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Formulation and Evaluation of Controlled Released Tablet

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Abstract: *A controlled-release drug preparation is released into the body in specified amounts over a specified period of time. The controlled- release system is designed to release the drug's active ingredient gradually over the day.*
In the modern era, sustained release dosage form is suppressing the use of conventional dosage form. The sustained release tablet provides uniform release of drug over a long period of time. Controlled release dosage form covers a wide range of prolonged action formula-tion which provides continuous release of their active ingredient at a predetermined rate and time. Sustained or controlled drug delivery system is to reduce the frequency of dosing [1] or to increase the effectiveness of drug by localization at the site of action, reducing dose required, providing continuous drug delivery, reduce incidence of adverse effect and maintain drug concentration in system.

Keywords: conventional dosage

I. INTRODUCTION

A controlled-release drug preparation is released into the body in specified amounts over a specified period of time. The controlled- release system is designed to release the drug's active ingredient gradually over the day.
In the modern era, sustained release dosage form is suppressing the use of conventional dosage form. The sustained release tablet provides uniform release of drug over a long period of time. Controlled release dosage form covers a wide range of prolonged action formula-tion which provides continuous release of their active ingredient at a predetermined rate and time. Sustained or controlled drug delivery system is to reduce the frequency of dosing [1] or to increase the effectiveness of drug by localization at the site of action, reducing dose required, providing continuous drug delivery, reduce incidence of adverse effect and maintain drug concentration in system.
Matrix tablets serve as an important tool for oral extended- release dosage forms. Hence, various problems like patient compliance, drug targeting, local side effects, frequent administration and fluctuations in blood concentration levels, associated with their counterparts, therefore the conventional dosage forms restricted [2,3]. A matrix tablet is the oral solid dosage form in which the drug or active ingredient is homogeneously dispersed throughout the hydro-philic or hydrophobic matrices which serve as release rate retardants.
Aspirin's efficacy in preventing myocardial infarction is related to preventing thrombus formation by decreasing platelet aggregation. Aspirin (AS) is a non-steroidal anti- inflammatory drug (NSAID) that permanently inactivates the cyclooxygenase (COX)mediated activities of prostaglandins through irreversible binding. There are two forms of COX: COX-1 and COX-2. COX-1 is responsible for the synthesis of thromboxane A2 in platelets and the production of prostacyclinine vascular walls. Thromboxane A2 is a vasoconstrictor and platelet aggregating [4,5] agent, while prostacycline acts as a vasodilator and platelet inhibitor. The major drawback of aspirin G.I. Mucosa ulceration can be avoided by providing the Effective enteric coating. In this study, an attempt was made to formulate aspirin delayed release tablets with the use of enteric polymer

II. DRUG PROFILE [6]:

1. Aspirin :
Iupac name : Acetylsalicylic acid
Molecular weight: 180.16g/mol. • **Molecular formula :** C9H8O4

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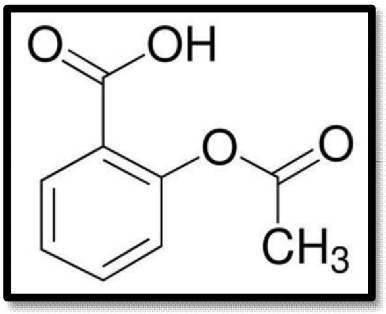
Molecular structure :



2-Acetoxybenzoic acid [50-78-2]
Aspirin, when dried, contains not less than 99.5% of C9H804.

Description :
Aspirin occurs as white crystals, granules or powder. It is odourless, and has a slight acid taste.
It is freely soluble in ethanol (95) and in acetone, soluble in diethyl ether, and slightly soluble in water.
It dissolves in sodium hydroxide TS and in sodium carbonate TS.
In moist air, it gradually hydrolyzes to salicylic acid and acetic acid.
Melting point: about 136 °c (bath fluid is heated at 130 °C previously).

Identification :
Boil 0.1 g of Aspirin in 5 mL of water for 5 to 6 minutes, cool, and add 1 to 2 drops of iron (Ill) chloride TS: a red-purple colour is produced.
Boil 0.5 g of Aspirin in 10 mL of sodium carbonate TS for 5 minutes, and add 10 mL of dilute sulphuric acid: the odour of acetic acid is perceptible, and a white precipitate is produced. Filter the precipitate, add 3 mL of ethanol (95) and 3 mL of sulphuric acid to the filtrate, and heat: the odour of ethyl acetate is perceptible.

