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Research Paper

Formulation and Evaluation of Sustained Release Aspirin and Lovastatin Combination Tablet

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ABSTRACT:
With constant release, side effects from medicinal medications can be minimized by minimizing fluctuations in the medicinal concentration in the body. A dosage of medication form designed to delay the medicinal agent discharge so that it stays in the circulation throughout the body for a prolonged duration and maintains its plasma profile throughout time is referred to extended release. Tablets with constant release medication administration method have been created to gradually release the medication within. It manages the rate at which medications are released through a variety of ways. The following formulation techniques have been used: matrix erosion, drug diffusion, and drug dissolution. The various aspects of sustained release tablets are the subject of the current review effort.
Keywords*: Sustained release, Controlled release, Classification, Drug design, Polymer*

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I. INTRODUCTION:

Combination therapy is becoming more and more popular in both developed and developing nations to treat a wide range of illnesses and disorders that call for long-term care, such as cardiovascular disease, diabetes, and hypertension. More than 90% of the composition produced now are consumed orally. One of the main goals of controlled drug administration is to lower the dosage frequency. A modified release pharmacological product's design aims to maximise a treatment plan by offering gradual and maintains medication administration for the duration of the dosing interval, increasing patient compliance and convenience The goal of the ongoing research is to create aspirin tablets with a pulsed release layer and atorvastatin tablets with an immediate release layer. The purpose of immediate release tablets is to break down and release the medication without the need for any regulating elements like coating or other formulation methods. Even while interest in controlled-release drug delivery methods is growing, the most popular tablets are ones meant to be ingested whole, which cause the medication to dissolve and release quickly in the digestive system. The ingredient in the drug formulation known as a disintegrant allows the tablet to fracture into smaller pieces when it comes into connect with digestive juices. The tablet matrix breaks so rapidly that the surface area between the tablet particles, enhancing the active ingredient's absorption and leading in the intended beneficial effect.

Novel and creative drug delivery systems are currently quickly replacing conventional drug dose forms. Drug administration by mouth is the most popular and useful mode of medication administration due to its high rate of patient adherence, cost effectiveness, absence of sterility limitations. Oral medication administration has historically been the most common way to administer drugs due to its better potency, greater precision in dosing, convenience of production, and preference for tablets as an oral dosage form. Oral delivery accounts for almost half of the medication products available in the market.

The industry offers a wide variety of tablet varieties, varying from straightforward instant release formulations to intricate sustained release or modified release dosage forms. By gently releasing the medication, a sustained release drug delivery method aimed to maintain plasma drug levels. Drug administration by mouth is the most popular and useful mode of medication administration due to its high rate of patient adherence, cost

effectiveness, absence of sterility limitations, adaptability in dosage form design and simplicity in production. Oral medication administration has historically been the most widely used method of medication administration because its better potency, greater precision in dosing, convenience of production, and preference for tablets as an oral dosage form. Oral delivery accounts for almost half of the medication products available in the market. The industry offers a wide variety of tablet varieties, varying from straightforward instant release formulations to intricate sustained release or modified release dosage forms. By gently releasing the medication, a sustained release drug delivery method aimed to maintain plasma drug levels. By gently releasing the medication, a sustained release drug delivery method aimed to maintain plasma drug levels. For medications with a shorter half-life, the sustained release drug delivery method is appropriate. One practical method for introducing prolonged release medication therapy is through matrix tablets since they are the most reasonably priced kind of sustained and controlled release solid dose forms.

II. METHODOLOGY:

Method of preparation of Aspirin and Lovastatin tablet:

1. Aspirin and Lovastatin tablet by using compression method.

2. Calculate the exact proportion of each ingredient according to formula.
3. Weighed all the ingredient according to required amount.
4. Aspirin, lovastatin and corn starch were blended and pass through sieve no 40.
5. The PVP dissolve in acetone and HPMC dissolve in methylene chloride until uniform mixture obtained.
6. Then this mixture added in aspirin and lovastatin blend with constant stirring until uniform granular mass was obtained.
7. Then granules are prepared and compressed into the tablet.

