exposed to air, moisture, heat, or light, its chemical stability must be carefully considered when formulating it as an oral tablet.In the context of oral drug delivery, vitamin C tablets are designed to dissolve in the gastrointestinal tract, where ascorbic acid is rapidly absorbed, especially in the duodenum and jejunum. Following absorption, the vitamin is dispersed throughout bodily tissues, supporting enzymatic processes and antioxidant defence systems.

FAST DISINTEGRATING TABLET



Oral medication delivery remains the most frequently accepted and convenient method of administration, giving various advantages such as ease of consumption, patient compliance, and cost-effectiveness. However, some patient populations, such as youngsters, the elderly, and people with dysphagia (difficulty swallowing), may find it difficult to take regular tablets . To overcome these constraints, fast disintegrating tablets (FDTs)— also known as Oro

dispersible tablets (ODTs) or mouth-dissolving tablets (MDTs)—have been created as new dosage forms that swiftly disintegrate and dissolve in the mouth, usually within seconds, without the need for water.

Vitamin C (ascorbic acid) is a water-soluble vitamin with high antioxidant capabilities, required for collagen formation, immunological function, and protection against oxidative stress. Since the human body cannot synthesise vitamin C. Incorporating vitamin C into a fast-disintegrating tablet has various therapeutic and practical advantages: faster beginning of action, greater patient compliance, and enhanced bioavailability by allowing pre-gastric absorption through the oral mucosa.Super disintegrants like sodium starch glycolate are commonly included in the formulation of fast-disintegrating vitamin C tablets because they help the tablet break apart quickly when it comes into contact with saliva. To improve stability and palatability, additional excipients such as sweeteners, flavouring agents, and moisture-protective agents are added. And quick therapeutic efficacy.

FORMULATION OF FDT

Fast-disintegrating tablets (FDTs) have drawn a lot of interest recently as a cutting-edge method for oral medication delivery systems that aims to increase patient compliance and achieve a quick start of action. FDTs are solid dosage forms designed to break down and dissolve rapidly—usually within seconds—when placed on the tongue, without the need for water. Paediatric, elderly, and dysphagic patients who have trouble swallowing traditional tablets or capsules can especially benefit from this technology.

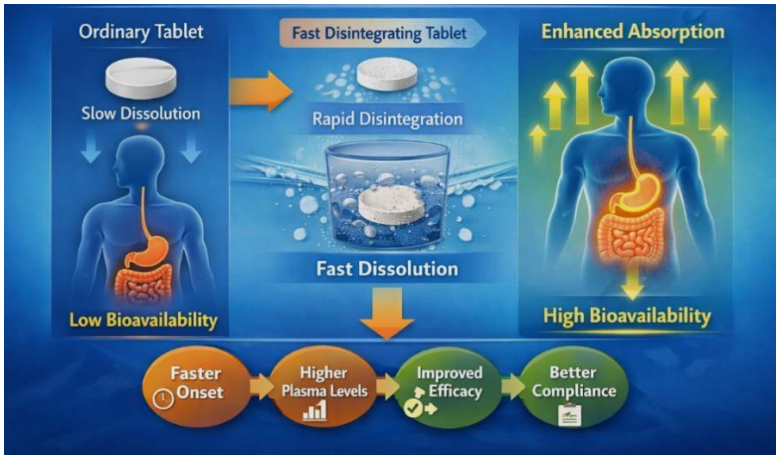
The formulation of a vitamin C FDT often comprises super disintegrants such as soluble starch, or sodium starch glycolate, which enhance tablet disintegration upon contact with saliva. Additional excipients— including diluents, sweeteners, and flavouring agents—are

introduced to improve mouthfeel and stability.

From a biopharmaceutical perspective, the FDT formulation allows pre-gastric absorption of a portion of the drug through the oral mucosa, leading to a faster onset of action. Moreover, by eliminating the need for water, the formulation enhances convenience and compliance in mobile or emergency situations. The design of a vitamin C fast-disintegrating tablet thus embodies the principles of modern patient-centric drug delivery, emphasising comfort, stability, and therapeutic efficiency.

