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REVIEW ON IMMEDIATE RELEASE DOSAGE FORM

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Abstract:

Most popular immediate release dosage forms such as tablet, capsule and pellet. Because of its convenience of self-administration, and simple to the manufacturing. The type of dosage from is some advantages such as improved stability of formulation. Improved bioavablity of Product. Rapid onset action and cost effective as compare to other dosage formulation. They disintegrant are selected as type of dosage and physical characteristics of drugs. The basic approach used in development tablets, capsule and pellet as the use of some excipient like superdisintegrants, Bulking agent, Emulsifying agent, Binders, Lubricants, Flavouring and Sweetening agent As a drug entity nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a latest and improved dosage form.

The manufacturing of Immediate release tablet, capsule and pellet they using various method such as, Tablet Modling, Wet Granulation, Direct Compression, Solid Dispersion. capsule Direct filling, wet Granulation, and pellets Extrusion, Sphronization, Globulation, Spray Drying, Spray congealing, Compression.

Key Words:- *Immediate Release, Superdisintigrent, Conventional Techniques.*

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INTRODUCTION:

Oral Solid Dosage:

The country of India with an increase in population, and the demand for health care services is an also increasing. With change in lifestyles and so-called "fast culture". The good health is almost important part. The change of the life style the disease is also changed. The ultimate goal of any drug delivery system is effective disease management and minimum side effects and greater patient compliance in a cost effective manner. The drug therapeutic index could be large while index of difficult reactions or side effects could be minimum by regulating the drug release in human body in a well-defined restricted manner. This would remove the haphazard and unrestrained blood plasma profiles of drugs usually associated with conventional dosage forms. Tablets, capsule and pellets are solid dosage form that is compacted into small, formed oval, round shapes. This formulation is use in the mouth for oral administration. They consist of several components. These components help to the formulation is properly digested in the body, is easy to swallow, and change the taste, and controls the timed release of the drug to produce the desired effect. Solid oral delivery systems the system of choice of all drug delivery system and they do not require special treatment. Based on their drug-release characteristics. (1,2)

The Immediate release formulation are those which disintegrate quickly and get dissolved to release the dosage' of immediate release may be provided for by way of an suitable pharmaceutically adequate diluents, which diluents does not delay, to an considerable extent, the rate of drug release and/or absorption. The FDA defined fast dissolving formulation as "a solid dosage form containing therapeutic substance it which disintegrate quickly usually within a subject of seconds when placed on the tongue.

Advantages of Immediate Release Drug Delivery System (10, 11, 21)

1. Improved stability.
2. Improved bioavability of product
2. Improved patient compliance.
3. Rapid onset of action.
4. Suitable for controlled/sustained release dosage form.
5. Allows large drug loading.
6. Adaptable and agreeable to active processing and packaging machinery.
7. Cost is minimum as compare to other dosage formulation.

Disadvantage

1. Frequent dose is necessary for drug with short half life.
2. Drug release at a time may produce high plasma concentration which may produce toxicity.

Ideal Characteristics of Drug In Immediate Release Dosage Form (3,6,10)

Immediate release dosage formulation should In the case of solid dose it dissolves in the stomach within a little time period.

1. In the case of liquid dosage formulation they should be compatible with taste masking.
2. It should not leave minimum or no residue present in the mouth after fill oral administration.
3. Display minimum sensitivity to environmental condition as humidity and temperature.
4.Have a placing mouth feel.

The Drug used in Immediate Release formulation used drug and Their Functional Category: (1,3,7)

Functional Category	Drug Used in immediate Release Formulation
Analgesics and Anti -inflammatory Agents	Azapropazone, Auronafin, Diflunisal, Fenoprofen Calcium, Fenaben, Ibuprofen, Indomethacin, Ketoprofen, Meclofenamic Acid, Mefenamicacid, Nabumetone, Oxyphenbutazone.
Anthelmintics	Albendazole, Dichlorophen Mebendazole, Oxantel, Oxamniquine Oxfendazol Embonate, Embonate, Thiabendazole.
Anti-Arrhythmic Agents	Amiodarone Hcl, Disopyramide, Flecainide Acetate.
Anti-bacterial Agents	Benethamine Penicillin, Penicillin, Ciprofloxacin HCl, Clarithromycin, Clofazimine, Cinoxacin, Doxycycline, Erythromycin, Nalidixic Acid, Nitrofurantoin, Rifampicin, Sulphamethoxazole, Sulphapyridine, Sulphabenzamide, Trimethoprim.
Anti-coagulants	Dicoumarol, Dipyridamole

