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# A Review On Formulation And Evaluation Of Nsaids Aspirin Tablets By Using Various Lubricants In Non Aqueous A Wet Granulation Method.

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**Abstract:**

Objective of study of the aspirin tablet formulation by wet granulation method with various lubricants and to comparative study with the other brand. Aspirin Tablet is in applicable to treat various types of diseases like anti inflammation, antipyretic, analgesic, antiplatelet and many more. Aspirin tablets are moisture sensitive drug, which easily absorb the moisture that directly shows impact on the shelf life of the tablet. To overcome this problem tablet is made up under minimal solvent efficacy. To reduce the excessive friction and for making it more diluent we add lubricant like Magnesium stearate, Calcium stearate, Talc, Polyethylene glycols, etc. The prepared tablets are evaluated with various aspects like dissolution, disintegration, bulk density, thickness, friability, hardness, compressed density, weight variation.

**Key words:** Aspirin, Non-steroidal anti-inflammatory drug, wet granulation, lubricants, hydrophobicity, evaluation, tests.

- **INTRODUCTION:**

Aspirin is also called as acetylsalicylic acid. It is comes under the Non-steroidal anti-inflammatory drugs class as Non-selective COX inhibitors (Salicylates). Aspirin is act similar like morphine but do not depress CNS and shows actively effectiveness in inflammatory pain and CNS pain tolerance. Thus it also known as nonnarcotic, non-opioid, aspirin like analgesics.

In 1971, Vane and Co-workers states an experimental observation point that Aspirin and other non-steroidal anti-inflammatory drugs are capable of blocking prostaglandin generation. It is oldest anti-inflammatory drug. It is weaker analgesic than morphine like drugs. So, that's why Aspirin 600 mg is very much level of quantity equally effective to only 60 mg Codeine.

- **Pharmacological Actions**

  1 Analgesic, antipyretic, atiinflamatory actions

  2 GIT

  3 Blood ( antiplatelets)

  4 Metabolic and other effects of high doses

- **Pharmacokinetics**

  **A**spirin is absorbed by the stomach and small intestines. It's not very much soluble in water so that affect in decrease in solubility rate. To enhance the solubility rate microfining the drug particles and increasing the pH by inclusion of an alkali. Higher pH is responsible for ionisation, thus decreasing the diffusible form. Aspirin is rapidly deacetylated in gut wall, plasma, liver and other tissues to release salicylic acid. Aspirin enters slowly in brain, but easily crosses placenta. The plasma t1/2 of aspirin is 15-20 mins. But in combination with salicylic acid it takes 3-5 hours. This elimination of drug is dose dependent.

- Mechanism of action :

  Aspirin is inhibits the Cyclooxygenase enzyme which is produce from arachidonic acid of the phospholipid membrane.

  By inhibiting COX enzyme it leads to prevention of producing prostaglandin, thromboxane secretion which is due to prohibited the pain, inflammation, and fever.

  By blocking the secretion of COX enzyme , reduces prostaglandin level thereby easing the symptoms and helps in recovery of health.

- **Adverse effects**

a) Side effects :
gastric mucosal damage, peptic ulceration, nausea, vomiting, epigastric distress, increased occult blood loss in stools, etc.

b) Hypersensitivity and idiosyncrasy :
This is critical side effect. Reactions include rashes, fixed drug eruption, urticaria, rhinorrhoea, angioedema, asthma and anaphylactoid reaction. Gastric bleeding is occurs in rare cases.

c) Anti-inflammatory doses (3-5g/day) :
In this the very serious side effects are shown like producing syndrome called 'salicylism' which relevantly does dizziness, tinnitus, vertigo, reversible impairment of hearing and vision, hyperventilation, excitement and electrolyte imbalance.
In children rheumatoid arthritis has been found and also indicates liver damage. Also children can having viral infection like varicella and influenza. Reye's syndrome is also rare side effects of aspirin.
In adults, the long term intake of high dose aspirin cause salt and water retention also hepatic injury.

d) Acute salicylate poisoning :
Commonly found in children. Fatal dose in adults to be 15-20 g , but considerably lower in children.

