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"Formulation and Evaluation of Rapid Dispersible Tablet by Using Different Concentration of Superdisintegrant and Comparision with Marketed Preparation"

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ABSTRACT:-
The present work focuses on formulation and evaluation of Asprin Rapid Dispersible tablets by using different concentration of superdisintegrant i.e. Sodium Starch Glycolate (SSG) by direct compression method and comparison with commercially available Marketed preparation. The main objective is to enhance patient compliance. The available marketed preparation tablet takes at least 1minute to disperse. The main focus is to make Rapid Dispersible Tablets in such way that it may disperse within fraction of seconds. Formulations were evaluated and compared with Marketed Preparations.We have formulated Aspirin Tablets by using different concentration of Sodium Starch Glycolate in different batches i.e. of 8% , 10% , 12% , 14%.It was observed that by using low concentration of Superdisintegrant,it takes more time to disperse and with increase in its concentration it disperses rapidly. As per the results obtained, it was found that the formulation batch No A3 having concentration 12% of SSG was found to be similar with the marketed Preparation with special reference to dispersion time.Formulation batch No A4 having concentration 14% of SSG was found to be having dispersion time very less in comparison with the marketed preparations and which was found to be very beneficial to patient as it disperse rapidly and gives faster effect as compare to marketed tablet.
Keywords :- Rapid Dispersible tablets , Aspirin , Sodium Starch Glycolate , Direct Compression Method.

I. INTRODUCTION:-

The tablet is the most widely used dosage form because of its convenience in terms of self administration, compactness, and ease in manufacturing. However, geriatric and pediatric patients experience difficulty in swallowing conventional tablets, which leads to poor patient compliance. To overcome this weakness, scientists have developed innovative drug delivery systems known as "Dispersible Tablets". Dispersible Tablets are also known as quick dissolves, fast melts, fast dissolving, fast disintegrating, rapid-dissolve, or orally dissolving tablets. Their advantages such administration, anywhere, anytime lead to their suitability to geriatric and pediatric patients. They are also suitable for the mentally ill, the bedridden, and patients who do not have easy access to water.

The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability, and good stability make these tablets popular dosage form of choice in the current market.[1] Despite increasing interest in controlled-release drug delivery systems, the most common tablets are those intended to be swallowed whole and to disintegrate and release their medicaments rapidly in the gastrointestinal tract (GIT). The proper choice of Super disintegrant and its consistency of performance are of critical importance to the formulation development of such tablets. In more recent years, increasing attention has been paid to formulating not only fast dissolving and/or disintegrating tablets that are swallowed, but also orally disintegrating tablets that are intended to dissolve and/or disintegrate rapidly in water and to be swallowed.

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Over a decade, the demand for development of dispersible tablets has enormously increased as it has significant impact on the patient compliance. Dispersible tablets offer an advantage for populations who have difficulty in swallowing. It has been reported that Dysphasia (difficulty in swallowing) is common among all age groups and more specific with pediatric, geriatric population along with institutionalized patients and patients with nausea, vomiting, and motion sickness complications. DTs with good taste and flavor increase the acceptability of bitter drug by various group of population.[2]

Aspirin is also known as acetylsalicylic acid (ASA), is a nonsteroidal anti-inflammatory drug (NSAID) used to reduces pain , fever ,inflammation and as an antithrombotic. Specific inflammatory conditions which aspirin is used to treat include Kawasaki disease, pericarditis, and rheumatic fever. Aspirin is also used long-term to help prevent further heart attacks, ischaemic strokes, and blood clots in people at high risk. For pain or fever, effects typically begin within 30 minutes. Aspirin works similarly to other NSAIDs but also suppresses the normal functioning of platelets. Aspirin is available without medical prescription as a proprietary or generic medication[3] most jurisdictions.

It is one of the most widely used medications globally, with an estimated 40,000 tonnes (44,000 tons) (50 to 120 billion pills) consumed each year[4] [5],and is on the World Health Organization's List of Essential Medicines[6]. In 2020, it was the 36th most commonly prescribed medication in the United States, with more than 17 million prescriptions[7] [8] . One common adverse effect is an upset stomach. More significant side effects include stomach ulcers, stomach bleeding, and worsening asthma. Bleeding risk is greater among those who are older, drink alcohol, take other NSAIDs, or are on other blood thinners. Aspirin is not recommended in the last part of pregnancy. It is not generally recommended in children with infections because of the risk of Reye syndrome. High doses may result in ringing in the ears[3].