Anti-depressants	Amoxapine, Ciclazindol, Maprotiline HCl,Mianserin HCl,Trazodone HCl
Anti-diabetics	Acetohexamide, Chlorpropamide,Glibenclamide,Gliclazide, Glipizide
Anti-gout Agents	Allopurinol,Sulphinpyrazone, Probenecid.
Anti-hypertensive Agents	Amlodipine, Carvedilol, Benidipine, Darodipine,Dilitazem Hcl,Diaxoide Dilitazem, Gunabenz Acetate, Isiradipine, Indoramin, Niciradipine, Nifedipine, Nimodipine, Reseripine.
Anti-migraine Agents:	Dihydroergotamine Mesylate, Succinate methyseragide maleate, Sumatriptan succinate pizotrfen maleate.
Anti-muscarinic Agents:	Atropine, Benzhexol Hcl, Biperiden, EthopropazineHcl, butyl bromide,mepenzolate bromide, oxyphenacycimine HCL, Tropicamide, biperiden.
Anti-neoplasticAgents and Immunosuppressants	Amsacrine,Aminoglutethimide, Azathioprne, Chlorambucil, Cyclosporin, Dacarbazine, Etoposide, Estramutine, Lomustine, Mercptopurine, Metomycin,Mitozantrone,Methotrexate, Procarbazine Hcl, Testolactone,Tamoxifen Citrate.
Anti-protazoal Agents	Benznidazole, Diloxanide Furoate, Decoquinate, Diiodohydroxyqunilone, Metronidazole, Nimorazole, Nitrofurazone,Omidazole, Tinidazole.
Anti-thyroid Agents	Carbimazole, propylthiouracil.
Anxiolytic, Sedatives, Hypnotics and Neuroleptics	Alprazolam, Amylobarbitone,Bentazepam**,** Bromoperidol, Barbitone, Brotzolm , Carbromal, Chlormethazole, Chlordiazepoxide, Clobazam, Clotiazepam,Clozapine, Flunitrazepam, Flunanisone, Fluopromazine Decanoate, Fluarzepam, Haloperidol.
Anti-fungal Agents	Amphotericin, Butoconazolenitrate, Clotrimazole, Econazolenitrate Grisiofulvin,Nysatatin,Nitreate,Ketoconazole,Terconazolae, Tioconazole,Terbinafine Hcl.
Cardiac Inotropic Agents	Amrinone, Digoxin,Digititoxin,Lanatoside C,Enoximine, Medigoxin.
Corticosteroids	Beclomethasone, Betamethasone, Budesonide, Cortisone Acetate, Desoxymethasone, Methylprednisolone, Prednisone, Prednisolone, Triamcinolone.
Diuretics	Acetazolamideamiloride, bendrofluazide, bumetanide, chlorthalidone, chlorothiazide,frusemide,metolazone,Spirolactone,ehacrynicacid,trimeterence.
Enzymes	All Enzymes.
Gastro-intestinal Agents	Bisacodyl, cimetidine, cisapride, diphenoxylate Hcl, loperamide, famotidine,mesalazine, omeprazole, ondansertron Hcl, nizatidine.

OTHER EXCIPIENTS (3,4,5,6,10)

Excipients are the properties of balance the active ingredients in use immediate release dosage forms. The need thorough belief of the chemistry of these ingredients to avoid interaction. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The part and purpose of excipients is main formulation of immediate dissolving tablets. They are unmoving foodstuff grade recipients, when incorporated in the formulation; impart the required organoleptic properties and product efficacy. Ingredients are local and can be used for a large range of activities, except some activities that require taste masking agents.

