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Review Article

Comparison Studies Of Enteric Coated And Uncoated Tablets

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ABSTRACT

Aspirin is belonging to the class of NSAID having analgesic, antipyretic, anti-inflammatory and antiplatelet activity at regular normal doses. At higher doses it causes gastrointestinal ulcers, stomach bleeding etc. This effect of aspirin can be minimized by preventing the drug exposure to the gastric region which is achieved by using enteric coating of the aspirin tablet. Clinicians recommend enteric-coated aspirin to decrease gastrointestinal bleeding in secondary prevention of coronary artery disease even though studies suggest platelet inhibition is decreased with enteric-coated vs uncoated aspirin formulations. . The present study involves comparison of physical evaluation of uncoated tablets with that of enteric coated tablets of Aspirin.

INTRODUCTION

An enteric coating is a polymer barrier applied to oral medication that prevents its dissolution or disintegration in the gastric environment.[1] This helps by either protecting drugs from the acidity of the stomach, the stomach from the detrimental effects of the drug, or to release the drug after the stomach (usually in the upper tract of the intestine).[2]

Uncoated tablets

Uncoated tablet is a single layer or more than one layer of formulation that consist of active singredients and excipients compressed together without any additional coat or cover.[3]

Advantages of enteric coated tablets over uncoated tablet

- Enteric coated protect active pharmaceutical ingredients, from the acidic environment of the stomach.
- To prevent gastric distress or nausea from a drug due to irritation.
- For the delivery of drugs that are optimally absorbed in small intestine to there primary absorption site in there most concentrated form.

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- To provide a delayed-release component for repeat action.
- Required for minimizing first pass metabolism of drugs.

Need of Evaluation test:

In the pharma industry, the significance of producing uniform dosage plays important role. Why?

Because the tablets are made of chemicals and bio-chemicals. The uniformity of dosage units defines the degree of uniformity of the amount of the chemicals and drug substances. It is critical to ensure optimal consistency in every batch of manufactured dosage units. Each unit in a batch must have equal drug content, ensuring optimal effectiveness for the treatment course. It is a pharmacopeia-evaluating technique, essential for the quality control checks for tablets. The uniformity of dosage units could be reviewed through – Content uniformity and Weight Variation. Both are effective and help the company make better decisions for quality enhancement.[4]

Evaluation of Dosage forms:

Evaluation is the process of confirming a drug's identity and assessing its quality and purity.

- Identity - Determining the drug's biological sources.
- Quality - The amount of the active ingredients that are present.
- Purity is the degree to which a medicine contains foreign organic components.[5]

Evaluation test for Tablets

The tablet evaluation can be done by different methods which help to check the identity, purity, quality and uniformity of the active pharmaceutical ingredients present in the particular formulation. [5]

Evaluation test for tablets consists

- Thickness
- Hardness test
- Disintegration test
- Weight variation
- Friability test

METHODOLOGY:

Sample Selection:

To compare the evaluation of different category of solid dosage forms has been done by using different marketed drugs like aspirin (uncoated tablet) and aspirin (Enteric coated tablet)

Sr. No.	Drug Category	Drug Name
01	Uncoated tablet	Aspirin
02	Enteric coated tablet	Aspirin

Evaluation Procedure:

Hardness Test:

Hardness test using Monsanto Hardness tester can be done by placing a tablet between moving jaw and fixed jaw. Moving jaw is moved and pressure is applied on tablet by means of screw knob. The point where tablet get break down, it is recorded by means of scale. The hardness is measured in Kg/cm2.[5]

Fig. 1.Monsanto Hardness Tester

Pfizer hardness tester compresses tablet between a holding anvil and a piston connected to a force-reading gauge when its plier-like handles are gripped. The point where tablet gets break down, it is noted by reading gauze. Official standards for Hardness: 5-8 kg/cm2 for standard compressed tablet except effervescent tablet, dispersible tablet or dispersible tablet, chewable tablet, etc.[5]

Fig. 2.Pfizer Hardness Tester

Friability Test:

Roche friabilator tester is most used for determining % friability of tablet The procedure for friability test involves

- Take 20 tablets and take initial weight of it and put it into friabilator.
- Now rotate the drum at 25 rpm per min or 100 rpm for 4 mins.
- During this, tablet gets dropped on plastic from 6 inch height, it will pass through mechanical shocks.
- After 4 minutes, calculate final weight of tablets and that of percentage friability.
- The percentage friability can be calculated by following formula.[5]

Percentage friability = W1 – W2/W1 × 100

Where,

W1 = weight of tablets before testing

W2 = weight of tablets after testing.