A novel development in oral dosage technology is the formulation of vitamin C as a fast-disintegrating tablet, which combines better bioavailability, improved taste and stability, and rapid disintegration to create an efficient supplement form suitable for all patient groups.

IMPROVE THE BIOAVAILABILITY



Oral medication delivery remains the most convenient and favoured route for the administration of therapeutic medicines due to its simplicity, safety, and patient acceptability. However, the bioavailability of orally taken drugs depends on various parameters, including solubility, stability, permeability, and first-pass metabolism. Ascorbic acid, also known as vitamin C, is a water-soluble micronutrient with strong antioxidant qualities that is needed for collagen production, iron absorption, and immune system defence. Despite its physiological relevance, the oral bioavailability of vitamin C is generally limited by its dose-dependent absorption, volatility, and susceptibility to degradation under environmental and gastrointestinal conditions.

Sodium-dependent vitamin C transporters (SVCT1 and SVCT2) facilitate the easy absorption of vitamin C in the small intestine. However, when significant amounts are taken orally, this

absorption becomes saturated at greater doses, leading to decreased efficiency. Furthermore, ascorbic acid is extremely unstable and experiences oxidative destruction in the presence of heat, light, air, or moisture, which lowers its effective concentration prior to absorption. Therefore, the design of an optimised vitamin C tablet formulation must address these problems to maximise stability, absorption, and overall bioavailability

EXPERIMENTAL METHODOLOGY

SNO	MATERIALS	MANUFACTURER
1	Ascorbic acid	Sample from Cipla pvt Ltd.
2	Starch soluble	Merck pvt Ltd
3	Sodium starch glycolate	Sd fine- chem Ltd
4	Mannitol	Merck pvt Ltd
5	Magnesium Stearate	Hetero Drugs pvt Ltd.

EQUIPMENTS

SNO	Equipment/Apparatus	MANUFACTURER
1	Analytical Balance	Shimadzu
2	Mortar and pestle	shimadzu
3	Sieve Shaker and Sieves	Remi elicol20
4	Rotary or Single Punch Tablet Machine	Model-118 systronics
5	Vernier Calliper	Syntegon
6	Roche Friabilator	Fette Compacting
7	FTIR Spectrophotometer	Remi elicol20

METHODS USED IN STUDY EQUIPMENT

1. PREFORMULATION STUDIES

Drug–Excipient Compatibility Study

Using a differential scanning calorimeter, ascorbic acid was combined with soluble starch, sodium starch glycolate, mannitol, talc, and magnesium stearate to complete the medicine (ascorbic acid) compatibility experiments with the excipients. Add one gramme of ascorbic acid and one gramme of each of the excipients to a transparent glass sample bottle. Next, a 1 mg mixture was carefully sealed and scanned with black in a small aluminium pan. The obtained thermograms from the ascorbic acid were compared after this procedure was repeated for each component separately.

Fourier transforms infrared (FT-IR) spectral analysis

FTIR is used to determine a molecule's functional group. To prepare mouth-dissolving tablets, the medication is combined with a potassium bromide disc that was scanned at 4 mm/s with a

resolution of 2 cm at a wavenumber range of 400-4000/cm. drug instability brought on by the medication's interaction with the polymer. When choosing the right polymers, pre-formulation investigations of drug-polymer interaction are crucial. The compatibility of a few chosen polymers was assessed using FTIR spectroscopy. Both the medicine and the drug-polymer combination were examined separately.

