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Formulation And Evaluation Of Tablet (Paracetamol Tablet IP)

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Abstract— **Oral dosage forms are the most popular way of taking medication, despite having some disadvantages compared with other methods like risk of slow absorption of the medicament, which can be overcome by administering the drug in liquid form, therefore, possibly allowing the use of a lower dosage. However, instability of many drugs in liquid dosage form limits its use. Effervescent technique can be used as alternate to develop a dosage form which can accelerate drug disintegration and dissolution, is usually applied in quick release preparations. The tablet is added into a glass of water just before administration and the drug solution or dispersion is to be drunk immediately.[1] The tablet is quickly broken apart by internal liberation of CO2 in water due to interaction between tartaric acid and citric acid with alkali metal carbonates or bicarbonates in presence of water. Due to liberation in CO2 gas, the dissolution of API in water as well as taste masking effect is enhanced Along with the development of new pharmaceutical technique, effervescent tablet are more and more extensively to adjust the behavior of drug release, such as in sustained and controlled release preparations, pulsatile drug delivery systems, and so on. In present work an attempt has been made to formulate an effervescent tablet containing immediate release of paracetamol using various acids and bases. In present work we are used different acids and bases in different concentration. The formulation of tablets was done by using wet granulation as well as dry granulation in that technique wet granulation which was found acceptable. Then formulated tablets were evaluated for hardness, friability, weight variation, and disintegration time. [1]**

INTRODUCTION:-

The oral dosage forms are the most popular way of taking medication despite having some disadvantages like slow absorption and thus onset of action is prolong. This can be overcome by administrating the drug in liquid from but, many APIs have limited level of stability in liquid form. So, effervescent tablets acts as an alternative dosage form. The tablet is added into a glass of water just before administration and the drug solution or dispersion is to be drunk immediately. The tablet is quickly broken apart by internal liberation of CO2 in water due to interaction between tartaric acid and citric acid with alkali metal carbonates or bicarbonates in presence of water. Due to liberation in CO2 gas, the dissolution of API in water as well as taste masking effect is enhanced.[2]

The advantages of effervescent tablets compared with other oral dosage forms includes an opportunity for formulator to improve taste, a more gentle action on patient's stomach and marketing aspects. To manufacture these tablets, either wet fusion or heat fusion is adopted. The tablets are compressed soft enough to produce an effervescent reaction that is adequately rapid. Water soluble lubricants are used to prevent an insoluble scum formation on water surface. To add sweetness to the formulation, saccharin is added since sucrose is hygroscopic and add too much of bulk to the tablet. The manufacturing shall be done under controlled climatic condition to avoid effervescent reaction.[2]

The aim of this study is to develop and physicochemically evaluate the Effervescent Tablets of Paracetamol. To enhance the onset of action of Paracetamol and increase the solubility of Paracetamol.[3]

• To produce faster onset of action

• To achieve better patient compliance.

• To Avoid the First Pass Effect

• The Effervescent tablets should have satisfactory property.

• Tablet having the greater bioavailability than other dosage form.

• The stability of Effervescent tablets can be increased.

• The effervescent tablets require strictly humid control area.

• The Effervescent tablets can be made in a normal area where the humidity and temperature Condition not maintained.

• Tablet has a better patient compliance and rapid onset of action .[3]

TABLET:-

According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents. Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration [5]

Properties Of Tablet :-

1) Should be elegant product having its own identity while being free of defects such as chips, cracks, discoloration and contamination.

2) Should have strength to withstand the rigors of shocks encountered in its production, packaging, shipping and dispensing.

3) Should have the physical stability to maintain its physical attributes over time.

4) Must be able to release the medicament agent(s) in the body in a predictable and reproducible manner.

5) Must have a suitable chemical stability over time so as not to allow

alteration of the medicinal agent[9]

Advantages Of Tablet :-

1) Tablets are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.

2) They are easiest and cheapest to package and strip.