- **Formulation parameters :**

**Wet granulation method- wet granulation forms granulation by binding the powders together with adhesive nature instead of by compaction process.**

**Granular formation :-**

| | Ingredients | Quantity given. | Q taken | use |
|---|---|---|---|---|
| 1. | Aspirin – | 250mg | 9mg | |
| 2. | Citric acid- | 30mg | 0.9g | Solubilize |
| 3. | Calcium carbonate | 100mg | 3g | Stabilizer |
| 4. | Saccharin sodium | 3mg | 0.09g | Sweetner |
| 5. | 10% PVP in alcohol | qs | 5ml. | Binder |

- **Post granulation :-**

| | Ingredients | Quantity given | use |
|---|---|---|---|
| 1. | Granules | | |
| 2. | HPMC. | 50 mg | |
| 3. | Sodium EDTA | 0.5% | Chelating agent |
| 4. | Magnesium stearate | 0.5% | Lubricant |
| | Or | | |
| | Sodium stearate | 1mg | Lubricant |
| 5. | Starch OR Talc | 5mg | Glidant<br>Disintegration |

- **Lubricants :-**
-

1. **Magnesium stearate: It is also known as metal salt of stearic acid. It is water insoluble compound. It prevent from stickiness in tablet thus used as lubricant and binder. It increase the flow properties of powder**

2. **Calcium stearate: It is waxy powder act as lubricant , emulsifier and stabilizer in the tablet formulation. It is thickening agent improves the texture of dosage form and also prevent tablet from cake forming process.**

3. **Stearic acid: it is insoluble in water and soluble in organic compound Like ethanol, acetone, etc. It used as hardening agent, lubricant, thickening agent and emulsifier.**

4. **Polyethylene glycol: It used in specific formulation and also known as PEGs. It is used to prepared laxative preparation due to its versatile nature. Also act as the stabilizer and lubricant in tablet preparation.**

5. **Talc: It is a bulking agent which increases the quantity of powder as well as it boost the flow ability of powder . It also absorbance ability of moisture and improve the texture and quality of product.**

6. **Hydrogenated vegetable oil : it is the water insoluble compound. Affects on the disintegration of the compound. Giving the longer shelf life to product also prevents the rancidity on exposure to air.**

7. **Sodium lauryl sulphate : it is also called as SLS. This is water soluble compound. This is actually as surfactant, lubricant and increase the drug dissolution rate. It also thickens the formulation tablet.**

- **Procedure :- (methodologies)**

a)Weigh and pass aspirin powder through 60# sieve.

b)Mix aspirin, citric acid, calcium carbonate, saccharine sodium uniformly in mortal pestle.

c)Then add HPMC binder and PVP solution drop by drop and stir well. Form the granules and then stored in cool and dry place.

**Tablet formation :-**

a)Tablets are prepared by using wet granulation method techniques as per composition given earlier.

b)Further granules were dried at 35℃-45℃ for 6 hours. The dried granules stored at desiccator until the compression of Tablets.

c)The required amount of granules were weighed and compressed using automatically operated tablet punching machine having 12mm flat faced punching diameter and during the tablet preparation to maintain the low resistance between the solid and die wall, lubricants are added in granules. Lubricant combinations are agents added in small quantities to the tablets while preparing the tablet.

d)The compressed tablets are stored in airtight container at room temperature for further evaluation

**Evaluation parameters :**

**1.** Assay : weigh and powder 20 tablets. Weigh accurately the quantity of powder containing about 0.5g of aspirin, add 30 ml of 0.5 M Sodium Hydroxide , boil gently for 10 min. Cool and titrate the excess of alkali with 0.5 M hydrochloric acid using phenol red solution as indicator. Repeat the operation without the substance under examination. The difference between the titrations represent the amount of sodium hydroxide required.

2. Weight variation test : Weight variation test is average weight of 20 individually weighed tablets on an analytical balance and compared with permissible limits. This evaluated as per USP XXIV monograph using digital electronic balance and mean , standard deviation was calculated. Individual weight of each tablet is compared with average weight.

