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Formulation And Evaluation Of Fast Dissolving Tablet Of Acarbose Using Effervescent Disintegrants

Shripad S Ahankari[1], Dr Ganesh Tolsarwad[2*], Rohini C Holkunde[3], Anjali R Gavhane[4], Navnath S Bendke[5]

[1,2*,3,4,5]Swami Vivekanand College of Pharmacy, Udgir
*Corresponding Author: Dr. Ganesh S Tolsarwad
*Swami Vivekanand College of Pharmacy, Udgir,
Mail ID: tolsarwadganesh988@gmail.com

ABSTRACT

Objective: *The objective of the present study was to address the issue of dysphagia, which is commonly observed across all age groups, by developing an alternative oral dosage form that enhances patient compliance. Fast-dissolving tablets (FDTs) of Acarbose were formulated with the goal of providing a more patient-friendly administration route compared to conventional solid dosage forms.*

Method: *In the present work, fast dissolving tablets of Acarbose were designed with a view to enhancing patient compliance by the direct compression method. In the direct compression method, Sodium Bicarbonate and Tartaric acid as an Effervescent mixture were used along with directly compressible Mannitol and Maltodextrin to enhance mouth feel.*

Results: *The prepared batches of tablets were evaluated for hardness, friability, drug content uniformity, water absorption ratio, and in vitro dispersion time. Short-term stability (250C/ 60% RH and 40°C/ 75% RH for 3 months) and drug-excipient interaction study (IR spectroscopy). Among all the formulations, the formulation prepared by using 80 mg Sodium bicarbonate and 40 mg Tartaric acid was found to have the minimum dispersion time (48 - 54 s)*

Conclusion: *The study successfully developed a fast-dissolving tablet formulation of Acarbose that offers rapid dispersion and improved patient compliance. The use of effervescent agents and taste-enhancing excipients proved effective, and the optimized formulation was found to be stable under short-term storage conditions. This approach presents a viable alternative for patients experiencing difficulty swallowing traditional oral dosage forms.*

Keywords: *Sodium Bicarbonate, Tartaric acid, Acarbose, Fast dissolving tablets.*

INTRODUCTION

Among the different routes of administration, the oral route of administration continues to be the most preferred route due to various advantages, including ease of administration, avoidance of pain, versatility, and, most importantly, patient compliance. The different dosage forms include tablets and capsules. Tablets are the most widely used dosage forms because of their convenience in terms of self-administration, compactness, and ease in manufacturing. Many patients find it difficult to swallow tablets and hard gelatin capsules and thus do not comply with the prescription, which results in a high incidence of noncompliance and ineffective therapy1. Recent advances in novel drug delivery systems (NDDS) aim to enhance the safety and efficacy of drug molecules by formulating a convenient dosage form for administration and to achieve better patient compliance [1-4].

Nearly 35-50% of the general population, especially the elderly and children, suffer from difficulty in swallowing, which results in a high incidence of non-compliance and ineffective therapy. Swallowing problems are also very common in young individuals because of their poorly developed muscular and nervous systems. Other groups who may experience problems in swallowing conventional oral dosage forms are patients with tremors of extremities, mentally ill, developmentally disabled, non-cooperative, and patients with reduced liquid intake or patients suffering from nausea, as well as patients travelling or who do not have easy access to water. The swallowing problems are also common in some cases, such as patients with motion sickness, sudden episodes of allergic attack, or coughing, and due to a lack of water.

To overcome this problem, scientists have developed an innovative drug delivery system known as “fast dissolving tablets”, which is a novel solid oral dosage form that disintegrates and dissolves rapidly in saliva without the need for drinking water. This tablet disintegrates instantaneously or disperses in saliva [5]. These tablets usually dissolve

within 15 s to 2 minutes. Some drugs are absorbed from the mouth, pharynx, and esophagus as the saliva passes down into the stomach and produce a rapid onset of action. In such cases bioavailability of the drug is significantly greater than that observed from conventional tablet dosage forms [1, 6].
The advantages of rapidly disintegrating tablets are increasingly being recognized in both industry and academia. Their growing importance was underlined recently when the European Pharmacopoeia [7] adopted the term "orodispersible tablet" as a tablet to be placed in the mouth where it disperses rapidly before swallowing.
Direct compression is the easiest method to manufacture fast-dissolving tablets (FDTs) and fast-melting tablets (FMTs). The great advantage of direct compression is its low manufacturing cost. It uses conventional equipment, commonly available excipients, and a limited number of processing steps.
Direct compression is the method of choice in tablet manufacture to produce a high-quality finished product and is applied to prepare dispersible tablets [8].
In many cases, the disintegrants used have a major role in the disintegration and dissolution process of fast-dissolving tablets made by the direct compression method.
The choice of a suitable type and an optimal amount of disintegrant is important for ensuring a high disintegration rate. The addition of other formulation components, such as water-soluble excipients or effervescent agents, can further enhance dissolution or disintegration properties.
The understanding of disintegrants' properties and their effect on formulation has advanced significantly during the last few years, particularly regarding so-called super disintegrants.
In the direct compression method [9], previously only crystalline compounds or materials were considered to be directly compressed, but nowadays the scenario is changing, and this technique is being applied for many non-crystalline materials too. The approach mainly employs importation or modification of certain physical properties of the material under consideration, such as cohesiveness, compactness, and flow properties. Formulations constituted by ≤25% w/w of drug material are easy to be directly compressed by simply using such diluents, which are easy to compress and which act as a carrier for the drug. The techniques used in the preparation of fast-dissolving tablets are:

CONVENTIONAL TECHNIQUES:
Tablet Molding: Tablets are formed using water-soluble ingredients that dissolve quickly in the mouth. Ingredients are blended, wetted with a hydro-alcoholic solvent, compressed at low pressure, and air-dried.