Purity :
Clarity of solution—Dissolve 0.5 g of Aspirin in 10mL of warm sodium carbonate TS: the solution is clear.
Salicylic acid—Dissolve 2.5 g of Aspirin in 25 mL of ethanol (95), and add 1.0 mL of this solution to a solution which is prepared by transferring 1 mL of a freshly prepared dilute ammonium iron (Ill) sulphate TS to a Nessler tube and diluting with water to 50 mL. Allow to stand for 30 seconds: the solution has no more colour than the following control solution.
Control solution: Dissolve 0.100 g of salicylic acid in water, and add 1 mL of acetic acid (100) and water to make1000 mL. Add 1.0 mL of this solution to a solution which is prepared by transferring 1 mL of freshly prepared dilute ammonium iron (Ill) sulphate TS and 1 mL of ethanol (95) to a Nessler tube and diluting with water to 50 mL. Allow to stand for 30 seconds.
Chloride—Boil 1.8 g of Aspirin in 75 mL of water for 5 minutes, cool, add water to make 75 mL, and filter. To 25 mL of the filtrate add 6mL of dilute nitric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.25 mL of 0.01 mol/ L hydrochloric acid VS (not more than 0.015%).
Sulphate—To 25 mL of the filtrate obtained in (3) add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.50 mL of 0.005 mol/ L sulfuric acid VS (not more than 0.040%).

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Heavy metals—Dissolve 2.5 g of Aspirin in 30 mL of acetone, add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 2.5 mL of Standard Lead Solution, 30 mL of acetone, 2 mL of dilute acetic acid and water to make 50 mL (not more than 10 ppm).
Readily carbonizable substances—Weigh 0.5 g of Aspirin, and perform the test. The solution has no more colour than Matching Fluid Q.

LOSS OF DRYING : Not more than 0.5% (3 g, silica gel, 5 hours).
Assay : Weigh accurately about 1.5 g of Aspirin, previously dried, add exactly 50 mL of 0.5 mol/ L sodium hydroxide VS, and boil gently for 10 minutes under a reflux condenser with a carbon dioxide-absorbing tube (soda lime). Cool, and titrate immediately the excess sodium hydroxide with 0.25 mol/ L sulfuric acid VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination.
Each mL of 0.5 mol/ L sodium hydroxide VS = 45.04 mg of C9H804

Containers and storage : Containers—Well-closed containers.
Mechanism of action:
Acetylsalicylic acid (ASA) blocks prostaglandin synthesis. It is nonselective for COX- 1 and COX-2 Enzymes. Inhibition of COX-1 results in the inhibition of platelet aggregation for about 7-10 days (average Platelet lifespan). The acetyl group of acetylsalicylic acid binds with a serine residue of the cyclooxygenase-1 (COX-1) enzyme, leading to irreversible inhibition . This prevents the production of pain-causing Prostaglandins. This process also stops the conversion of arachidonic acid to thromboxane A2 (TXA2), which's a potent inducer of platelet aggregation. Platelet aggregation can result in clots and harmful venous and Arterial thromboembolism, leading to conditions such as pulmonary embolism and stroke .
It is important to note that there is 60% homology between the protein structures of COX-1 and COX-2. ASA Binds to serine 516 residue on the active site of COX-2 in the same fashion as its binding to the serine 530 Residue located on the active site of COX-1. The active site of COX-2 is, however, slightly larger than the Active site of COX-1, so that arachidonic acid (which later becomes prostaglandins) manages to bypass the Aspirin molecule inactivating COX-2. ASA, therefore, exerts more action on the COX-1 receptor rather than On the COX-2 receptor. A higher dose of acetylsalicylic acid is required for COX-2 inhibition.

Half life - 3.5 and 4.5 hours.
Volume of distribution- Body tissues .
Protein Binding – 80 to 90% Hormones, DNA, Haemoglobin.
Metabolism - liver .
Route of elimination:- Renal.