2. PRECOMPRESSION PARAMETERS

a) Angle of repose

The friction forces in a loose powder θ can be measured to find the angle of repose. It is precisely defined as the greatest angle that can be created between the powder pile's surface and the horizontal. The method known as Newman's funnel is used to calculate the angle of repose. The measured quantity is placed inside the funnel. The funnel is positioned so that the blend heap at the top is simply fixed by the tip. It is permissible for the mixture to pass freely through the exterior of the funnel. Tan (θ) = h/r, where θ is the angle of repose, r is the cone base's radius, and h is its height.

$$\mathbf{Tan\ (\theta) = h/r}$$

b) Bulk density

The mass of the powder divided by the bulk volume is called bulk density (Db). The unit of measurement is g/cm³. The final step is to get the bulk density by dividing the total volume in cubic centimetres by the sample weight in grammes. Bulk density is calculated as follows:

M**vb = Mass of powder in grams / bulk volume of powder.**

c) Tapped density

The tap density of the powder can be computed by dividing its total mass by the tap volume. A measuring cylinder of mass can be added to the drug-excipient configuration to measure this. Every two seconds, a cylinder can fall naturally from a height of 10 cm onto a hard surface. Until the gap between consecutive dimensions is less than 2%, settlement will proceed. The unit of measurement is grams/ml.

Tapped density = mass of powder in grams / bulk volume

d) Compressibility indicates

This is the powder's propensity to compact. With a change of no more than 2%, it is measured using a thread density device for 500, 750, and 1250 needles. The formula was used to determine the compressibility of the powder mixture in percentage terms based on the

superficial bulk density and tap density.

% Compressibility = (Tapped density - Bulk density) / Tapped Density x 100.

e) Hasuners ratio

A value that corresponds to a powder or granular material's flowability is known as the Hausner ratio. The following formula was used to determine the bulk Hausner's ratio and bulk densities.

Hausner's ratio = Tapped density / Bulk density.

Standard value of angle of repose and compressibility index

Flow property	Angle of repose	Compressibility index
Excellent	25-30	<10
Good	31-35	11-15
Fair	36-40	16-20
Passable	41-45	21-25
Poor	46-55	26-31

Formulation of Ascorbic Acid

Ascorbic acid (500 mg) was used as the active pharmaceutical ingredient in vitamin C tablets medicinal significance and antioxidant qualities. The soluble starch served as a binder to improve granule formation and tablet strength, while mannitol was utilised as a diluent to improve tablet bulk, palatability, and compressibility. To guarantee quick tablet breakdown after administration, sodium starch glycolate was added as a super disintegrant. To lessen friction during compression and promote smooth tablet ejection, magnesium stearate was used as a lubricant., the tablets were made utilising both wet and dry granulation techniques. The tableting was done it different compression loads using single punch tableting machine was equipped with 12 mm normal concave facing punches. The weight of the desired tablet was 500 mg. Ascorbic acid and excipients were combined consistently and granulated using an appropriate binder solution in the dry granulation method. The granules were then dried and sized. In order to enhance the powder blend's flow characteristics, content homogeneity, and compressibility, the tablets were made utilising dry granulation techniques.

By dry granulation method to usually performed on a material with good properties such as flow ability. Important advantages of cost efficacy and operational safety. Sieve the ascorbic acid mannitol through the 16 and 20 no sieve mesh using a mixer and seieve the sodium starch glycolate, soluble starch, mannitol, 20mm mesh mixture for 5 mins after passing the magnesium stearate through the 20mm mesh. Add the above mixture of 2 mins. Finally the mixture should be compressed in to tablets in single punch machine.

Composition and formulation of fast disintegrating tablets

SNO	INGREDIENTS(Mg)	F1	F2	F3	F4	F5	F6
1	Ascorbic acid	500	500	500	500	500	500
2	Starch soluble	50	45	40	35	30	25
3	Sodiumstarchglycolate	25	30	35	40	45	50
4	Mannitol	70	70	70	70	70	70
5	Magnesium stearate	5	5	5	5	5	5
TOTAL TABLETS WEIGHT		650	650	650	650	650	650

Post Compression Parameters

Inspection of manufactured tables after compression is crucial. These characteristics include things like brittleness, hardness, appearance, thickness, and weight fluctuation. The table displays all assessed metrics for all dose formulations. Odour, colour, shape, and texture were all visually assessed in the tablet's typical appearance.

1. Thickness

The thickness of the tablet was measured with a Vernier calliper. Six tablets were utilised in this study, and the breadth was measured when the tablet was upright between the two oral cavities. The measurements were expressed in millimetres.