Lyophilization (Freeze Drying): This technique dries heat-sensitive drugs at low temperatures by sublimation. It produces highly porous tablets that dissolve rapidly, enhancing absorption and bioavailability.

Spray Drying: A method to create fine, porous powders using bulking agents (e.g., mannitol), disintegrants (e.g., sodium starch glycolate), and effervescent agents, resulting in fast-dissolving tablets upon compression.

Sublimation: Involves mixing a sublime salt (like camphor) with other ingredients, compressing into tablets, and removing the salt through sublimation to leave behind a porous structure for rapid disintegration.

Addition of Disintegrants: Super disintegrants like microcrystalline cellulose, cross-linked CMC sodium, cross-linked PVP, and partially substituted HPC rapidly absorb water and swell, promoting quick tablet disintegration through capillary action.

Sugar-Based Excipients: Sugars like sorbitol, mannitol, dextrose, and xylitol act as bulking agents. Their high solubility and sweetness enhance taste masking and mouthfeel, making them ideal for fast-dissolving tablets.

Mass Extrusion: The drug blend is softened using solvents (e.g., PEG and methanol), then extruded into cylinders and cut into uniform tablets. This method helps in a uniform shape and rapid dissolution.

MATERIAL AND METHODS

CALIBRATION CURVE FOR ACARBOSE IN WATER: Procedure: Preparation of Standard Stock Solution: - 100 mg of acarbose was accurately weighed into a 100 ml volumetric flask and dissolved in a small quantity of water. The volume was made up to 100 ml with the water solution to get a concentration of (1000 μg/ml) SS-I. From this, 10 ml was withdrawn and diluted to 100 ml with water to get a concentration of (100 μg/ml) SS-II. Scanning of Drug: - From stock solution (SS-II), 1 ml was withdrawn and the volume was made up to 10 ml with water to get a concentration of 10 μg/ml. The UV scan range was taken between the wavelengths 200-400 nm. It gave a peak at 208 nm, and the same was selected as the maximum for acarbose. Calibration Curve in water: - From the standard stock solution (SS-II), 1, 2, 3, 4, and 5 ml were withdrawn and volume was made up to 10 ml with water to give a concentration of 10, 20, 30, 40, and 50 μg/ml. Absorbance of these solutions was measured against a blank of water at 208 nm for Acarbose, and the absorbance values are summarized in the Table.4 Calibration curve was plotted, drug concentrations versus absorbance were given in Figure 1

EFFERVESCENT MIXTURE AND MECHANISM OF ACTION:- [10]

$$2\ NaHCO3 + C4H6O6\ C4H4Na2O6 + 2CO2 + 2\ H2O$$

(Sodium Bicarbonate) + (Tartaric acid) (Sodium Citrate) + (Carbon di oxide) + (water)
When two molecules of base react with one molecule of acid results in the evolution of two molecules of carbon dioxide. Effervescence is the evolution of gas bubbles from a liquid, as a result of a chemical reaction. The most common reaction for pharmaceutical purposes is the acid base reaction between sodium bicarbonate and Tartaric acid or citric acid. Acid-base reactions between alkali metal bicarbonates and citric or tartaric acid give rise to the evolution of Carbon dioxide giving rise to bubbles formation. This method has been used for many years to produce pharmaceutical preparations that effervesce as soon as water is added. This reaction starts in presence of water and because water is one of the reaction products, it will accelerate the rate of reaction, leading to difficulty in stopping the reaction. For this reason, the whole manufacturing and storage of effervescent products is cannot be carried out in normal thermo hygrometric condition. So these products are planned by minimizing the contact with water (Moisture).

DRUG-EXCIPIENT COMPATIBILITY STUDIES BY I.R : -
Excipients are integral components of almost all pharmaceutical dosage forms. The successful formulation of a stable and effective solid dosage form depends on the careful selection of the excipients, which are added to facilitate administration, promote the consistent release and bioavailability of the drug and protect it from degradation.
Infra-Red spectroscopy is one of the most powerful analytical techniques to identify functional groups of a drug. Method: - The pure drug and its formulation were subjected to IR studies. In the present study, the potassium bromide disc (pellet) method was employed.