II. REVIEW OF LITERATURE:

The Review of Literature was taken from different Text Books, Reference Books, Journals, Internet,etc.

1.S.B.Jadhav et.al. /Int.J. PharmTech Res.2011, [9]
They reviewed that disintegration time of Dispersible Tablets enhances its rate with the help of superdisintegrant which is very beneficial to patient.

2. Paul et.al./ IJCPR May - July, 2011: 2(2) ,[10]
They worked, formulated and evaluated Rapid Dispersible Tablet and investigated that with increase in the concentration of superdisintegrant tablet disintegrate rapidly.

3. Journal of Applied Pharmaceutical Research 7 (3); 2019: 9 – 16 [11]
They evaluate the procedures , analyzing components and effect on the patient.

4.AAPS PharmSciTech , 2000; 1 (3) article 20 [12]
They evaluated the tablet on the basis of various characteristics i.e. Preformulation characteristics of tablet .

5. IJPRD/2009/PUB/ARTI/VOL-7/SEP/001; ISSN 0974 – 9446 [13]
They developed and evaluated compression characteristics of tablets .

III. AIM, OBJECTIVES AND NEED OF RESEARCH :-

Aim: -Formulation and Evaluation of Rapid Dispersible Tablet by using different concentration of Superdisintegrant and Comparison with marketed preparation.

Objectives:-

1. To make Rapid Dispersible Tablets in such way that it may disperse within fraction of seconds.

2. To make the tablet in such a way that it enhances the patient compliance.

Need of Research :-

Generally marketed preparation takes at least 1min to disperse. But our work focuses on to make Rapid Dispersible Tablets in such way that it may disperse within fraction of seconds thereby increasing patient compliance. Our formulated tablet takes 45-50 sec to disperse. Formulations were evaluated for the standard Rapid Dispersible Tablets and compared with marketed preparation . It was observed that by increasing concentration of Sodium Starch Glycolate , it takes less time to disperse which becomes very much beneficial to patient.

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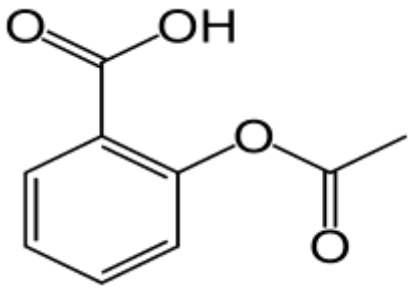
DRUGS PROFILE:-

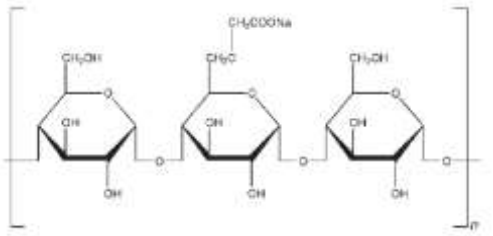
1.Aspirin



IUPAC Name **:-** 2-acetoxybenzoic acid
Molecular Formula**:-** $C_9H_8O_4$
or $CH_3COOC_6H_4COOH$
Molecular Weight **:-** 180.16g/mol
Melting Point **:-** 135 ^{0}C
Boiling Point **:-**140 ^{0}C
Density :- 1.4 g/cm^3

Solubility**:-** It has a limited solubility in water, which amounts to 2–4 mg/mL and its solubility varies significantly with temperature . Aspirin is more soluble in ethanol, ethyl ether, chloroform, sodium hydroxide solution, and sodium carbonate solution than in water.
Physical Properties **:-**Acetylsalicylic acid appears as odorless white crystals or crystalline powder with a slightly bitter taste.
Plasma Protein binding :- Protein binding of aspirin was estimated at 58.3% +/- 9.6% by in vivo ultrafiltration and could not be estimated by in vitro ultracentrifugation because the concentration of unbound aspirin in plasma was below the limit of detection for the assay.
Uses **:-** Used to Reduces fever
Relieve mild to moderate pain from headaches
Menstrual periods
Arthritis
Toothaches
Muscle aches