Sr. No.	**Ingredient**	**Quantity Batch A**	**Quantity Batch B**
1.	Aspirin	225 mg	225 mg
2.	Lovastatin	30 mg	30 mg
3.	PVP	5 mg	5 mg
4.	HPMC	8 mg	16 mg
5.	PEG	7 mg	7 mg
6.	Corn starch	25 mg	17 mg
7.	Acetone	q. s.	q. s.
8.	Methylene chloride	q. s.	q. s.

Table 1

EVALUATION OF TABLETS

Tablet Evaluation

Prepared sustained release tablet of aspirin and lovastatin were evaluated for hardness, friability, disintegration time, dissolution time, weight variation

1. Shape of tablets

In the pharmacopeia the shape of tablet is defined as circular with flat or convex faces.
The tablets are circular with flat faces.

2. Mechanical strength

1. The Pharmacopeia has not Fix any standard for Mechanical strength or hardness of tablets. The manufacturer has employed their own tests to ensure that their tablets will withstand the normal risk of handling and transportation
2. To check mechanical strength following equipment are used:

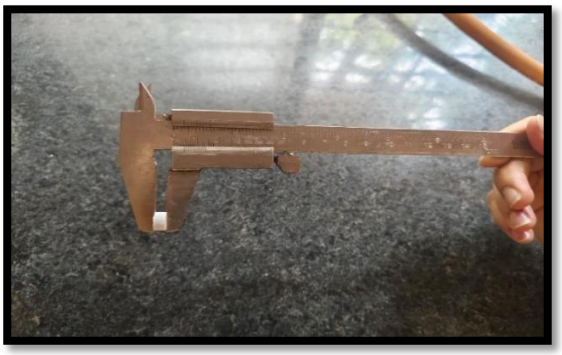
1. Monsanto hardness tester
2. Pfizer hardness tester

3. To ensure hardness of tablets most commonly Monsanto hardness tester is used.
4. The hardness of tested aspirin and lovastatin tablet of batch 1 and batch 2 was found to be 16Kg/Sq.cm & 17Kg/Sq.cm respectively.

Monsanto Hardness Tester

3. Thickness test

To determine the uniformity and determine the physical dimension of tablet, thickness is measured by vernier caliper for randomly selected 10 tablets from formulation. Thickness should be control within a ± 5 % variations of standard value. The thickness of aspirin and lovastatin tablet is 0.5mm.



Vernier calliper tester

4. Content uniformity test

1. Uniformity of Content is a pharmaceutical analysis parameter for the quality control of tablets and capsule. In this this test multiple capsules or tablets are selected at random and a suitable analytical method is applied to assay the individual content of the active ingredient in each tablet or capsule.
2. The preparation complies if not more than one [all within limits] individual content is outside the limits of 98% to 101% of the average content.
3. The preparation fails to comply with the test if more than 3 individual contents are outside the limits of 98% to 101% of the average content.
4. In this test the amount of active ingredient in tablet is determined by using assay stated in monograph.
5. Procedure for calculation of drug content in tablet:

Calibration curve of Aspirin and Lovastatin

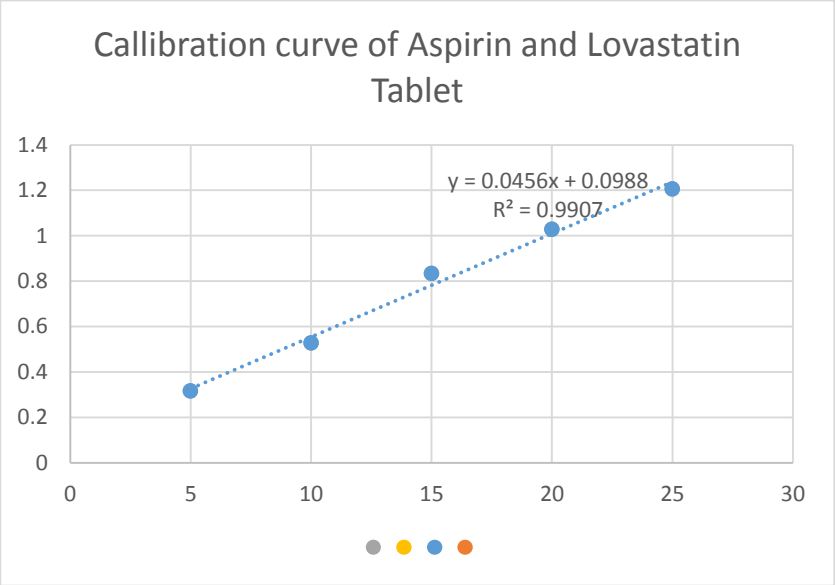
i. Weigh 10 mg Tablet and dissolve in 100 ml of 0.1N HCL.
ii. Take 1 ml from above solution and dilute with 10 ml of 0.1N HCL
iii. Note down the absorbance and calculate the content of drug in tablets