FORMULATION OF FAST DISSOLVING TABLETS OF ACARBOSE: [11]
Fast dissolving tablets of Acarbose were prepared by direct compression according to the formulae given in the table 4. All the ingredients except magnesium stearate were passed through # 60 mesh sieve separately and Magnesium Stearate was passed through # 80 sieve. All the ingredients were mixed properly in order to get uniform mixture and kept aside. The tablets were compressed using hydraulic press. Compression force of the machine was adjusted to obtain the hardness in the range of 40-60 Newtons for all batches. The weight of the tablets was kept constant for all formulations F0 to F7. The powder blend was compressed into tablets on a twelve-station rotary punch tableting machine (Rimek Mini Press II MT) using 11 mm standard concave (SC) punch set.

Table No.1: Composition of Different Batches of Fast Dissolving Tablets of Acarbose

Ingredients(mg/tab)	Formulation Code							
	F_0	F_1	F_2	F_3	F_4	F_5	F_6	F7
Acarbose	100	100	100	100	100	100	100	100
Tartaric acid	20	30	30	30	40	40	40	25
Sodium bicarbonate	40	40	60	70	70	80	40	50
Mannitol DC	223.5	211.5	153.5	148.5	143.5	138.5	154.5	164.5
Maltodextrin			35	30	25	20	44	39
Sucralose	5	7	10	10	10	10	10	10
Strawberry Flavor	7	7	7	7	7	7	7	7
Colloidal Silicon dioxide	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Magnesium Stearate	4	4	4	4	4	4	4	4
Total Weight	400	400	400	400	400	400	400	400

EVALUATION OF FAST DISSOLVING TABLETS

Evaluation was performed to assess the physicochemical properties and release characteristics of the developed formulations. I) Preformulation studies:

a) Bulk Density (Db):[82] It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weighed powder (passed through standard sieve # 20) into a measuring cylinder and the initial volume was noted. This initial volume is called the bulk volume. From this, the bulk density is calculated according to the formula mentioned below. It is expressed in g/cc and is given by:

$$Db = M/Vo$$

Where, M = mass of the powder Vo = bulk volume of powder.

b) Tapped density (Dt):[82] It is the ratio of total mass of powder to the tapped volume of powder. The volume was measured by tapping the powder for 500 times. Then the tapping was done for 750 times and the tapped volume was noted (the difference between these two volumes should be less than 2%). If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. It is expressed in g/cc and is given by:

$Dt = M/Vt$

Where, M = mass of the powder

Vt = tapped volume of powder

c) Angle of Repose (θ): [12] This is the maximum angle possible between the surface of a pile of powder or granules and the horizontal plane. The powders were allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of granules formed.

$\tan \theta = h/r$

$\theta = \tan\text{-}1 (h/r)$

Where, θ = angle of repose

h = height of the heap r = radius of the heap

The relationship between Angle of repose and powder flow is as follows:

Angle of repose	Powder flow
< 25	Excellent
25-30	Good
30-40	Passable
> 40	Very poor

d) Compressibility Index: [13] The flow ability of powder can be evaluated by comparing the bulk density (Db) and tapped density (Dt) of powder and the rate at which it packed down. Compressibility index is calculated by –

$$\text{Compressibility index (\%)} = \frac{Dt - Db}{Dt} \times 100$$

Where, Db = Bulk density
Dt = Tapped density

Percent compressibility	Type of flow
5-15	Excellent
12-16	Good
18-21	Fare-passable
23-25	Poor
33-38	Very poor
>40	Extremely poor

II) Post-compression parameters:

a) Shape of Tablets: Directly compressed tablets were examined under the magnifying lens for the shape of the tablet.

b) Tablet Dimensions: Thickness and diameter were measured using a calibrated vernier caliper. Three tablets of each formulation were picked randomly and thickness was measured individually.

c) Hardness: [14] Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Pharmatron Digital hardness tester. It is expressed in Newtons (N). Three tablets were randomly picked and hardness of the tablets was determined.

d) Friability test: [13] The friability of tablets was determined by using Roche Friabilator. It is expressed in percentage (%). 6.5 gm tablets were initially weighed (WI) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (WF). The % friability was then calculated by –

$$\%F = 100\ (1\text{-}WI/WF)$$

% Friability of tablets less than 1% was considered acceptable.

e) Weight Variation Test: [13] 20 tablets were selected randomly from each batch and weighed individually to check for weight variation. A little variation was allowed in the weight of a tablet according to U.S. Pharmacopoeia. The following percentage deviation in weight variation was allowed

Average weight of a tablet	Percentage deviation
130 mg or less	±10
>130mg and <324mg	±7.5
324 mg or more	±5

In all formulations, the tablet weight is 400 mg, hence 7.5% maximum difference allowed.

f) Test for Content Uniformity: [15] Tablet containing 100 mg of drug was dissolved in 50 ml of water taken in volumetric flask. The drug was allowed to dissolve in the solvent. The solution was filtered, 2 ml of filtrate was taken in 10 ml of volumetric flask and diluted up to mark with water and analyzed spectrophotometrically at 208 nm. The concentration of Acarbose was obtained by using standard calibration curve of the drug. Drug content studies were carried out in triplicate for each formulation batch.

g) In vitro Dispersion Time: 85 Tablet was added to a Petri dish containing 5 ml of water and test tube containing 10 ml of water at 37±0.50C. Time required for complete dispersion of a tablet was measured.

h) MOISTURE UPTAKE STUDIES: [16] Moisture uptake studies for Mouth Dissolving Tablets should be conducted to assess the stability of the formulation. Ten tablets from formulation were kept in a desiccator. The tablets were then weighed. Required humidity was achieved by keeping saturated solution of Sodium chloride (75% RH) and Potassium carbonate (40% RH) at the bottom of the desiccator for 3 days. Tablets were weighed and the percentage increase in weight was recorded.