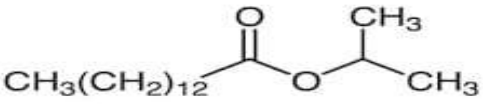
2.Sodium Starch Glycolate



IUPAC Name :- Sodium Carboxymethyl Starch
Molecular Formula:- $CH_3Na_2O_3$
Molecular Weight :- 98.03 g/mol
Melting Point :- 80 °C
Boiling Point :- 575 °C to 625 °C.
Density :- 0.756 g/cm3
Solubility :- Disperses in water to form a viscous colloidal solution. Insoluble in ethanol and in ether
Physical Properties :- Appearance - White powder
Color- White to Off-White

- Uses :-
  - It used super-disintegrant employed to promote rapid disintegration and dissolutionof IR solid dosage.
  - It is manufactured by chemical modification of starch, i.e., carboxymethylation to enhance hydrophilicity and cross-linking to reduce solubility.
  - It is used as suspending agent, gelling agent, buffering agent and in pharmaceutical grade for tablets and capsules.
  - It is used in cosmetics and personal care products primarily as an exfoliant, as pH adjusters, skin-conditioning agents and as a flavoring agent.

3.Magnesium Stearate



IUPAC Name :- Magnesium octadecanoate
Molecular Formula :- Mg(C18H35O2)2
Molecular Weight :- 591.27 g/mol
Melting Point :- 88.5 °C
Boiling Point :- 359.4 °C
Density :- 0.159 g/cm
Physical Properties :- Appearance - Light white powder
Odor – slight
Solubility :- negligible in ether and alcohol slightly soluble in benzene
Uses :-Used as emulsifier
Binder and thickener
Anticaking agent
Lubricant

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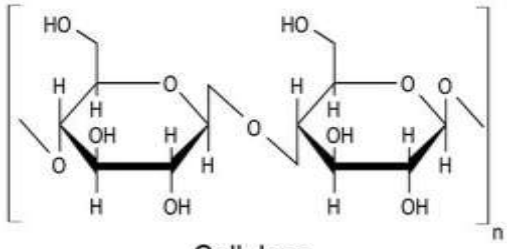
Antifoaming agent.

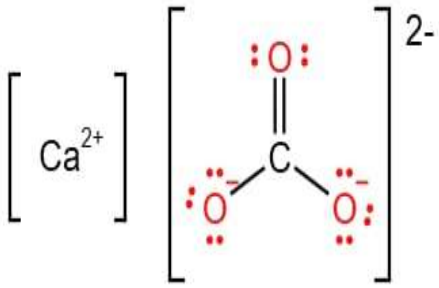
IV. MICROCRYSTALLINE CELLULOSE



Cellulose

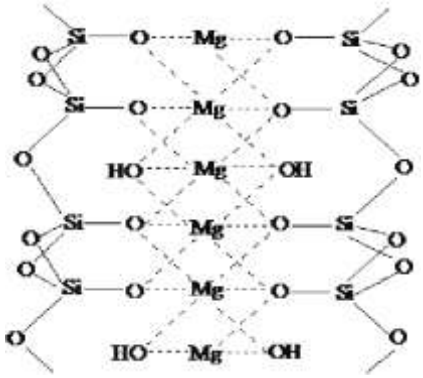
IUPAC Name :- 4-O-[(1S)-hexopyranosyl]-D-glycero-hexopyranose
Molecular Formula :-(C12H20O10)n
Molecular Weight :-324.28g/mol
Melting Point :- 76-78 °C
Boiling Point :- 667.9°C
Density :- 1.582 and 1.599 g/cm3
Physical Properties :- Appearance - White powder
Odor - Odorless
Taste - Tasteless
Solubility :- Insoluble in water, insoluble in dilute acid, organic solvent and oil, swollen in dilute alkali solution, partially dissolved.
Uses :-Used as texturizer
Anti-caking agent
Fat substitute
Emulsifier
Extender
Bulking agent in food production

V. CALCIUM CARBONATE



IUPAC Name :- Limestone or calcite
Molecular Formula :-$CaCO_3$
Molecular Weight :-100.09g/mol
Melting Point :- 825 °C
Boiling Point :- 899 °C
Density :- 2.71 g/cm³
Physical Properties :- Appearance - Fine white powder
Odorless
Solubility :-Slightly soluble in water
Uses :- Used asdietary supplement used when the amount of calcium taken in the diet is not enough.