2. Weight variation

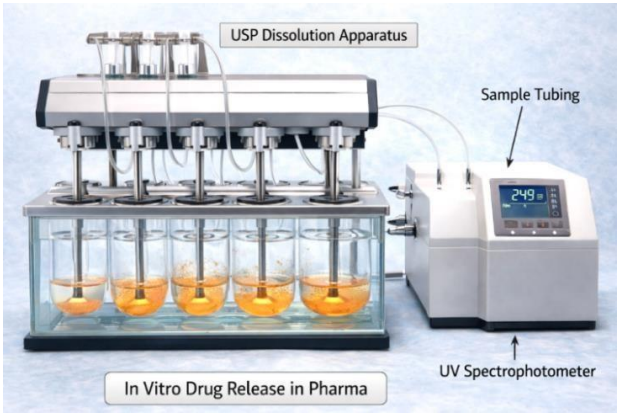
To perform the weight change test, 20 medications are balanced independently, the average weight is calculated, and the weight of each pill is compared to the average. An enjoyable method of assessing the consistency of the tablets' medication content would be the weight change test.

3. Hardness

Another term for hardness is tablet crushing strength. Tablet hardness was measured with a Monsanto hardness tester. Tablet hardness was measured in kg/cm² when the tablet was positioned laterally between the upper and lower pistons and power was delivered by rotating the threaded bolt until the tablet shattered.

% Friability = Initial weight–Final weight/Initial weight.

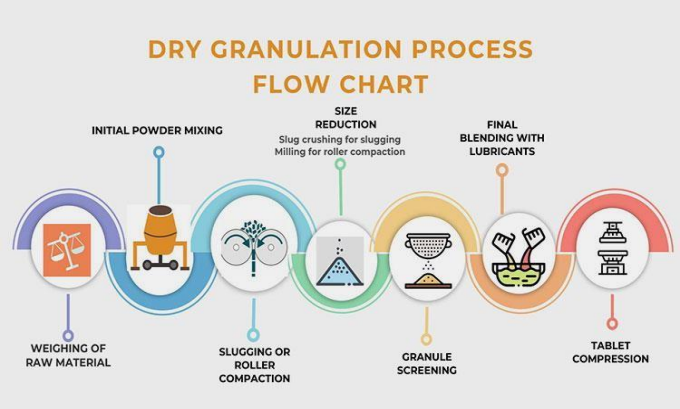
5. In vitro drug release



Using USP Dissolution Apparatus II, the tablet's dissolution profile was measured in 900 mL of simulated gastric fluid (0.1 N HCl) at 37 ± 0.5°C with stirring at 75 rpm. The same volume of replacement-simulated fluid was used in many samples at 10, 20, 30, 40, 50, and 60 minutes. Whatman filter paper was used to sieve the samples, and a UV spectrophotometer and calibration curve were used to measure the absorbance.

METHOD OF PREPARATION VITAMIN C TABLETS

Dry granulation method



Vitamin C and other medications that are susceptible to heat and moisture are particularly well suited for the dry granulation method. Using this technique, the active substance and excipients—like disintegrants, mannitol, and microcrystalline cellulose—are evenly mixed in dry form. Using a roller compactor or a heavy- duty tablet press, the mixture is subsequently compacted into huge tablets or slugs without the need for any liquid glue. To create uniformly sized granules, these slugs are crushed or milled and then sent through a #16 or #20 sieve. To enhance flow and avoid sticking during compression, the granules are then lubricated with talc and magnesium stearate. The lubricated granules are then compacted into tablets with the appropriate hardness and weight. This technique is favoured for formulations that are susceptible to oxidation or hydrolysis because it preserves the chemical stability of vitamin C without the use of heat or moisture. In contrast to wet granulated tablets, the resultant tablets could be less mechanically strong.