STABILITY STUDIES [17-19]

Introduction: - In any rational drug design or evaluation of dosage forms for drugs, the stability of the active component must be a major criterion in determining their acceptance or rejection. Stability of a drug can be defined as the time from the date of manufacture and the packaging of the formulation, until its chemical or biological activity is not less than a predetermined level of labeled potency and its physical characteristics have not changed appreciably or deleteriously. Objective of the Study: [20, 21] The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, enabling recommended storage conditions, re-test periods and shelf-lives. The International Conference on Harmonization (ICH) Guidelines titled "Stability Testing of New Drug substance and Products" (QIA) describes the stability test requirements for drug registration applications in the European Union, Japan and the United States of America.

ICH specifies the length of study and storage conditions.
Long-term Testing: 250C ± 20C / 60 % RH ± 5 % for 12 Months.

Accelerated Testing: 400C ± 20C / 75 % RH ± 5 % for 6 Months.
Stability studies were carried out at 250C / 60 % RH and 40°C/75% RH for the selected formulation for the period of 3 months.

Method: The selected formulation was packed in flip top polypropylene container with desiccant integrated inside the wall of the container; polypropylene spiral spring designs inside the lid with tamper evident seal. They were then stored at 250C / 60 % RH and 40°C and 75% RH for 3 months and evaluated for their physical appearance, drug content and in vitro dispersion time at specified intervals of time.

RESULT AND DISCUSSION

SL. No.	Concentration (µg/ml)	Absorbance*
1	0	0
2	10	0.132
3	20	0.231
4	30	0.324
5	40	0.436
6	50	0.558

Table No. 4: Calibration data of Acarbose in water at λ_{max} 208 nm

***Average of 3 determinations**

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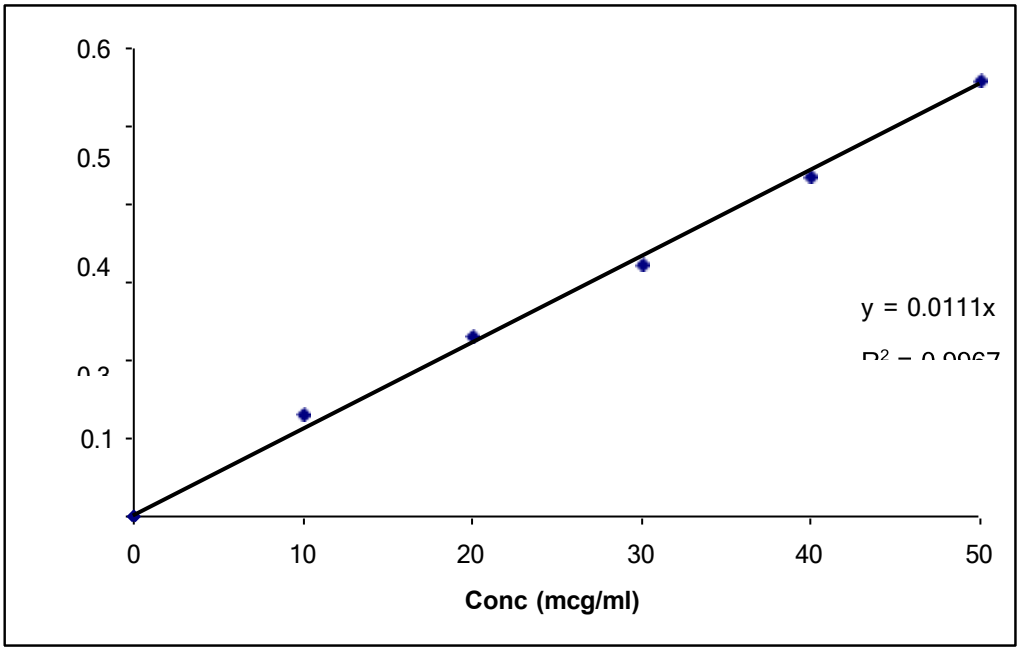
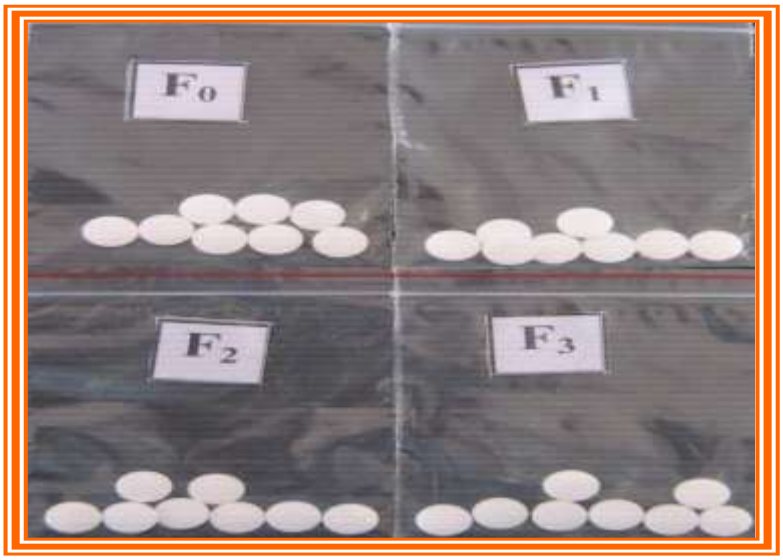