3) Low in cost.

4) Lighter and compact.

5) Having greatest chemical and microbial stability over all oral dosage forms.

6) Suitable for large scale production.

7) Easy to swallow with least tendency for hang-up.

8) Objectionable odour and bitter taste can be masked by coating technique.

9) Sustained release product is possible by enteric coating.

10) Easy to handling.[5,6.9,10]

Disadvantages Of Tablet :-

1) Difficult to swallow in case of children and unconscious patients. 2) Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.

3) Drugs with poor wetting, slow dissolution properties, optimum

absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.

4) Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.

5) Irritant effects on the GI mucosa by some solids (e.g., aspirin).

6) Possibility of bioavailability problems resulting from slow disintegration

and dissolution[5,6,9,10]

Ingredients of Tablet :-

1) Diluents:

Diluents are fillers used to make required bulk of the tablet when the drug dosage itself is inadequate to produce the bulk. Also used to improve cohesion, to permit use of direct compression.

2) Binders:

To form cohesive compacts for directly compressed tablet.

3) Lubricants:

Lubricants are intended to prevent adhesion of the tablet materials to the surface of dies and punches, reduce inter particle friction and may improve the rate of flow of the tablet granulation.

4) Glidants:

Glidants are intended to promote flow of granules or powder material by reducing the friction between the particles.

5) Anti–adherents:

Anti-adherents are added to the tablet formulations to prevent the material from sticking to the walls of the tablet press.

6) Disintegrates:

Added to a tablet formulation to facilitate its breaking or disintegration when it contact in water in the GIT.

7) Coloring Agents:

The use of colors and dyes in a tablet has three purposes:

(A) Masking of off color drugs

(B) Product Identification

(C) Production of more elegant product.

8) Flavoring Agents:

Flavoring oils are needed for chewable tablets. The oil is generally added in a dry form such as spray-dried beadlets.

9) Absorbents:

The inclusion of absorbents in a tablet formulation is necessary if the product contains a substance with a high affinity to water. [4]

PREPARATION METHOD OF TABLET:-

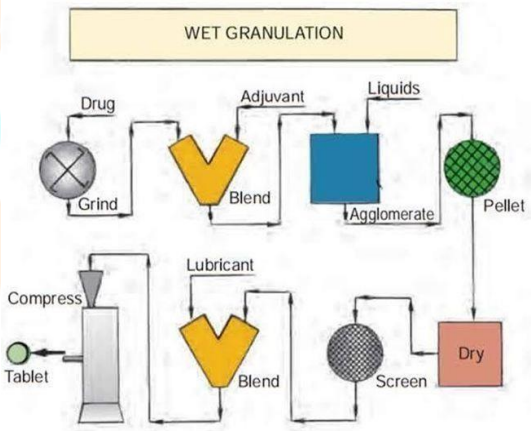
Tablets are prepared by three methods :-

1) Wet granulation method

2) Dry granulation method

3) Direct compression

1) Wet Granulation Method : –



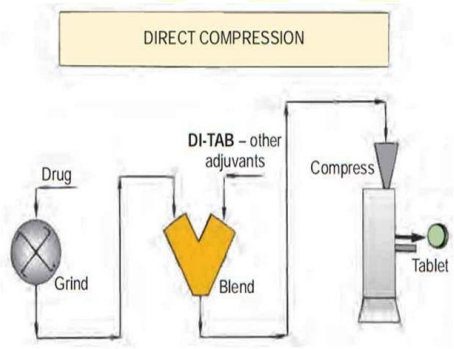
It is the most common and widely used method. This method involves various steps like weighing of ingredients, mixing, granulation, and screening of damp pass, drying, lubrication and compression of tablets. The main active ingredient, diluent, disintegrant are blended together, and then it is allowed to pass through the sieve (sifting). Solutions of the binding agent are added to the initial mixture with stirring. The amount of binding agent added should be sufficient, in order to avoid over wetting of the tablet [46-60]. If the powder is not wetted properly, the granules will be too soft and can be broken down during lubrication, which is difficult during compression of tablet. Tray drying is most common method of drying the tablet granules, Tray drying was the most widely used method of drying tablet granulations in the past, which might be replaced by fluid –bed dryers as a novel approach. After drying the granules, they are allowed to pass through the screen; usually 60-100 mesh nylon cloth is used. After dry granulation, lubricant is added as fine powder, which is required for proper filling of the die cavity[4]