VI. 6. Talc



IUPAC Name :- trimagnesium;dioxido(oxo)silane;hydroxy-oxido-oxosilane
Molecular Formula :-$H_2Mg_3O_{12}Si_4$

Molecular Weight :- 379.27g/mol
Melting Point :- 1500°C
Boiling Point :- 9002.6- 2.8°C
Density :- 2.6- 2.8 g/cm³
Physical Properties :- Appearance - Whitish grey to green with a vitreous and pearly luster
Solubility :-Insoluble in water and slightly soluble in dilute mineral acids
Uses :-Used to absorb moisture
Prevent caking
Improve consistency
To make a product opaque.

PLAN OF WORK

STEP : I

Collection of Drugs from College laboratory and Biovencer Healthcare Pvt.Ltd.

STEP: II

All the ingredients were weighed and mixedaccording to the formula and made into powder form

STEP : III

Tablets were prepared according to the formula

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STEP : IV
Evaluation of the tab on the basis of Pre-Compression Characteristics of Powder like Bulk Density ,Tapped Density , Angle of Repose , Husner's Ratio

STEP :V
Evaluation on the basis of compression characteristics of tablet like Weight Variations , Hardness , % Friability , Thickness .

STEP :VI
Evaluation of tablet for parametersafter likeWetting time , Wetting volume , Uniformity of Dispersion , Content of Active Ingredients , Water absorption Ratio,Dispersion Time,Disintegration Time

STEP : VII
Store the tablet: To preserve their stability and effectiveness, the final pills should be kept in a dry, cool location away from moisture, heat, and direct sunlight.

STEP VIII
Comparison with Marketed tablet

VII. MATERIALS AND METHODS

7.1 Collection of Materials :

Ingredients like aspirin, magnesium stearate, calcium carbonate, starch, talc were collected College laboratory of Nagpur College Of Pharmacy . Sodium Starch Glycolate was obtained as a gift sample from Biovencer Healthcare Pvt Ltd. Different solvents and reagents were collected from college laboratory.

Table No 1 : **Formula for preparation of Rapid Dispersible Tablet**

Ingredients Per Tablet (mg)						
Formulation on Code	**Aspirin**	**Sodium Starch Glycolate**	**Magnesium Stearate**	**Cellulose**	**Calcium Carbonate**	**Talc**
A1	325	26	22.5	120	100	10
A2	325	32.5	22.5	120	100	10
A3	325	39	22.5	120	100	10
A4	325	45.5	22.5	120	100	10

Table No 1 : **Formula for preparation of Rapid Dispersible Tablet**

7.2 Methods of Preparation:
Preparation of tablet by Direct Compression Method: -
7.2.1 Procedure: -
All the ingredients were weighed accurately and mixed thoroughly. Tablets was prepared by Direct Compression Method.This method can be defined as basically mixing and processing of formulation ingredients then compressing into tablets. The tablets were obtained directly from the powder and other excipients.

VIII. RESULT AND DISCUSSION

- **Evaluation**

8.1 Pre-compression characteristics of tablet
Pre-compression characteristics of tablet like Bulk density, Tapped density, Angle of Repose, Hausner's ratio , Carr's Compressibility Index by using standard procedures.

1. Bulk density :-
Bulk density is determined by placing the powders blend in a measuring cylinder and the total volume is noted. The weight of powder bed is determined by using digital weighing balance. Bulk density is calculated using the following formula:-

Bulk Density = Weight of the powder / Volume of the powder

2. Tapped density :-
Tapped density is determined by taking the dried powders in a measuring cylinder and measures the volume of powders after 100 tapping's and take weight of the total powders.

Tapped Density = Weight of the powder / Tapped Volume of the powder

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3. Angle of repose :-

Angle of repose was determined by measuring the height andradius of the heap of the powder bed. A cylindrical two side open tube of 6 cm length is place on graph paper. Powders are placed in the tube and slowly removed the tube vertically. With the help of scale the height and radius of the heap were measure and note.

$\theta = \tan^{-1} h / r$

Where,
h = height of heap of granular bed
r = radius of heap of granular bed.

4. Hausner's Ratio:-

The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material . It is expressed in percentage and is expressed by,

H=Dt/Db

Where,
D_t =Tapped density of the powder.
D_b = Bulk density of the powder.