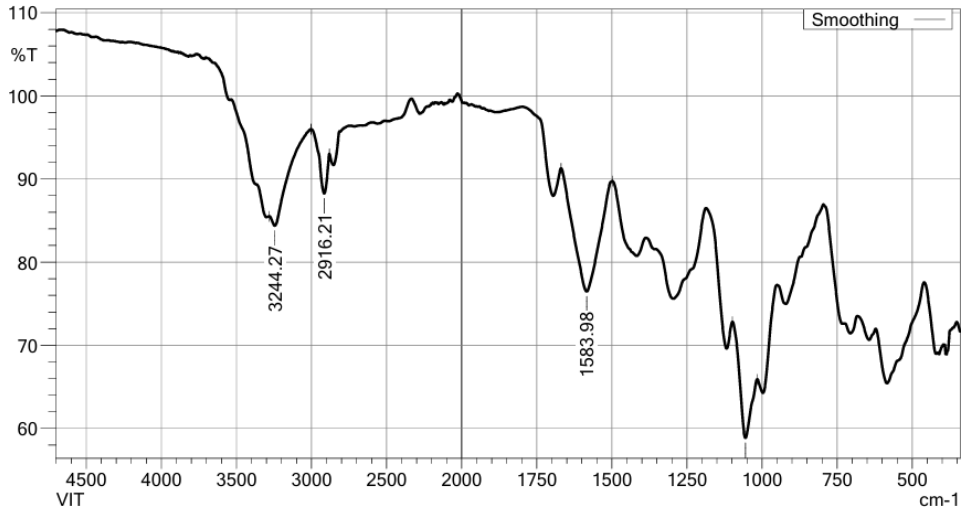
RESULTS AND DISCUSSION

Drug excipient combability study

Fourier-transforms infrared spectral analysis

The sample was analysed and contrasted with the ascorbic acid standard reference spectrum, which is shown in the picture. Ascorbic acid's FTIR spectra revealed distinctive absorption

peaks at 3244.27 cm^{-1}, 2916.21 cm^{-1}, 1583.98 cm^{-1}, and 1054.80 cm^{-1}. The presence of hydroxyl groups is shown by the large peak around 3244.27 cm^{-1}, which corresponds to O–H stretching vibrations. C-H stretching vibrations are responsible for the absorption peak at 2916.21 cm^{-1}. While the peak at 1054.80 cm^{-1} is linked to C–O stretching vibrations, the peak at 1583.98 cm^{-1} is associated with C=C stretching. These distinctive peaks match the ascorbic acid FTIR spectra that has been described.



Fourier transform infrared spectroscopy (FTIR) of pure ascorbic acid Functional Group Assignment of Ascorbic Acid

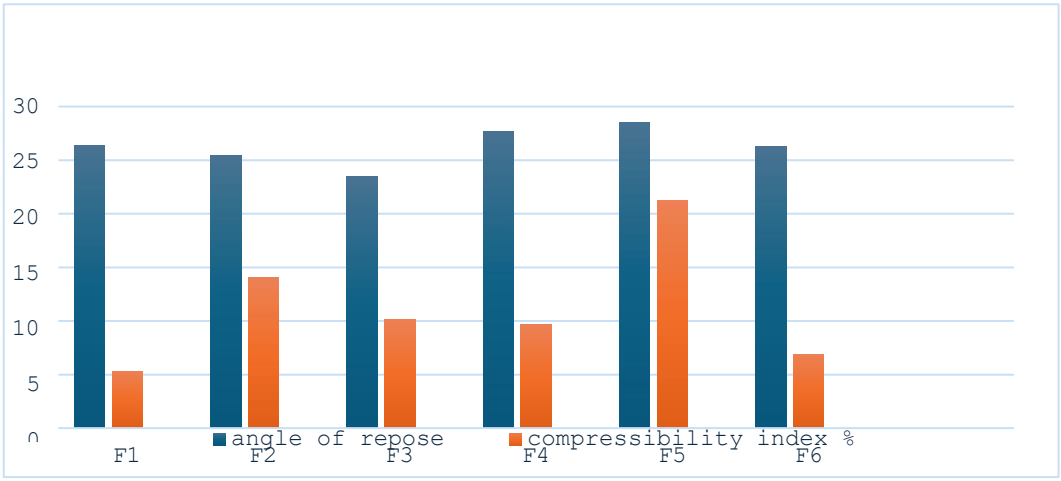
Observed Peak (cm^{-1})	Functional Group	Type of Vibration
3244.27	-OH (hydroxyl group)	O-H stretching(broad)
2916.21	C–H	C–H stretching
1583.98	C=C	C=C stretching
1054.80	C–O	C–O stretching