2) Dry Granulation Method: -

This method is used for tablet preparation, in case tablet ingredients are highly sensitive to moisture, or unable to with stand elevated temperatures during drying, slugging may be used to form the granules. Dry granulation or double compression, usually eliminates various steps, which involves slugging of the powder mass.The active ingredient, diluent and lubricant are blended together, to form the slug. Thus, the compressed slug is passed through the mesh or through the mill nd the remaining lubricant is added to the granulation, blended properly and compressed to form the tablets .[5]

3) Direct Compression:

Direct compression involves direct compressing the powdered material into tablets. Direct compression is adopted, if drug constitutes major portion of tablet [86-90] total weight Tablets containing 25% or less of drug substances can be formulated, with a suitable diluent which acts as a carrier or vehicle for the drug. Tablets prepared by above method are subjected to compression machine which may be single station or multiple stations[5,8]



TYPES OF THE TABLET :-

1. Oral Tablets for Ingestion:-

I. Standard Compressed Tablets

II. Multiple Compressed Tablets Compression Coated Tablets a) sugar coated

b) film coated tablets

c) gelatin coated tablets

d) enteric coated tablets

Layered tablet

Inlay tablet

III. Targeted Tablets

a) Floating Tablet

b) Colon Targeting Tablet

IV. Chewable tablets

V. Dispersible tablets

2. Tablets used in the Oral Cavity :-

I. Lozenges and troches

II. Sublingual tables

III. Buccal tablet

IV. Dental cones Mouth dissolved / rapidly dissolving tablets

3. Tablets used to prepare Solution:-

I. Effervescent tablets II. Molded tablets

Hypodermic tablet

Dispensing /soluble tablet

III. Tablet Triturate

4. Structure Wise :-

I. Divisible Tablets

II. Aperture Tablet

III. Concave Convex Tablets

IV. Core Tablet[4,5,6]

Apparatus Use in Paracetamol Tablet Preparation:-

1) Mortar And Pestel:-

2) mortar and pestle, ancient device for milling by pounding. The mortar is a durable bowl commonly made of stone, ceramic, or wood. The pestle is a rounded grinding club often made of the same material as the mortar. Together with the saddle quern (a round stone rolled or rubbed on a flat stone bed), the mortar and pestle was the first means known for grinding grain; the grain was placed in a shallow depression in a stone, the mortar, and pounded with a rodlike stone, the pestle. Smaller refined versions of the mortar and pestle have continued to find use in kitchens for preparing pastes and other finely ground elements of cuisine, in pharmacy for preparing medicines, and in chemical laboratories.[11]

2) Hot air oven :-

1) A hot air oven is used to sterilize equipment and materials used in the medical field. A hot air oven is a type of dry heat

sterilization. Dry heat sterilization is used on equipment that cannot be wet, and on material that will not melt, catch fire, or change form when exposed to high temperatures. Moist heat sterilization uses water to boil items or steam them to sterilize and does not take as long as dry heat sterilization. Examples of items that are not sterilized in a hot air oven are surgical dressings, rubber items, or plastic material. Items that are sterilized in a hot air oven include

1) Sterilizing by dry heat is accomplished by conduction. The heat is absorbed by the outside surface of the item, then passes towards the centre of the item, layer by layer. The entire item will eventually reach the temperature required for sterilization to take place

3) Electronic balance:-

Electronic balance is an instrument used in the accurate measurement of weight of materials. Electronic balance is a significant instrument for the laboratories for precise measurement of chemicals which are used in various experiments. Laboratory electronic balance provides digital result of measurement.