5. Carr's Compressibility Index:-

Carr's Compressibility Index is also called as Carr's Index.Carr's Indexof any solid is
CI=100[(ρT–ρB)/ ρT

Where,
ρT =True density of the powder
ρB =Bulk density of the powder

Table No :-2Evaluation of Pre-Compression Characteristics of Powder

Formulation Code	Bulk Density (g/cm3)	Tapped Density (g/cm3)	Angle of Repose(θ°)	Hausner's Ratio	Compressibility Index
A1	0.452 ± 0.01	0.501 ± 0.01	26.70 ± 1.31	1.10 ± 0.003	11.33 ± 0.30
A2	0.479 ± 0.01	0.541 ± 0.01	28.25 ± 1.81	1.12 ± 0.004	12.01 ± 0.33
A3	0.425 ± 0.02	0.493 ± 0.01	24.51 ± 1.17	1.16 ± 0.002	12.40 ± 1.81
A4	0.460 ± 0.01	0.512 ± 0.01	25.77 ± 0.73	1.12 ± 0.003	11.55 ± 0.30

Table No :-2 Evaluation of Pre-Compression Characteristics of Powder.
*Average of three determinations ± Standard deviation

8.2 Compression characteristics of tablet: -

The tablets from all the batches were evaluated for different parameters as follows:

1.Appearance: -

Tablets were evaluated for organoleptic properties.

1) The general appearance of a tablet, its identity, and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and tablet-to-tablet uniformity.

2) The control of general appearance involves the measurement of size, shape, color, presence or absence of odor, taste, etc.

2.Thickness ;-

Thickness of tablets was determined using Vernier calliper, three tablets from each batch were used and an average value was calculated in terms of (mm).

3.Weight Variation :-

Twenty tablets were selected and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight.

Formula for Weight Variation of Tablets:-

Average weight of 20 tablets was calculated using the formula:

$$\text{mean} = \frac{(X1 + X2 + X3 \ \ldots \ + X20)}{20}$$

Percentage deviation of Weight Variation

$$= \frac{\left(\begin{array}{c}\text{Individual tablet} \\ \text{weight}\end{array} - \begin{array}{c}\text{Average weight of} \\ \text{20 tablets}\end{array}\right)}{\begin{array}{c}\text{Average weight} \\ \text{of 20 tablets}\end{array}} \times 100$$

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4.Hardness **:-**

Tablets were selected at random from each formulation and hardness was checked using Monsanto Hardness Tester .The hardness was measured in terms of kg/cm2 . Triplicate readings were taken and average was determined.

5.Friability test :-

Roche friabilator was used for testing the friability of the tablets. For this test, 20 tablets were weighted accurately and placed in the friabilator chamber and rotated at 25rpm for a period of 4 min. Tablets were again weighted and the percentage weight loss was determining by using formula given by,

% Friability = [(W1-W2)100]/W1

Where,

W_1= Weight of tablet before test

W_2 = Weight of tablet after test

6.Content of Active Ingredient**:-**

Drug content of all the batches was determined. For this purpose six tablets were weighed and crushed with pestle in a small glass mortar. The fine powder was weighed to get 200 mg (equivalent to 60 mg of Disprin), and transferred to 250 ml conical flask containing 100 ml of Distilled water stirred for 45 min in ultra sonicator. Solution was filtered and the filtrates obtained were analyzed UV spectrophotometrically and drug content was determined.

7.Uniformity of Weight :-

Two tablets were placed in 100 ml of water and stirred gently until completely dispersed. A smooth dispersion was obtained which passes through a sieve screen with a nominal mesh aperture of 710 μm (sieve number 22).

8.Wetting Time :-

A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of purified water, then a tablet was placed on the paper and the time required for complete wetting was measured. Wetting time corresponds to the time taken for the tablet to disintegrate when placed gently on the tissue paper in a Petridish. Less wetting time indicates more porous tablets.

9.Wetting Volume :-

The tablet was placed in the center of the Petri dish and with the help of 5 ml pipette distilled water was added drop wise on the tablet. The volume required to completely disintegrate the tablet was noted as the wetting volume.

10.Water Absorption Ratio :-

A piece of tissue paper folded twice was placed in a small Petri dish (10 cm diameter) containing 6 ml of water. A tablet was put on the tissue paper and allowed to wet completely. The wetted tablet was then reweighed. Water absorption ratio, R was determined using following equation,

$R = 100 (Wa-Wb)/Wb$

Where;

Wa= weight of tablet after waterabsorption

Wb= weight of tablet before water absorption.

11.Dispersion Time :-

Tablet was added to 10 ml of water and time required for complete dispersion was measured. Three tablets from each formulation were randomly selected and Dispersion time was performed.