Evaluation of precompression parameters

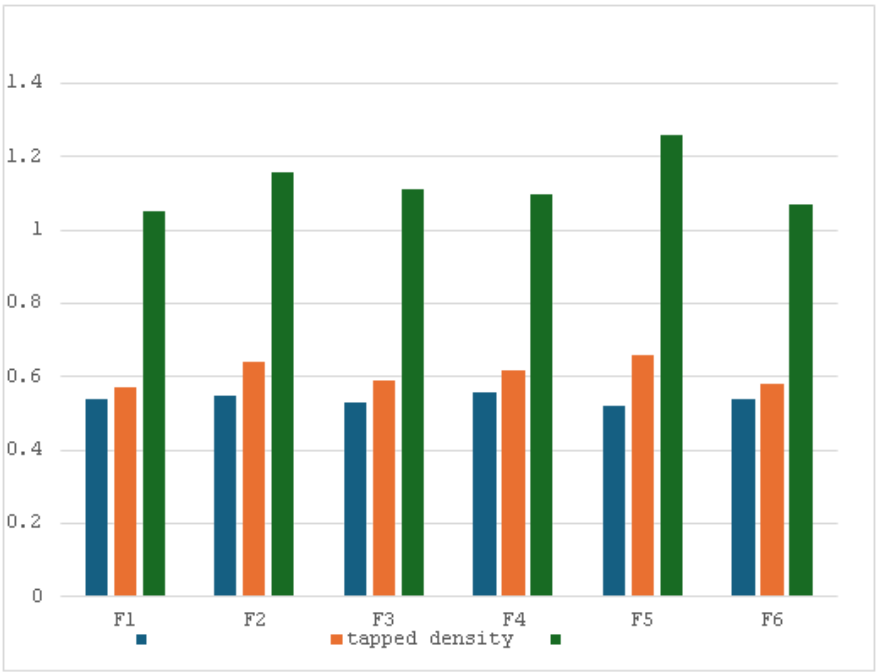
Sno	Formulation	Angle of repose	Bulk density	Tapped density	Compressibility index (%)	Hausner's ratio
1	F1	26.4	0.54	0.57	5.26	1.05
2	F2	25.4	0.55	0.64	14.06	1.16
3	F3	23.5	0.53	0.59	10.16	1.11
4	F4	27.7	0.56	0.62	9.67	1.10
5	F5	28.5	0.52	0.66	21.21	1.26
6	F6	26.3	0.54	0.58	6.89	1.07

IP limit for pre compression parameters of powder blend

Flow property	Angle of repose	Compressibility index	Hausner's ratio
Excellent	25-30	5-10	1.00-1.11
Good	31-35	11-15	1.12-1.18
Fair	36-40	16-20	1.19-1.25
Passable	41-45	21-25	1.26-1.34
Poor	46-55	26-31	1.35-1.45
Very poor	56-65	32-37	>1.45



Angle of repose and compressibility index (%)



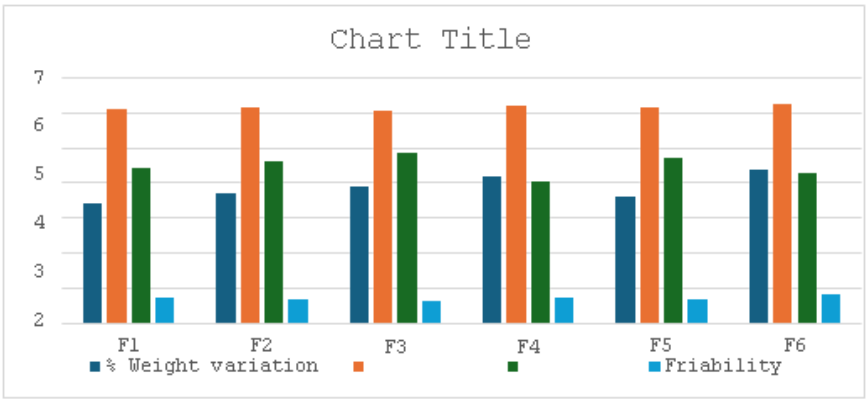
Bulk density, tapped density, Hausner's ratio