III. LITERATURE REVIEW

Sahoo et al (2017) -Formulated controlled release tablet of Aspirin, by compression method using different ratio of expient and polymer. The tablet were evaluated for post compression parameters and in vitro release. They found that formulation release. They found that formulation with Asf3 ratio of drug and expients shown best controlled release profile with 96.14+-1.17% of drug end of 10hr.[7]
Dhas et.al (2024) - formulated and Evaluated Aspirin +tablet In addition Aspirin Contain HPMC, Magnesium stearate ,Starch by wet granulation Method. And evaluate pre- Compression and post compression such as weight+ variation , friability, Hardness, Drug Content. [8]
Gamal asman Elhassan (2014) – Design and evaluated Of controlled Released matrix Tablet or Aspirin by using Hydrophobic polymer. And direct Compressìon methods. Using various Concentration 5% 10% 15%.and 20 % of different Polymers. The
Hydrophobic polymer was used was ethyl cellulose. In Formulation of F2 10% ethyl cellulose showed best release profile for 10hr .controlled release where it released 88.87% of drug. [9]

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pawan Singh et.al (2017) -Formulated and evaluated of Aspirin tablet by using Different lubrication in combination for better Drug release study. Wet granulation technique suggested that conventional excipients can be modified by a simple granulating procedure to provide better physical properties for being used in matrix tablet. [10]

R. Somati et al (2000) -Formulation and evaluation of controlled released Aspirin tablet in which Both in vitro and in-vitro dissolution and in-vivo urinary excretion studies done to ensure effective of formulation study proves usefulness of carbopol resin for formulating Aspirin tablet for minimum risk and maximum therapeutic benefits to patients. [11]

kannan et al (2010) -Design and evaluated delayed Release tablet of Aspirin aim of work to avoid degradation of drug in acidic environment of stomach due to enteric coating drug release into small intestine so that drug gets larger surface for absorption. The formulation evaluated which has in vitro release 0.1 m HCl for 120min and 6.8pH phosphate buffer for 45min .[12]

karim (2016) – Formulated and in vitro evaluation of Aspirin sustained released tablet using Hydrophillic polymer the developed matrix tablet formulation with. HPMC and ethyl cellulose provided sustained release profile for prolonged periods than commercial formulation. [13]

Tabandeh et al (2023) -Prepared of sustained – release matrix tablet of aspirin with ethyl cellulose Eudragit Rs100 and Eudragit s -100 for studying release profile and their sensitivity to tablet hardness .[14]

METHODS [15] :

Preparation of controlled release (CR) tablets:

Sustained release tablets of AS using varying Concentration of starch and synthetic (HPMC K100M) Polymers were prepared by direct compression method. Other ingredients like lactose was used as diluent, Magnesium stearate as lubricant and talc as glidant. All The excipients along with API weighed as shown in Table 1 and passed through sieve no.20. Then, all Ingredients were mixed following geometric mixing Excluding glidant and lubricant for 15 minutes. The Powder blend was thoroughly mixed with talc and Magnesium stearate and compressed into tablets on Twelve station rotary punch tabletting machine (Karnavati, Rimek Mini Press- 2).

Table 1: Composition of CR tablets

Ingredients(mg)	ASF1	ASF 2	ASF 3
Aspirin(AS)	81	81	81
Lactose	178	142	106
Starch	6	12	18
HPMC K100M	30	60	90
Magnesium Stearate	3	3	3
Talc	2	2	2
Total weight(mg)	300	300	300

Coating of core tablets:

The coating solution was prepared taking required Ingredients from table 2 and acetone was added quantity Sufficient maintaining proper viscosity of solution. The Coatings of tablets were performed by dip coating. Coated tablets were dried at 50ºC for 12 hours.

Table 2: Coating composition for CR tablets

Formulation code	CAP (g)	PEG 400 (g)	TiO_2	Acetone (ml)
ASF1	6	2	1.5	300
ASF2	6	2	1.5	300
ASF3	6	2	1.5	300

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Evaluation of controlled released matrix :

Pre compression parameters of CR powder Blend[16,17] :

Angle of repose :

The angle of repose of granules blend was determined by The fixed funnel method. The accurately weighed Quantity of granules was taken in a funnel. The height of Funnel was adjusted in such a way that the tip of the Funnel just touched the apex of the heap of the granules. The granules are allowed to flow through the funnel Freely onto the surface. The diameter of powder cone Was measured and angle of repose was calculated using The following equation. Tan Θ=h/r

Θ= tan-1(h/r)

Where ,Θ is the angle of repose,

h is the height of cone in cm

r is the radius of the cone base in cm.