Some of the application areas for laboratory electronic balance are pharmaceutical research, scientific research, industrial, food research, educational research and others. On the basis of types of products electronic balance instrument can be classified into top loading balance and analytical balance.

4)Sives :-

Asieve or screener is an essential part of every pharmaceutical production process, particularly as product quality and integrity are so important. The use of a sieve gets rid of oversized contamination to ensure that ingredients and finished products are quality assured during production and before use or dispatch.[12]

Benefits :-

1. Pleasant Taste Compared to Regular Tablets:-

Effervescent tablet can be liquefied in a liquid such as fruit juice or water, which is the main cause of their approval. Due to which their taste gets way improved than regular tablet.

2. Distributed More Evenly:-

The dissolution of predictable tablet is gradually in sometime and can sometime be gateway causing there to the motive of irritation in some cases, in difference the dissolution of effervescent tablet is comprehensive and even through the stomach which stops the accumulation of component in local area. This makes effervescent tablet taste better and fewer irrigative and on effervescent method of ingestion of ingredient. Apart from providing nutritional benefit intended effervescent tablet also rise liquid consumption.

3. Increased Liquid Intake :-

Increased Liquid Consumption is more helpful during period of desiccation ill time and in less liquid ingestion.

4. Easy Alternative to Regular Tablets

Effervescent tablet can use in residence of regular tablet. Which cause trouble in swallowing either due to sickness or age, old age people who administer medicine or supplement on daily basis reports problem associated to swallowing of tablet to overcome these difficulties effervescent tablets are of great significance and can be on relaxed way to swallow a tablet.[1]

5. To Sum Up :-

Effervescent tablets are receiving progressively popular and it's easy to work out why. They supply a way more effective way of taking supplements or medicine since being spread consistently and far faster than regular medicines.

Reason for selection of effervescent tablets of Paracetamol:-

Fast onset of action :-

Effervescent tablet has main advantage that the drug product is already in solution on the time it is consumed. Therefore, the absorption is earlier and further complete than with predictable tablet. Earlier absorption means faster onset of action. Effervescent drug is distributed to the stomach at a pH that is just correct for absorption. Numerous medications. Portable slowly through the stomach or have absorption that is hindered by food or anotherdrug.

Good stomach and intestinal tolerance

effervescent tablet liquefy completely in a buffered solution. Reduced localized contact in the upper stomach leads to fewer irritation and greater acceptability. Buffering also prevent intestinal acids from interrelating with drug themselves, which can be a main cause of stomach tolerance.

More portability

effervescent tablet is more simply delivered than liquid medication because no water is added until it is complete to use.

Improved palatability

drugs transported with effervescent base, taste improved than most liquids, mixture and suspensions. Greater taste masking is attained by limiting offensive characteristics and adding formulations with flavor and fragrances.

Good stomach and intestinal tolerance :-

effervescent tablet liquefy completely in a buffered solution. Reduced localized contact in the upper stomach leads to fewer irritation and greater acceptability. Buffering also prevent intestinal acids from interrelating with drug themselves, which can be a main cause of stomach tolerance. **More portability :-**

effervescent tablet is more simply delivered than liquid medication because no water is added until it is complete to use. Improved palatability drugs transported with effervescent base, taste improved than most liquids.[4][1]

CHEMICAL NATURE AND INGREDIENT:-

1. **Name:** Paracetamol
2. **IUPAC name:** N-(4-hydroxyphenyl) ethanamide
3. **Molecular formula:** C8H9NO2
4. **Molecular mass:** 151.163 gm/mol
5. **Density:** 1.263 g/cm3
6. **Melting point:** 169o c
7. **Boiling point:** 420 c
8. **Solubility in water:** 7.21g/kg (0c)[1]