Post compression parameters of tablets

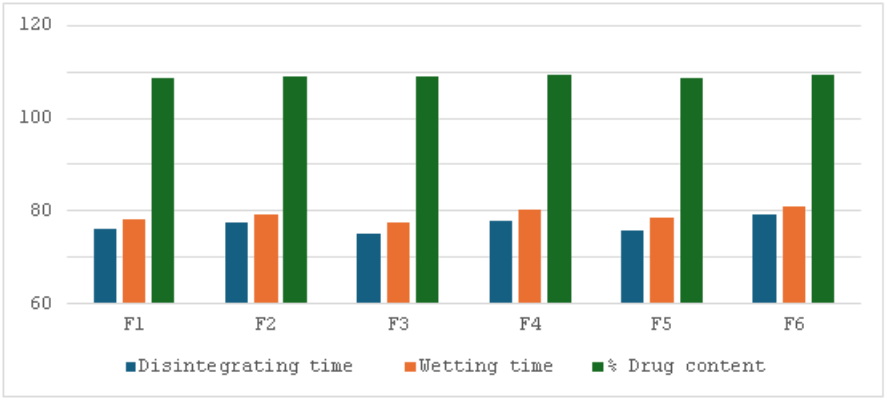
Formulation	Weight Variation%	Thickness (mm)	Hardness (kg/cm^2)	Friability	Disintegration time (sec)	Wetting time (sec)	% Drug content
F1	3.4	6.10	4.45	0.74	32.40	36.10	97.20
F2	3.7	6.18	4.62	0.69	34.55	38.25	98.05
F3	3.9	6.05	4.88	0.63	29.80	34.60	97.88
F4	4.2	6.22	4.05	0.71	35.90	40.15	98.60
F5	3.6	6.15	4.74	0.67	31.70	37.30	97.45
F6	4.4	6.28	4.30	0.81	38.25	41.80	99.10

Ip limit criteria for post compression parameters

SNO	QUALITY PARAMETER	IP LIMIT CRITERIA
1	**Weight variation**	+/- 5%
2	**Thickness**	+/- 5% 4.5 - 6.5
3	**Hardness**	3-6 kg cm^2
4	**Friability**	Not more than < 1.0% w/w
5	**Disintegration time**	<15 mins
6	**Wetting time**	< 60 sec
7	**% Drug content**	90% - 110%



Thickness, Hardness, %Weight variation and Friability



Wetting time, Disintegrating time, % Drug content.

CONCLUSION

The present investigation is concerned with formulation and evaluation of vitamin c tablet fast-disintegrating tablets (FDTs) in order to enhance oral bioavailability, quick onset of action, and patient compliance. Vitamin C is a necessary water-soluble vitamin that has immunomodulatory and antioxidant qualities. such as ascorbic acid and super disintegrants sodium starch glycolate including soluble starch, mannitol, and magnesium stearate, several formulations were made with varying quantities of the tablet was tested for weigh variation , hardness, thickness, friability, disintegrating time, wettingtime, and drug–excipient compatibility experiments that used FTIR analysis to confirm the lack of any significant interactions.

All formulations met pharmacopeial limits. The efficiency of super disintegrants in facilitating quick tablet breakdown and drug release was confirmed by the optimised formulation's quick disintegration (within 30 to 60 seconds).the formulation is particularly helpful for dysphagic, elderly, and paediatric patients for Fast- disintegrating vitamin C potential for improved bioavailability and therapeutic effectiveness, according to the study's overall findings.

Altogether six formulation were made and formulation F3 was found to be the best one in terms of disintegrating time 29.80 sec, friability (0.63) %, hardness 4.88 kg/cm^{2}and wetting time 34.60 sec.

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