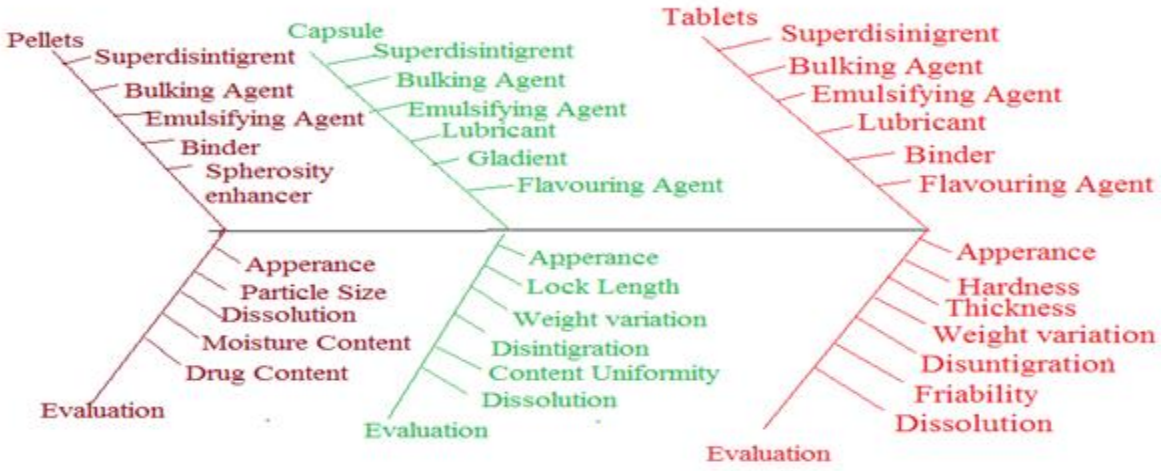

Fig.1:- Ingredient used in different Immedeate dosage formulation.

Bulking Materials:
Bulking ingredients are significant in the formulation of Immediate release formulation. The substance contributes functions of a filler, diluents and price reducer. Bulking agents are add in the range of 10 percent to about the 90 percent by weight of the final composition .Ex. mannitol, polydextrose, lacitalol, starch hydrolysate.

Emulsifying Agents:
Emulsifying agents are important ingredient for manufacturing of immediate release formulation they help in quick drug release and disintegration. These agents can be included in the range between the 0.05 percent to about 15 percent of the weight by final composition. Ex. propylene glycol esters, lecithin, sucrose esters, and others.

Lubricants:
Lubricants, are not essential ingredient, can more assist in manufacture these formulations more edible after the disintegrate to the mouth. Lubricants are removed the grittiness and drug transfer mechanism from the mouth to the stomach.eg. Magnesium state, Talc, Boric acid, Steric acid.

Flavours and Sweeteners:
Flavors and taste-masking ingredients make the products are more palatable and pleasant of the patients. The addition of some flavoring ingredients to assists in overcome bitterness and undesirable tastes of some formulation. Ex. Sugar, fructose and dextrose, as well as non- nutritive sweeteners as also used such as sodium saccharin, sugar alcohols and sucrluose.

Super Disintegrant: A disintegrant is a substance, which is fill up to a tablet or capsule blend to aid in the breakup of the compressed mass when it is place into a fluid of the surroundings. They increase moisture of the tablet. Superdisintegrants are used at a little amount in the solid dosage foam, typically 1-10 % by weight relative to the total weight of the dosage unit.
Superdisintegrants are contact with water the tablet, capsules or pellets are swell and hydrate they modify volume in the tablet, capsule or pellet. Effective superdisintegrants provide improve compressibility, Compatibility and have no harmful impact on the mechanical strength of formulations containing large-dose of drugs. eg**.** Sodium starch glycolate, Polyvinylpyrrolidone, Calcium Silicate. (2,5,10,21)

Advantages:
1. Effective in low concentrations
2. Minimum effect on compressibility.
3. More effective in itragranularly.