Fig. 1: Standard calibration curve for Acarbose in water at λ_{max} 208 nm

The linear regression analysis for standard curve in water.
The linear regression analysis was done on absorbance data points. The results are as follows:
The Slope = 0.0111
The intercept = 0
The correlation coefficient = 0.9967

A straight-line equation (y = mx + c) was generated to facilitate the calculation for amount of drug. The equation is as follows.



Absorbance = 0.0111 X Concentration
Fig.No.2: Picture depicting the formulations F0-F3

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Fig.No.3: Picture depicting the formulations F4-F7

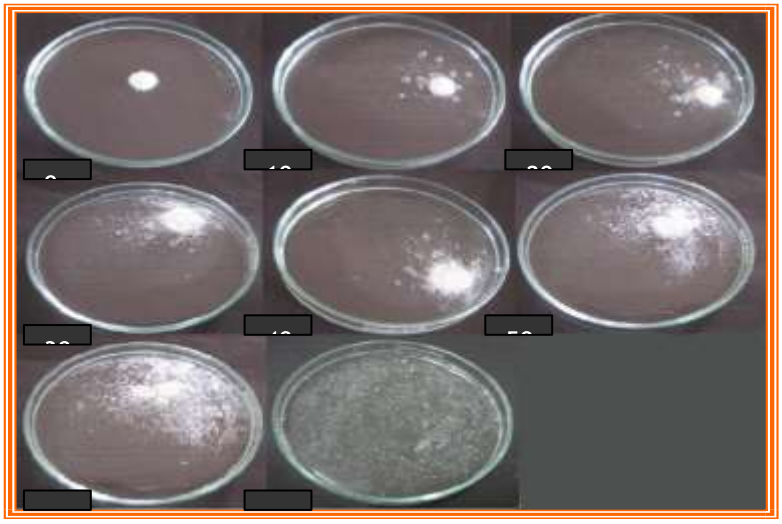

Fig.No.4: Photograph showing In vitro Dispersion time of tablet (F5) in Petri dish containing 5 ml water.

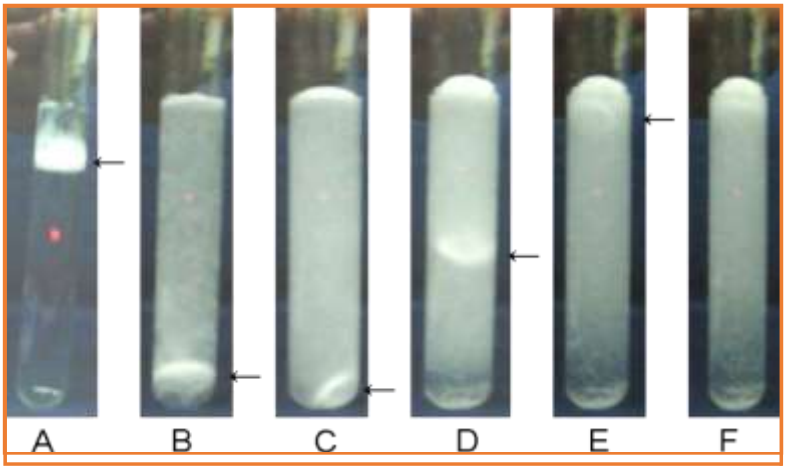

Fig.No.5: Photograph showing In vitro Dispersion time of tablet (F5) in test tube containing 10 ml water.

A = 0 sec, B = 10 sec, C = 20 sec, D = 30 sec, E = 40 sec, F = 50 sec (complete dispersion)
← Indicates presence of tablet

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Fig.No.6: Tablets before kept for Moisture uptake studies.

Fig.No.7: Tablets after removed from Moisture uptake studies.

COMPATIBILITY STUDY:

Compatibility studies were performed using FT-IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and polymer were studied by making a KBr disc. The characteristic absorption peaks of Acarbose were obtained at different wave numbers in different samples.

The peaks obtained in the spectra of each formulation correlates with the peaks of drug spectrum. This indicates that the drug is compatible with the formulation components. The spectra for all formulations are shown below.