12.Disintegration Time :-

The disintegration time of tablet was measured in water (37^0C) according to USP Disintegration test apparatus. Three trials for each batch were performed.

13.Solubility analysis :-

A semi quantitative determination of the solubility was made by adding solvent in small amount to a test tube containing fixed quantity of solute or vice versa. Aspirin is freely soluble in ethanol(95 %),soluble in chloroform and ether and slightly soluble in water.

Table No.3 (a) :- Evaluation ofcompression characteristics of table

Formulation Code	**Weight Variation* (mg)**	**Hardness* (kg/cm^2)**	**%Friability***	**Thickness* (mm)**
M	**202.65 ± 1.71**	**3.57 ± 0.09**	**0.90 ±0.006**	**3.42 ± 0.09**
A1	198.70 ± 1.45	3.40 ± 0.16	0.91 ±0.04	3.41 ± 0.09

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A2	205.25 ± 1.92	3.43 ± 0.09	0.88 ± 0.01	3.47 ± 0.04
A3	**202.65 ± 1.71**	**3.57 ± 0.09**	**0.90 ±0.006**	**3.42 ± 0.09**
A4	200.60 ± 1.30	3.50 ± 0.16	0.92 ± 0.05	3.42 ± 0.09

Table No.3 (a) :- Evaluation of compression characteristics of table
*Averages of three determination ± Standard deviation

Formulation Code	Wetting Time (sec)	Wetting Volume (ml)	Uniformity of Dispersion	Content of Active Ingredients %
M	**27.66 ± 1.24**	**4.20 ± 0.08**	**Passes**	**100.78**
A1	26.66 ± 1.24	4.16 ± 0.04	Passes	99.56
A2	46.33 ± 1.69	4.83 ± 0.04	Passes	100.48
A3	**27.66 ± 1.24**	**4.20 ± 0.08**	**Passes**	**99.91**
A4	**28.66 ± 0.47**	**4.40 ± 0.08**	**Passes**	**98.94**

Table No.3 (b):- Evaluation of compression characteristics of tablet
Table No.3 (b):- Evaluation of compression characteristics of tablet
*Averages of three determination ± Standard deviation

Table No.3 (c) :- Evaluation of compression characteristics of tablet

Formulation Code	Water absorption Ratio* (%)	Dispersion Time* (sec)	Disintegration Time* (sec)
M	**99.34 ± 1.99**	**50 ±0.00**	**45±0.00**
A1	114.63 ± 13.58	60 ± 0.00	50.66±2.08
A2	92.04 ± 2.53	55 ± 0.00	45.62±1.04
A3	**99.34 ± 1.99**	**50 ±0.00**	**45±0.00**
A4	**97.68 ± 2.03**	**45 ± 0.00**	**35±3.06**

Table No.3 (c) :- Evaluation of compression characteristics of tablet
*Average of three determinations ± Standard deviation

IX. SUMMARY

The present study is to formulate Rapid Dispersible Tablets in such way that it may disperse within fraction of seconds as compared to the marketed preparations. Overall, the results suggest that Rapid Dispersible tablets of Aspirin containing superdisintegrants (sodium starch glycollate) can be successfully formulated, the present study demonstrated potentials for rapid absorption, improved bioavailability, effective therapy and patient compliance. It was observed that all formulations were acceptable with reasonable limits of standard required for dispersible tablets. The study reveals that Sodium Starch Glycolate used as superdisintegrants was effective in low concentration and increased concentration it was found to be highly effective. After certain limits there was the error in formulation of the tablets and gives cracking in the tablet. As a result, the above formulated tablet was found to be very beneficial to patients as it disperse rapidly and gives faster desired effect as compared to the marketed tablet and hence, can be used in emergency condition.

X. CONCLUSION

It was concluded that Rapid dispersible tablet of Aspirin can be successfully prepared by direct compression techniques using various concentrations superdisintegrants like Sodium Starch Glycolate for the better patient compliance and effective therapy. It was also found that the

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superdisintegrants are effective at low concentration, on increasing their concentration it gives faster dispersion but after certain limits of concentration it gives the error like cracking in the tablets.. Amongst all the batches batch A3 having 12% concentration of SSG was found to be similar with the marketed preparation and the batch A4 having concentration 14% of SSG was having the least dispersion time as compared to marketed preparation..So with this we achieved our aim and objectives.

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