Some Common Super disintegrate are used as Tablet, Capsule, and Pellet Formulation: (23)

Name Of Super Disintegrant	Mechanism of Action.
Sodium Starch Glycolate (Explotab, Primogel)	Rapid and extensive swelling with nominal gelling. Microcrystalline cellulose used in concentration of 2-15% of tablet weight. And Water wicking.
Cross-linked Providone (Killiodone)	Water wicking, swelling and probably some deformation recovery. Fastly disperses and swells in water, but does not gel even after prolonged exposure. Greatest rate of swelling compared to other disintegrant. Greater surface area to volume ratio than other disintegrants .Used in concentration 2-5% of weight of tablet.
Low substituted Hydroxy propyl cellulose	This is insoluble in water. Fastly swells in water. Grades LH-11 and LH-21 exhibit the greatest degree of swelling. Certain grades can also provide some binding properties while retaining disintegration capacity. Recommended concentration 1-5%
Cross linked carboxy methyl cellulose	Wicking due to fibrous structure, swelling with minimal gelling. Effective Concentrations: 1-3% Direct Compression, 2-4% Wet Granulation
Cross linked cellulose	Swells 4-8 folds in < 10 seconds. Swelling and wicking both.
Calcium silicate	Wicking action.

Conventional Techniques used in The Preparation of Immediate Release formulation:

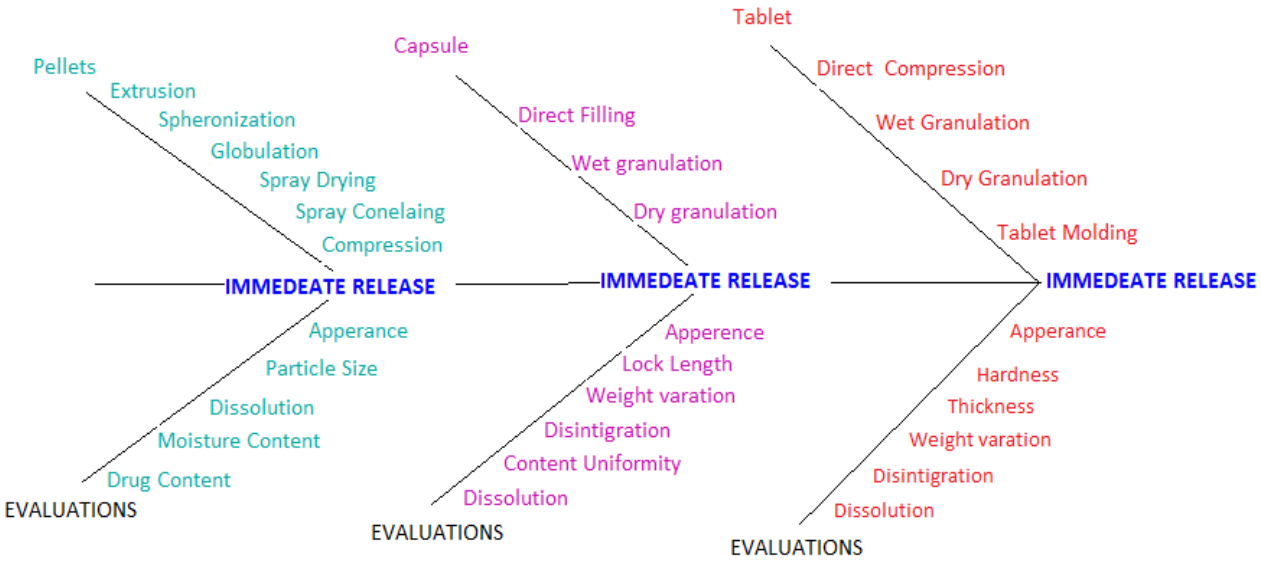

Fig.2:- Formulation of dosage from preparation Method And Evaluation Parameter.

1. Tablet Moulding Technique: (4,)

These methods, used in water-soluble ingredients that tablet disintegrate and dissolve rapidly.

The powder mixture is moistened with a hydro alcoholic solvent and is moulded in to tablet using compression pressure lower than used in conventional tablets compression. The solvent is the separate by air-drying. Moulded tablets have a leaky structure that improved dissolution. They two problems normally found are mechanical strength and

reduced taste masking characteristics of tablet, capsule or pellets. Using binding of the agents such as sucrose, acacia or poly vinyl pyrrolidone can improved the mechanical force of the tablet.
To overbear reduced taste masking characteristic Van Scoik incorporated drug containing discrete particles, which were formed by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium bicarbonate, lecithin, polyethylene glycol and active excipients into a lactose based tablet triturate form.