Bulk density (eb):

Bulk density was determined by pouring the granules Into a graduated cylinder in bulk density apparatus (Sisco,India). The bulk volume (Vb) and mass (m) of the Granules was determined. The bulk density was Calculated by using the following formula.

Eb=m/Vb

Where, Eb is bulk density M is a mass.

Vb is bulk volume

Tapped density (et):

The measuring cylinder containing known mass (m) of Granules blend was tapped 1000 times for a fixed time in Bulk density apparatus (Sisco, India).The minimum Volume occupied in the cylinder (Vt) and mass of the Granules (m) was measured. The tapped density was Measured by using the following formula.

Et = m/Vt

Where, Et is Tapped density

M is mass

Vt is Tapped volume .

Compressibility index (Carr's Index):

The compressibility index determines the flow property Characteristics of granules developed by Carr. The Percentage compressibility of granules is a direct Measure of the potential powder arch and stability. TheCarr's index can be calculated by the following formula.

$$\% \text{ Carr's Index (C.I)} = \frac{Et - eb}{eb} \times 100$$

Where , et is the tapped density of granules and eb is bulk Density of granules.

Hausner's ratio :

Hausner's ratio is used for the determination of flow Properties of granules. The ratio can be calculated by the taking the ratio of tapped density to the ratio of bulk Density.

Mathematically , Hausner's ratio (H.R)= et/eb

Where, et is Tapped density eb is bulk density

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Table 3: Scale of flowability determined by different methods [8]

Flow property	Angle of repose	Compressibility index	Hausner's ratio
Excellent	25-30	≤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	1.46-1.59
Very very poor	> 66	> 38	>1.6

Table 4: Precompression parameters of CR formulations

Formulation code	Angle of repose (degree)[a] ± S.D	Bulk density (g/ml)[a] ± S.D	Tapped density (g/ml)[a] ± S.D	Carr's Index (%)[a] ± S.D	Hausner's Ratio[a] ± S.D
ASF1	26.20 ±0.13	0.492±0.06	0.538±0.12	8.55±0.06	1.09±0.12
ASF2	25.08 ±0.13	0.488±0.12	0.524±0.11	6.87±0.08	1.07±0.11
ASF3	24.12 ±0.14	0.485±0.13	0.518±0.12	6.37±0.06	1.06±0.12

N.B.All values are expressed as mean± S.D, [a]n = 3.

Post compression parameters of CR tablets [18,19] :

Thickness:

The thickness of individual tablets is measured by using Vernier caliper which gives the accurate measurement of Thickness. It provides information of variation of Thickness between tablets. Generally the unit for Thickness measurement is mm.The limit of the thickness Deviation of each tablet is ± 5%.

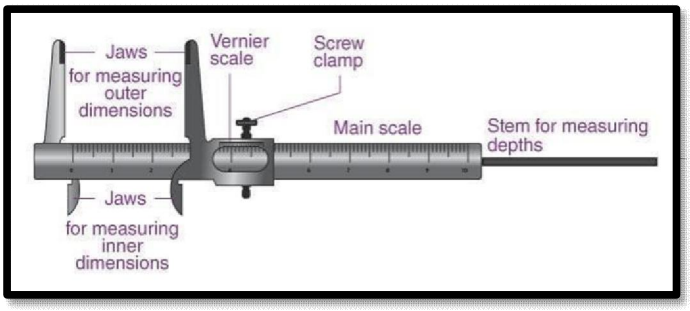

Fig no. 1 Vernier caliper

Hardness:

The hardness of a tablet is associated with the resistance Of the solid specimen towards fracturing and attrition. The hardness of tablets can be determined by using Monsanto hardness tester and measured in terms of Kg/cm2.

Fig no. 2 Monsanto Hardness Tester

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Friability

Friability of tablets was performed in a Roche friabilator. Ten tablets were initially weighed (WI) together and Then placed in the chamber. The friabilator was operated For 100 revolutions and the tablets were subjected to the Combined effects of abrasion and shock because the Plastic chamber carrying the tablets drops them at a Distance of six inches with every revolution. The tablets Are then dusted and reweighed finally (WF).The Percentage of friability was calculated using the Following equation.

$$\text{WF\% Friability (F)} = \left(1 - \frac{Wf}{WI}\right) 100$$

Where, WI and WF are the weight of the tablets before (initially weight) and after (final weight) the test Respectively.