3. Hardness : hardness is tablet crushing strength. It is tested by monsanto tester, strong-cobb tester, Pfizer tester, Erweka tester and schleuniger tester. Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shakes during handling in the manufacturing, packaging and shipping. Hardness of randomly selected 10 tablets batch was measured Load was given to tablets diametric direction to determine an actual load when tablet was broken.

4. Friability : friability tester known as Roche Friabilator. A 20 tablets weighed and placed in Roche friabilator where they're exposed to repeated shocks and rolling. The tablets are tumbled at a distance of 6 inches at each turn. After 100 revolutions and if cracked, cleaved and broken tablets present after tumbling then it fails the test. It revolves at 25 rpm and run for 4 minutes. After test tablet can remove from any loose dust and their final weight was determined to calculate the loss.

5. Disintegration test : The USP device to test disintegration consists of 6 glass tubes that are 3 inch long, open at the top and 10 mesh screens at the bottom end. During the disintegration test, one tablet is placed in each tube and the basket rack is positioned in a 1-L beaker of either water, simulated gastric fluid or intestinal fluid at 37°C to 39°C such tablet remains 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of beaker in their downward movement move the basket containing the tablet up and down through 5-6 cm at a frequency of 28 to 32 cycles per minute.

6. Dissolution test : dissolution of tablet was measured by paddle method in dissolution apparatus Erweka GmbH using 0.05 M acetate buffer solution 500ml (pH 4.5) at 50 rpm, maintained at 37 +/- 0.5°C. After 30 min the absorbance of suitably diluted portions in same medium was determined against absorbance of standard preparation at 265nm using uv-vis spectrophotometer.

7. Diameter and thickness : random sample of 10 tablets from each batch their diameter and thickness was calculated in centimetres with the help of micrometer screw gauge. Also the vemier caliper used to determine thickness of tablet and results were expressed as mean values of 10 determinations with standard deviations.

- Precautions and contraindications :

1. Aspirin are contraindicated in patients who sensitive to it and in those with peptic ulcer or bleeding tendencies. In children suffering from chickenpox or influenza.
2. Due to risk of reye's syndrome pediatric formulation of aspirin are prohibited
3. In chronic liver disease aspirin can precipitate hepatic necrosis.
4. It should not given to breastfeeding mothers. It Should be avoided in diabetics.
5. Aspirin should be stop 1 week before handling elective surgery.

- **Interactions :**

1.Aspirin decrease the effect of warfarin, sulfonylureas, phenytoin and methotrexate from binding site. Its antiplatelet action can increase the risk of bleeding in patients.

2.Aspirin cuts diuretic action of furosemide and thiazides and decrease k+ conserving action of spironolactone.

3.Aspirin inhibits tubular secretion of uric acid and antagonized uricosuric action of probenecid.

- **Uses :**

To treat Analgesic
To treat Antipyretic
To treat Acute rheumatic fever
To treat rheumatoid arthritis
To cure osteoarthritis
In Post myocardial infarction and post stroke patients
Prevention of preeclampsia

- Advantages of aspirin

1.Useful in Post surgical recovery and injury related swelling.
2.Works by inhibiting COX enzyme, reducing prostaglanding synthesis which mediated pain and inflammation.
3.Low dose aspirin (75-100mg) is used to secondary prevention of heart attack and strokes. Can be easily administrated to pediatric, elderly and mentally disabled patients.
4.Accurate dosing as compared to liquid.
5.Emerging research aspirin may reduce the risk of colorectal, breast and gastrointestinal cancers by modulating inflammatory pathways and promoting apoptosis.

- Disadvantages of aspirin

1.Aspirin is acidic and may irritates gastric mucosa, leading to ulcers, gastritis or GI bleeding
2.Requires anhydrous formulation condition and moisture resistant packaging.
3.Absorption can be affected by gastric pH, food intake and tablet disintegration rate.
4.In children can cause reye's syndrome and drug interactions.

- **Conclusion :**

- The perspective of review is to achieve a overall information about aspirin with in standard deviation limits
- In the present work , the aspirin tablet made by using fewer excipients were manufacturing procedure fulfils all the pharmacopoeial limits.
- This study of drug is may done to get cost effective product.
- Further occurring work may using optimization techniques to recommended for future studies using present data as a reference guide.

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