2. Wet granulation
Wet granulation is a process of used in a small amount of liquid binder to lightly agglomerate the powder blend.
The amount of liquefy the substance has to be the controlled, as over-wetting will cause the granule to be rigid and under-wetting will cause them to be soft and spindly.
i. The active substances and excipients are checked, weighed and mixed the properly.
ii. The wet granulation is prepared by adding the liquid binding agent–adhesive to the powder blend and mixing thoroughly.
iii. Screening the damp mass through a mesh to form the granules.
iv. Dry granules is a conventional fluid-bed dryer are most commonly used.
Limitation of wet granulation
The great disadvantage of wet granulation is it's a minimize the cost or cost effective. It is a large process because of labour, equipment, time, energy and time requirements for preparation of granules.
1. Loss of material during various types of processing to preparation of granules.
2. Stability may be a main issue for dryness sensitive or thermo labile drug.

3. Direct Compression (4,5)
The name direct compression is used to define the method by which tablets are compacted to direct from of powder material of the active substance and appropriate excipients which will uniform flow of powder in die cavity and form this powder substance are compacted.

Advantages
1.Direct compression technique is more capable and cheap process as compared to wet granulation, molding, mass extrusion techniques because it involves only dry blending and compression of tablet used of API and necessary excipients.
2. The most popular advantage of direct compression is that it is an cheap process. Reduced time, Reduced cost of labour, fewer manufacturing steps, and minimum number of equipment's are required, less process validation, reduced use of energy.
3. Uniformity of particle size.

4. Solid dispersions technique
The formulation of solid amorphous dispersions into fast release solid dosage formulation for oral administration through GI tract of an animal and human, it is frequently desirable to maximum quantity of dispersion present in the dosage formulation. This low volume of the solid dosage form required to complete the desired dose. Such large drug loadings of dispersion in a solid dosage form reduce the dosage formulation volume, making it easier for the patient to swallow it and cure to advance patient compliance.

The minimum quantity, the dispersions used in the current device present concentration and development of relative control consist of crystalline drug is alone. Thus, the concentration is increasing polymer is present in a suitable quantity so that the dispersion is administered to the use of environment, then dispersion provides improved drug concentration relative to a control consisting of an the same amount of crystalline drug, but with no concentration-increasing polymer present.

The immediate release dosage formulation containing a solid dispersion that enhances the solubility of "minimum-solubility drug," meaning that the drug may be either "mostly water-insoluble," which means that the drug has a minimum aqueous solubility at physiologically relevant pH (e.g., pH 1-8) of less than 0.01 mg/mL, "sparingly water-soluble," that is, has an aqueous solubility up to about 1 to 2 mg/mL, or even minimum to moderate aqueous-solubility, having an aqueous-solubility from about 1 mg/mL to as high as about 20 to 40 mg/mL.

5. Mass-Extrusion (5)
Here become softer of active mixture is done with solvent mixture of water-soluble methanol and polyethylene glycol as subsequent elimination of softened mass through the syringe to get a cylinder of the substance into flat segments using the heated cutting edge to form tablets. In case of bitter drug granules can be coated with the help of dried cylinder to achieve taste masking.

6. Extrusion: (22)
Prepared wet mass was immediately extruded through sieve number 14 (B. S. S.) to get compact cylindrical extrudates of uniform diameter.

7. Spheronization: (22)
The extrudates were spheronised using lab Spheronizer (Shakti Pharmatech) at 800 rpm with 5 mm friction plate to get spherical pellets. Wet pellets were dried in Fluid Bed Dryer (FBD) for 10 min keeping product temperature below 65 °C.