A standard calibration curve of Aspirin and Lovastatin Tablet was constructed in 0.1 N HCL and assayed spectrophotometrically at 211 nm, data obtained is given below

Table 2:

Sr. No.	Concentration	Absorbance
1	5ug/ml	0.316
2	10ug/ml	0.528
3	15ug/ml	0.834
4	20ug/ml	1.028
5	25ug/ml	1.205

Callibration curve:



5. Disintegration test

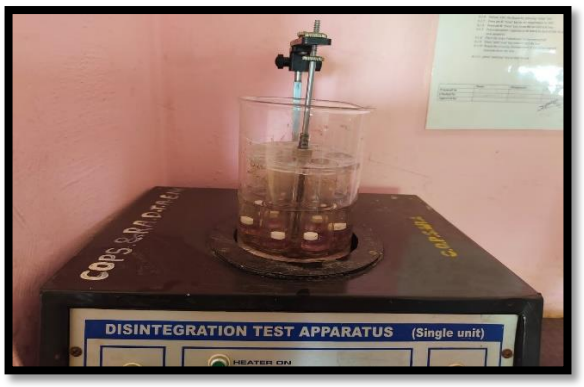
Disintegration of tablet means to break the tablets into smaller particles after swallowing. The time required to disintegrate the tablet is known as disintegration time.

i. Place one tablet in each 6 tubes of basket and suspend the assembly in water at 37^0c to 40^0c.

ii. Operate the apparatus as stated in monograph.

iii. The tablets pass the test if 6 tablets dissolve completely.

iv. The prepared tablets of Asprin and lovastatin tablet had shown disintegration tame less than 30 min[24].



Disintegration test apparatus

6. Friability test

Friability test used to ensure to ensure that tablets can withstand the wear and tear during transportation, handling.

i. 20 tablets are weighed placed in plastic chamber.

ii. The chamber is rotated at 25 rpm for 4 min.

iii. Tablets fall from distance of 6 inch.

iv. Tablets are collected and weighed. Loss in weight indicate friability. Friability (%) = $W_1 - W_2 / W_1 \times 100$.

W_1 = Weight of Tablets (Initial / Before Tumbling) W_2 = Weight of Tablets (After Tumbling or friability) Limit: Friability (%) = Not More Than 1.0%

Friability (%) = $W_1 - W_2 / W_1 \times 100$.

= 2350-2339/2350x100

= 0.46%

Roche Friability apparatus

7. Dissolution test

This test is done for measuring the amount of time required for given percentage of drug substance in a tablet go into solution as under specified condition in vitro. Drug release study for formulation were determined by using USP II dissolution apparatus[40].

Dissolution apparatus

i. Place 900 ml of 0.1N HCL into the vessel at 37.5^0 and place the specified number of tablets into vessels.

ii. Start the apparatus and adjust the speed of 100 rpm.

iii. Withdraw the 5 ml of solution at 15min, 30min, 45min, 60min intervals.

iv. The tablet pass the test if amount of drug release is not less than 70 % of total amount.

Sr. no	Tests	Result
1.	Hardness	16Kg/Sq.cm
2.	Thickness	0.5 mm
3.	Content uniformity	98.8
4.	Friability tests	0.46 %
5.	Disintegration test	30 min

Result of evaluation tests

III. CONCLUSION:

One of the main goals of controlled drug administration is to lower the dosage frequency. A modified release pharmacological product's design aims to maximise a treatment plan by offering gradual and maintains medication administration for the duration of the dosing interval, increasing patient compliance and convenience. The goal of the ongoing research is to create aspirin tablets with a pulsed release layer and atorvastatin tablets with an immediate release layer. The sustained release effect of aspirin and lovastatin tablet is by using super disintegrant HPMC.

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