PREPRATION OF PARACETAMOL TABLET:-

1. Weigh and pass paracetamol powder through 100 no sieve.

2. Mix paracetamol and starch powder uniformly in mortar and pestle.

3. Prepare 10 % starch paste in boiling water and stir until it becomes translucent.

4. Add starch paste dropwise in mortar to get cohesive mass. Record quantity ofStarch paste used for granulation.

5. Screen prepared cohesive mass through 12# granulating sieve and collect it onGranulating tray.

6. Dry granules in tray at 50oC for 30 min. Pass 50 % dried granules through 16 No sieve.Sieve to get uniform particle size and continue drying for 30 min.

7. Using 22/44 no sieve separate granules and fine particles. Material on 22no sieve is final granules and on 44 no sieve is fines. Record the weight of final granules and fines.

8. If the quantity of fines is more than 10% of final granules then recycle the fines.

9. Finally take the weight of granules and blend granules with remaining ingredients In a polybag.

10. Store prepared granules in well closed and labelled container till evaluation.[13]

EVALUATION TEST:-

1. WEIGHT VARIATION:-

This is an important in process quality control test, which has to be checked frequently (every half hour). Corrections are made during the punching of tablet if necessary. Any variation in the weight of tablet (for any reason) leads to either under medication or overdose. This is particularly true when the drugs are potent or low dose drugs. All tablet machines have provision to receive a known quantity (volume which is correlated to weight) of granules. Improper flow of granules from the hopper into the die is responsible for weight variation. The range of variation is 10 % for tablets weighing less than 80 mg, 7.5% for tablets weighing in the range of 80 to 250 mg, 5.0 % for tablets weighing above 250 mg. For paracetamol the deviation allowed is 5 %.

2. FRIABILITY:-

Friability is the loss of weight of tablet in the container/ package, due to removal of the particles from the surface. This in process quality control test is performed to ensure the ability of tablets to withstand the shocks during processing (coating and strip. - packaging) handling, transportation and shipment (Rahman Z U et al.,2013) (Binega G et al.,2013). The friability of tablets is indicated by chipping, capping, breaking. The extent of friability is less than 0.8%. This limit is strictly adhered when the tablets are further processed for coating.

3. HARDNESS:-

Hardness is a force required to break a tablet across the diameter. The hardness of the tablet is an indication of its strength. This is a valuable test which might influence tablet disintegration and dissolution rate.

4. DISINTEGRATION:-

Disintegration is defined as that state in which any residue of tablet except fragments of insoluble coating, remaining on the screen of the test apparatus consisting of a soft mass having not palpably firm un moistened core. Disintegration process involves the breaking of tablet into small particles. The quicker the disintegration the faster could be the action .disintegration roughly indicates the possible pattern of dissolution of active substance. Hence the experimental conditions closely mimic the situation that a tablet encounters in GI tract, in terms of temperature, pH and mechanics. [15]

5. DISSOLUTION:-

Dissolution is defined as “the amount of drug substance that goes into solution per unit time under standardized conditions of liquid/solid interface, temperature and solvent composition”. Dissolution is

conducted to know the minimum time taken by the drug to dissolve itself in the systemic circulation and starts its action in the body. There are 2 methods of to know the dissolution rate,

1. In vitro studies

2. In vivo studies

MATERIALS AND METHODS:-

The various marketed paracetamol tablet containing 650 mg (Medamol 650 mg, Paracip 650 mg, P-650 mg, Crocin 650 mg, paracetamol (janushad)650 mg and Dolo 650 mg.