The spectral details for all types of formulations are shown as follows:

A. Pure drug Acarbose.

IR Spectrum	S.No	(KBr Disc) peaks at	Indications
	1.	3291 cm^{-1}	OH Stretching
	2.	1589 cm^{-1}	C=C stretching
	3.	1369 cm^{-1}	C=C stretching
	4.	1037 cm^{-1}	C-O stretching

B. Mixture of Acarbose + Excipients.

	S. No	(KBr Disc) peaks at	Indications
IR Spectrum	1.	3284 cm^{-1}	OH Stretching
	2.	2938 cm^{-1}	C-H str of methyl group
	3.	1388 cm^{-1}	C=C stretching
	4.	1020 cm^{-1}	C-O stretching

Table No. 2: PRE-COMPRESSION PARAMETERS OF ALL FORMULATIONS*

Formulations	Bulk density (g/cc)	Tapped density (g/cc)	Angle of repose (θ)	Compressibility Index (%)	Hausner's ratio
F0	0.8698 ± 0.0004	0.9454 ± 0.0006	$25^0.84'$ ± 0.0624	7.996 ± 0.0439	1.086 ± 0.0102
F1	0.5280 ± 0.0021	0.5860 ± 0.0025	$26^0.15'$ ± 0.2030	9.890 ± 0.5173	1.109 ± 0.0125
F2	0.8052 ± 0.0002	0.8920 ± 0.0064	$26^0.82'$ ± 0.0808	9.730 ± 0.1701	1.107 ± 0.0096
F3	0.6419 ± 0.0003	0.7241 ± 0.0005	$25^0.14'$ ± 0.0854	11.35 ± 0.1234	1.128 ± 0.0098
F4	0.4832 ± 0.0004	0.5371 ± 0.0003	$27^0.35'$ ± 0.0651	10.03 ± 0.00661	1.111 ± 0.0356
F5	0.5198 ± 0.0004	0.5803 ± 0.0008	$25^0.96'$ ± 0.1955	10.42 ± 0.1258	1.116 ± 0.0085
F6	0.6392 ± 0.0004	0.7015 ± 0.0009	$27^0.63'$ ± 0.2095	8.880 ± 0.1153	1.097 ± 0.0117
F7	0.4926 ± 0.0006	0.5428 ± 0.0008	$28^0.05'$ ± 0.1305	9.248 ± 0.0129	1.101 ± 0.0035

*mean±SD, n=3

Table No. 3: PHYSICAL PROPERTIES OF TABLETS OF ALL FORMULATIONS

Formulations	Diameter* (mm)	Thickness*(mm)	Weight variation # (mg)	Hardness [a] (Newton)	Friability (%)
F0	10.98±0.052	3.59±0.007	398.2±3.58	56.0±1.2	0.526
F1	11.02±0.049	3.59±0.013	401.0±4.37	58.2±1.5	0.492
F2	10.96±0.053	3.57±0.042	398.8±4.13	48.6±1.1	0.391
F3	10.98±0.043	3.55±0.048	400.6±3.83	45.4±1.2	0.428
F4	11.00±0.026	3.57±0.021	399.1±4.06	45.2±1.3	0.502
F5	11.00±0.023	3.60±0.004	397.8±4.22	46.5±1.0	0.465
F6	10.97±0.024	3.58±0.008	398.0±4.05	48.3±1.3	0.621
F7	10.98±0.042	3.59±0.011	398.5±4.12	47.5±1.8	0.625

*mean±SD, n=3, #mean±SD, n=20, [a]mean±SD, n=5

Table No. 4: POST COMPRESSION PARAMETERS OF TABLETS OF ALL FORMULATIONS

Formulations	In vitro dispersion time* (in sec)	Drug content* (%)
F0	136.67 ± 1.15	99.97 ± 0.1050
F1	114.67 ± 2.08	99.98 ± 0.0585
F2	93.33 ± 2.51	100.02 ± 0.1101
F3	77.67 ± 0.57	100.01 ± 0.0472
F4	66.00 ± 1.73	99.98 ± 0.1059
F5	55.33 ± 2.08	100.01 ± 0.0602
F6	110.33 ± 1.52	99.96 ± 0.0754
F7	94.33 ± 2.08	99.99 ± 0.1159

*mean±SD, n=

Table No. 5: MOISTURE UP TAKE STUDIES AT 25°C & 75% RH

Sl No	Time (hours)	Weight (gm)*
1	0	4.1461 ± 0.0031
2	2	4.2089 ± 0.0850
3	4	4.2240 ± 0.0835
4	6	4.2869 ± 0.1062
5	8	4.3087 ± 0.1052
6	12	4.3587 ± 0.1038
7	24	4.3931 ± 0.1171
8	32	4.4462 ± 0.1596
9	48	4.4803 ± 0.2599

*mean±SD, n=4

Table No. 6: MOISTURE UPTAKE STUDIES AT 25°C & 40% RH

Sr. No	Time (hours)	Weight (gm)*
1	0	4.0731 ± 0.0610
2	2	4.0739 ± 0.0625
3	4	4.0743 ± 0.0641
4	6	4.0748 ± 0.0211
5	8	4.0752 ± 0.0664
6	12	4.0759 ± 0.0571
7	24	4.0764 ± 0.0578
8	32	4.0771 ± 0.0616
9	48	4.0782 ± 0.0654