Fig.No. 3 Roche friabilator

Weight Variation:

The weight variation test was done by weighing 20 Tablets individually (Shimadzu digital balance), Calculating the average weight and comparing the Individual tablet weights to the average. The percentage Weight deviation was calculated and then compared with USP specifications.

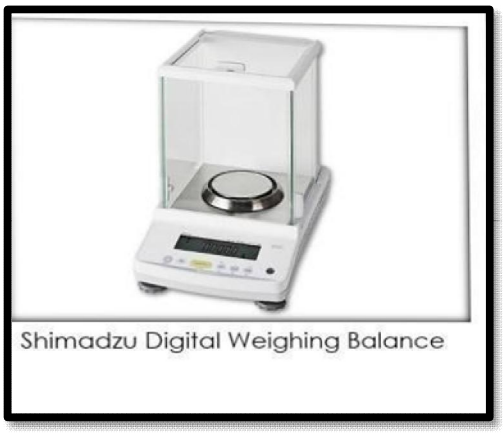

Fig No. 4 Shimadzu Digital Weighing Balance

Dissolution Test:

Dissolution of commercially available brands and formulated aspirin tablets was measured by paddle method in Dissolution apparatus (Erweka GmbH, Germany) using 0.05M acetate buffer solution 500 mL (pH 4.5) at 50 rpm, Maintained at 37±0.5°C. After 30 minutes the absorbance of suitably diluted portions in same medium was Determined against absorbance of standard preparation at 265nm using UV-VIS Spectrophotometer (Shimadzu UV-150- 02 Double beam spectrophotometer .

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Fig No. 5 Paddle Method in Dissolution Apparatus

in vitro dissolution studies :

The in vitro dissolution studies were carried out using USP apparatus type II (Tab Machines, Mumbai, India) at 100 rpm. The dissolution medium consisted 0.1N HCl For 2 hours after 2 hours medium is replaced with Phosphate buffer pH 6.8 for remaining h (900 mL), Maintained at 37°C±0.5°C. The drug release at different

Time intervals was measured by UV-visible Spectrophotometer (Systronics UV spectrophotometer-117, Mumbai, India) at 265 nm for 0.1N HCl and 280 Nm for 6. 8 phosphate buffer and calculated the drug Release using calibration curve of AS

Accelerated stability studies:

The packed tablets in air tight container were placed in Stability chambers(Thermo lab Scientific equipment Pvt.Ltd., Mumbai, India) maintained at 40±20C/75±5% RH conditions for accelerated testing) for 3 months[11]. Tablets were periodically removed and evaluated for Physical characteristics, drug content, in-vitro drug Release etc

Post-compression parameters of CR formulations:

All the post compression parameters for various batches Evaluated accordingly such as thickness, hardness, Friability, weight variation, drug content and diameter of Tablet etc. It is observed all the parameters fall within Specified limit. It is mentioned in Table 5.

Table 5: Postcompression parameters of CR formulations

Formulation code	Thickness (mm)[a]± S.D	Hardness (kg/cm²)[a] ±S.D	%Friability (%)[b] ± S.D	Weight Variation(%)[b] ± S.D
ASF1	3.02±0.02	6.8±0.13	0.23±0.08	1.62±1.13
ASF2	3.00±0.12	6.9±0.12	0.18±0.07	1.1±1.12
ASF3	3.01±0.13	7.1±0.09	0.14±0.06	2.1±1.14

N.B.All values are expressed as mean ± S.D, [a]n = 10, [b]n = 20, [c]n = 3

Table No. 5 Postcompression Parameters of CR Formulation

Dissolution test :

Formulation	Dissolution study
ASF 1	81.37+-1.14%
ASF2	88.01 +-1.19%
ASF3	96.14+-1.17%

Table No. 6 Dissolution Test

Expected Outcome :

After Comparing three formulations (ASF1,ASF2 &ASF3) and determines which one is best. We all need to evaluate them based on specific criteria such as Preformulations (angle of repose, bulk density, tapped density, carr's index, and

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Hausner's ratio) and post compression (Thickness, Hardness, weight variation,and in vivo and in vitro study of drug) whichever is best has potential in comparison to other formulation for development of controlled drug delivery system.

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