WEIGHT VARAITION:-

Tablets of each brand were weighed individually using a analytical balance .20 tablets were weighed individually, average weight is calculated from the total weight. The percentage difference in the weight variation should be within the permissible limits.[15]

HARDNESS:

The hardness of tablet is tested using the Monsanto hardness tester. The tester is placed across the diameter in between the spindle and the anvil. The knob is adjusted to hold the tablet in position. The reading of the pointer is adjusted to zero. The pressure is increased slowly to break the tablet. "Hardness factor" - the average of the several determinations is determined and reported [15]

USE OF PARACETAMOL TABLET:-

1. Fever and Body Temperature

It is well known that paracetamol is antipyretic. It reduces fever in multiple species. A central site of antipyretic action against induced fever was demonstrated in rabbits by direct injection into the organum-vasculosum-laminaterminalis (OVLT) located in the anterior wall of the third intra-cerebral ventricle. It is less well known that paracetamol can also lower a febrile body temperature. For example, several studies, employing different methods and routes of administration, have shown that paracetamol produces hypothermia in mice when the drug is administered intravenously (160mg⁄kg, 2.5°C decrease), intraplantarily (100–300mg⁄kg with 0.4–2°C decrease respectively) or intracerebrovascularly (dose, 0.25°C decrease).

2. Inflammation

Paracetamol has been reported to suppress various inflammation-related substances in animals and in inflamed dental tissue (1000 mg pretreatment and 4000 mg post-surgery in patients with two-third molar extractions), but paracetamol is generally not considered to display very effective antiinflammatory action in the clinical setting. For example, paracetamol given i.p. or orally at 100mg⁄kg (62), i.v. at 100–300mg⁄kg or intrathecally at 200 micro g⁄kg reduced inflammatory pain, but had no effect on edema and in a randomized, double-blind, placebo-controlled trial no significant improvement was seen in the paracetamol (1000mg four times daily) group when assessed 2 and 12 weeks into treatment. The relatively poor anti-inflammatoryeffect of paracetamol is a characteristic distinction from the NSAIDs and might be a reflection of different mechanism of action.[16]

3. Platelet Aggregation

Because of the common impression that paracetamol lacks clinically relevant anti-platelet action, it is often used to avoid the bleeding risk associated with aspirin and other NSAIDs. There is some evidence of anti-platelet activity of paracetamol in human blood samples using in-vitro and ex-vivo assays, but other studies suggest a lack of anti-platelet action. Such an action, when present, is believed to be reversible (shorter acting), in contrast to the irreversible action of aspirin and NSAIDs. At least two recent clinical trials report that paracetamol did not interrupt platelet aggregation when given at 1000mg (73) or 3000mg i.v. Paracetamol might or might not interact with NSAIDs on this endpoint. The relatively poor inhibition of platelet aggregation by paracetamol is another characteristic distinction from the NSAIDs that might be a reflection of a different mechanism of action.[16]

BRAND NAME:-

CONCLUSION:-

The study was under taken with an aim to formulate effervescent tablets of analgesic and antipyretic drug (paracetamol). The literature review showed that paracetamol having similar mechanism of action to aspirin because similarity in structure. Paracetamol act by reducing production of prostaglandin which involved in pain and fever process, by inhabiting the cyclo-oxygenase enzyme. In present work an attempt has been made to formulate an effervescent tablet containing immediate release paracetamol using various acids and base. the effervescent tablets were prepared by wet granulation technique. Lactose as a binder and talc as lubricant were used. There are three formulations that content thecitric acid and sodium bicarbonate were formulated.These five formulations were evaluated for hardness, friability, weight variation, Disintegration time .From above study it was conclude Various stories are heard about this very helpful at the same time deadly drug. While some appreciate it for its Relief of muscle and joint pain, cold and flu symptoms, common headache, antipyretic, anti-inflammatory functions, others curse it for its ability to lead to renal and hepatic complications in the human body. Paracetamol is one drug known and recognized by many but its chemistry is known by a select few. This article has brought to light the chemical

properties of Paracetamol which can be used as a pre-cursor in the production of other chemical substances. One of its chemistry that should be taught to all is the drug interaction of this very powerful drug.

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