*mean±SD, n=4

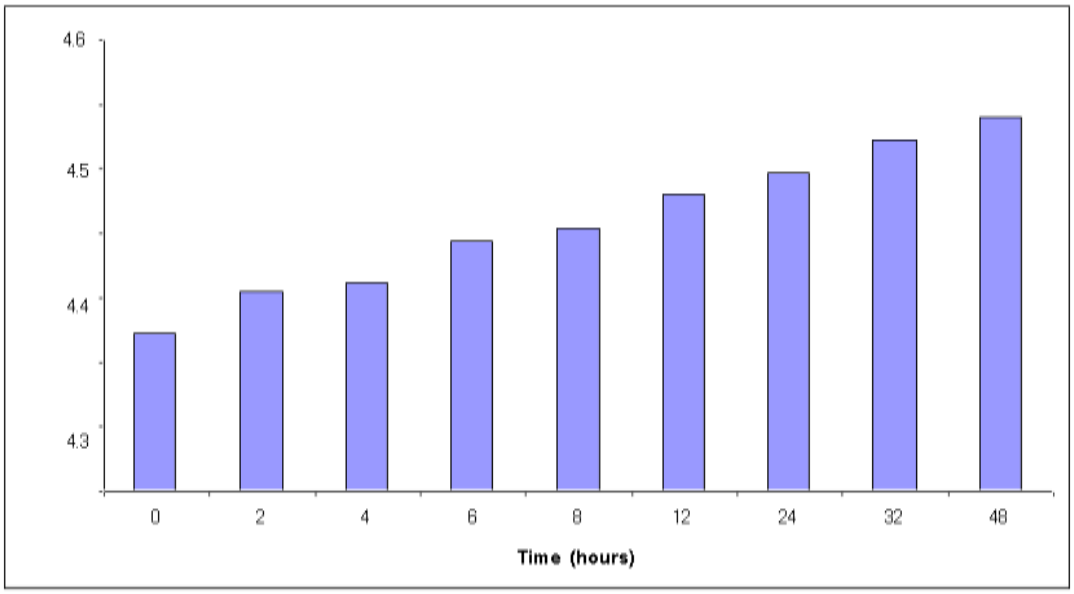

Fig.No.5: MOISTURE UPTAKE STUDIES AT 25°C & 75% RH

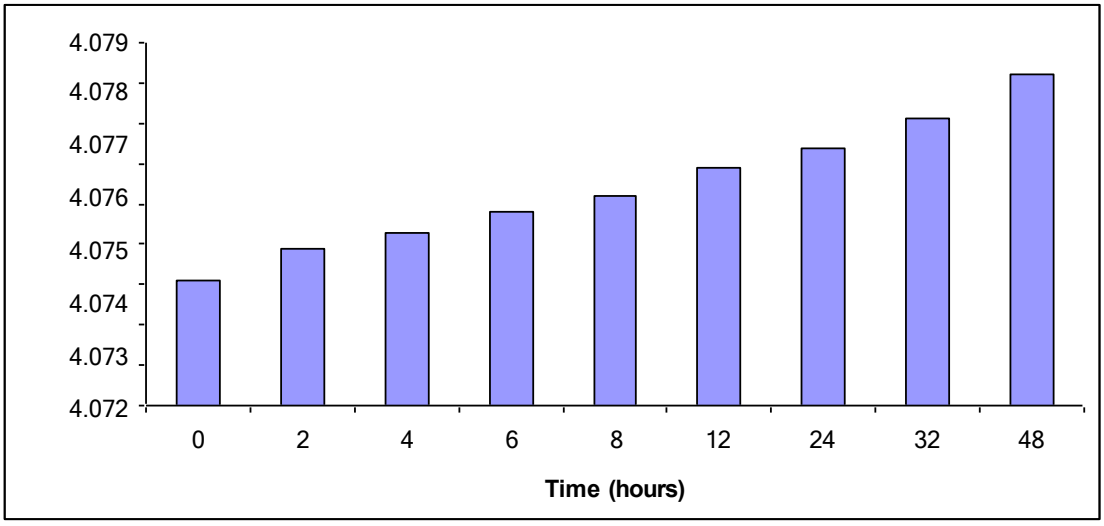

Fig.No.6: MOISTURE UPTAKE STUDIES AT 25°C & 40% RH

Time in months	Formulation F3 stored at 40°C/ 75% RH	
	Physical appearance	% Drug content
1	+++	98.75
2	+++	98.36
3	++	97.99

Table No 7: Stability data of F3 formulation

+++ = Same as on zero day, ++ = Slight change in color

EVALUATION OF FAST DISSOLVING TABLET FORMULATIONS:

Pre-compression Parameters:

Bulk Density:-

The values obtained for bulk density for all (F_0-F_7) formulations are tabulated in Table No. 5. The values were found to be in the range of 0.4832 to 0.8698 g/cm³.