Fig. 3.Roche's Friabilator Tester

Disintegration Test:

Disintegration apparatus is an instrument designed for the accurate estimation of disintegration time of tablet as per IP/USP standards.

The construction consists of

- Two batches of six tablets can be simultaneously tested with this instrument.
- The USP device to test disintegration uses 6 glass tubes that are 3 inches long
- Open at the top, and held against a 10-mesh screen at the bottom end of basket rack assembly.
- Each glass tube has percolated sieve (no.10) at the bottom.

The procedure for disintegration test involves one tablet is placed in each tube, and the basket rack is positioned in a 1litre beaker of water, simulated gastric fluid or simulated intestinal fluid, at 37◦C±2◦C, such that tablets remain 2.5 cm below the surface of liquid on their upward movement and descend not closer than 2.5 cm from the bottom of beaker. A standard motor-driven is used to move the basket assembly containing the tablets up and down through 5-6 cm at frequency of 28-32 cycles per minute. Thus, in this way, note the time required to complete disappearance of tablet from glass tube. [5]

Fig. 4 Disintegration Apparatus

RESULTS:

The Evaluation test conducted for Enteric coated and uncoated tablets has been represented in the table 1 and the results for different evaluation parameters has been reported in table 2.[6]

Table1: List of evaluation techniques used to evaluate Enteric coated and Uncoated tablets

Evaluation test	For Enteric Coated Tablet	For Uncoated Tablet
Hardness	✓	✓
Weight variation	✓	✓
Friability	✓	✓
Disintegration	✓	✓
Thickness	✓	✓

Table2: Evaluation Results for Enteric coated and Uncoated tablets

Evaluation test	For Enteric coated Tablet	For Uncoated Tablet
Hardness (kg/mg)	4.75	3.12
Weight variation (%)	0.44	0.63
Friability (%w/w)	0.27	0.24
Disintegration time	56 minutes	2 minutes
Thickness(mm)	3.24	2.53

DISCUSSION:

The Aspirin Enteric coated tablets and Uncoated tablets were evaluated. The thickness of Aspirin Enteric coated were found to be greater than the Aspirin Uncoated tablet .The results related to hardness, friability, weight variation, and disintegration time of uncoated and enteric coated tablet were mentioned in the table no 1.The disintegration time for enteric coated tablet was more as compared with that of uncoated tablet because the dissolution fluid needs more time to dissolve the enteric coating layer and for this reason the process of disintegration is slow for enteric coated tablet .[7] The time required for the release of maximum amount of drug is more for enteric coated tablet due to presence of enteric coating over the tablets. The drug was released into the dissolution medium only after dissolution of coating layer which requires more time, so the time required to release drug from the enteric coated tablet formulation was more as that of uncoated tablet.[8]

CONCLUSION:

Aspirin is a salicylate drug used as an analgesic to relieve aches and pains, as an antipyretic to reduce fever, and as an anti-inflammatory drug and is also having antiplatelet activity by inhibiting the production of thromboxane. Aspirin is available in different doses and in different forms as uncoated tablets and enteric coated tablets for various pharmacological purposes. In the present study both the uncoated and enteric coated aspirin tablets were selected and it evaluated by different evaluation tests.[9] The main comparison study was done by considering the disintegration time for both uncoated and enteric coated tablets. Aspirin enteric coated tablets were found to have more disintegration time and more time to release the drug from the formulation. This is due to the presence of coating material which retards the release of drug from the formulation. This indicates the presence of coating on to the drug particles prevents the degradation of drug and also mitigates the gastrointestinal bleeding effect of drug.[10]

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