Tapped Density: -
The values obtained for tapped density for all (F_0-F_7) formulations are tabulated in Table No 5. Tapped density ranges from 0.5371 to 0.9454 g/cm^3.
Angle of Repose (θ): -
The values were found to be in the range from 25^0 - 28^0, tabulated in Table No. 5. This indicates good flow property of the powder blend.
Compressibility Index: -
Compressibility index value ranges between 7.99% - 11.35%, tabulated in Table No. 5, indicating that the powder blends have the required flow property for direct compression.
Hausner's Ratio:-
The values were found to be in the range from 1.086 – 1.128, tabulated in Table No. 5.

Post-compression Parameters:
Shape of the tablet: -
Microscopic examination of tablets from each formulation batch showed a circular shape with no cracks.
Tablet dimensions: -
The dimensions determined for formulated tablets are tabulated in Table No 6.
Tablet mean thicknesses were almost uniform in all the formulations and were found to be in the range of 3.55 mm to 3.60 mm. The diameter of the tablet ranges between 10.96 mm to 11.60 mm.

Hardness test: -The measured hardness of tablets of each batch ranged between 40 to 60 Newtons and was tabulated in Table No. 6. Tablet hardness increased as increasing compression force. This ensures good handling characteristics of all batches.
Friability Test: -The values of the friability test are tabulated in Table No 6. The % friability was less than 1% in all the formulations, ensuring that the tablets were mechanically stable.
Weight Variation Test: - The percentage weight variation for all formulations is shown in Table No 6. All the tablets passed the weight variation test as the % weight variation was within the pharmacopoeial limits. The weights of all the tablets were found to be uniform with low standard deviation values.
Drug Content Uniformity: -The percentage of drug content was found to be between 95.54 and 100.5 of acarbose, which was within acceptable limits. Table No 7 showed the results of drug content uniformity in each batch.

In vitro Dispersion Time: -The most important parameter that needs to be optimized in the development of fast dispersible tablets is the dispersion time in tablets. In the present study, all the tablets dispersion in ≤ 1.2 min, fulfilling the official requirement (<3 min) for dispersible tablets [76]
The in vitro dispersion times for all formulations are shown in Table No 7. The tablets prepared by using Sodium bicarbonate and Tartaric acid as effervescent mixture, all the formulations have different dispersion time. With F0 formulation the dispersion time is more (134 – 137 sec) as it contains Sodium bicarbonate and Tartaric acid in lesser concentration. F5 had showed least dispersion time 48 – 54 sec as it contains higher concentration of Sodium bicarbonate and Tartaric acid.
The dispersion time of all formulations depends on the concentration of effervescent mixture, dispersion time decreases as the concentration of effervescent mixture increases.

h) Moisture Uptake Studies: - Different data generated in this experiment indicate that % RH of the manufacturing environment has a great effect on the moisture level of acarbose, as the tablets were prepared by the effervescent technique absorbs the maximum amount of moisture at higher % RH. This higher moisture level is responsible for various physical stability problems. Therefore, by controlling the % RH of the manufacturing environment, we can overcome the various stability problems, 20-25% RH is considered the optimum moisture level for tablets prepared by the effervescent technique.
i) Stability Studies: The selected Formulation F_3 was evaluated for stability studies, which were stored at 40C °C at 75% RH tested for 3 months, and were analyzed for their drug content at the monthly interval. The residual

drug contents of formulations were found to be within the permissible limits, and the results of 3 months duration are shown in the Table no 10 which was estimated by seeing drug content uniformity.

CONCLUSION

In the present work, fast-dissolving tablets of acarbose were prepared by the direct compression method using effervescent disintegrants such as sodium bicarbonate and Tartaric acid. Acarbose is soluble in water, but its bioavailability is limited and hence, this method is useful for improving its bioavailability of the drug. The dispersibility of tablets was increased by increasing the concentration of effervescent disintegrants like sodium bicarbonate and tartaric acid. The use of Maltodextrin and mannitol improves the binding property cooling effect of the tablets respectively. Colloidal silicon dioxide (Aerosil) prevents capping problem of the tablets, the use of Sucralose is helpful for diabetic patients as it is sugar free and contains zero calories. From the findings obtained, it can be concluded that, the flow properties of excipients and drug were good. FT-IR studies revealed that there is no chemical interaction between acarbose and the excipients used in the study.

The tablets prepared were found to be good without any chipping, capping and sticking. Formulated tablets gives satisfactorily result for various physico-chemical evaluations of tablets like tablet dimension, hardness, friability, weight variation, in vitro dispersion time, water absorption ratio and drug content. The low values of standard deviation for average weight and drug content of the prepared tablets indicate weight and drug content uniformity within the batches prepared. Based on in vitro dispersion time, formulation F4 and F5 were found to be promising and displayed a dispersion time of approximately 48-67 s. Based on moisture uptake studies, higher moisture level is responsible for various physical stability problems. Therefore, by controlling the % RH of manufacturing environment, we can overcome the various stability problems, 20-25% RH is considered as the optimum moisture level for tablets prepared by effervescent technique Short-term stability studies of promising formulation indicated that there is no significant change in drug content and in vitro dispersion time. From the present study, it may be concluded that the fast-dissolving tablets of acarbose can be prepared by direct compression method using effervescent mixtures (sodium bicarbonate & tartaric acid).

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CONFLICT OF INTERESTS

There is no conflict of interest among authors.

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