Preformulation Study of Immedeate Release Dosage Form:-

A) Evaluation of Blend: (4,13,)

1. Angle of repose
2. Tapped density
3. Bulk density
4. Carr's index
5. Hauser's ratio

1. Angle of Repose:
Angle of repose of Active Pharmaceutical Ingredients the bleach was resolute by the use of funnel method. The correctly weigh of bleach mixture was placed in the funnel. The height of the funnel adjusted in such a way that the tip of the funnel now touches the top of the powder mixture. The bleach mixture was the certified and flow through the funnel freely on to the surface. The width of the bleach cone was calculated and angle of repose was calculated using the following equation.

$$Angle\ of\ repose = Tan^{-}(\text{Height of cone / Radius of disc})$$

2. Tapped density:
Tapped density is achieved by automatically tapping of measuring cylinder containing the bleach sample. Correctly 25 g of drug was weighed, which was previously passed through 20 # mesh and transferred in 100 ml graduated cylinder. Then the cylinder contain to the sample was automatically tapped by raising the cylinder and allowing it to drop under its own weight using the automatically tapped density tester. After observe the original volume, the tube is automatically tapped and volume reading is taken until little further volume changes are the observed. The automatic tapping is achieve by raising the tube and allow it to fall under its own weight of a definite distance. Instruments that rotate the tube during tapping may be preferred to decrease any achievable separation of the mass during tapping down. Tapped density is the calculated in gm / ml. (Martin et al 2001).
The tapped density was calculated by using the following formula

$$Tapped\ Density = \frac{\text{Weight of powder in gm}}{\text{Tapped volume in blend in cm}}$$

3. Bulk Density:
The bulk density is described as weight per unit volume. Bulk density is defined as the mass of the bleach divided by the bulk volume and is expressed as gm / cm3. Correctly of drug was weighed, which was before passed through mesh and transfer in 100 ml graduated cylinder. Carefully level the bleach without compacting, and read the disturbed apparent volume (V0). The bulk density was calculated by using the following formula

$$Bulk\ Density = \frac{\text{Weight of Powder}}{\text{Bulk Volume}}$$

4. Compressibility Index:
The simple way for measurement of free flow of bleach is compressibility, an warning of the ease with which a material can be induced to flow is given by compressibility index (I) calculated as follows

$$\%\ Compressibility = \frac{\text{Untrapped Volume} - \text{Tapped Volume}}{\text{Tapped Volume}}$$

5. Hasusner Ratio:
The hasusner ratio is an not direct index of ease of bleach flow. It was calculated by the following formula

$$Hasusner\ Ratio = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

B) Evaluation study of Immedeate release dosage form: (1, 3, 4, 17)

A.
1. Appearance:
The common explanation of formulation is its visual identity and all above elegance, textures, color, shape, and surface. These all parameters are essential for consumer acceptance.
But they some environmental factor are affect such as temperature, storage area, manufacturing process etc.

2. Weight variation:
The weight variation test is establish twenty tablets or capsules was selected to the random from each formulation and weighed separately to check for weight variation. Some factor are affected to the weight variation such as manufacturing process, hardness of tablets, preparation process of granules, used in low amount of binding agent.

3. Friability:
Friability is the loss of weight of tablet in the container due to remove of fine material from the surface. Friability test is carried out to access the capacity of the tablet or to withstand abrasion in packaging, handling and moving. Roche friabilator was used working for finding the friability of the tablets. They 20 tablets for the same formulation were weighed and these tablets are taken in Roche friabilator that rotated at 25 rpm for 4 minutes. The tablets were degusted and weighed of these tablets are again. The percentage of weight defeat was calculated again. The amount of weight defeat was calculated using the formula.

$$Friability = \frac{\text{W initial} - \text{W final}}{\text{W final}} \times 100$$

4. Thickness:
The thickness of the tablets was determined by the use of venire calipers. 10 tablets are randomly choose were used for function of thickness that expressed in Mean± SD and unit is mm.
The some factor are affecting the thickness of tablet is diameter of punch, granules size etc.

5. Hardness:
The hardness of the tablet is an sign of its power against struggle of tablets to capping**,** abrasion or breakage under storage condition, handling and transportation before usage Selected 10 tablets from pooled sample and measured the hardness of tablet using calibrated hardness tester like Monsanto hardness tester. Hardness measured in kg/cm. The some factor is affect in the hardness of tablet such as machine speed, binding agent, diameter of die, etc.

6. Disintegration:
Disintegration test of the tablet was performed on the 6 tablets. Placed one tablet in each of the six tubes of the basket, added the disc to each tube and manage the apparatus using water at 37 ± 2˚C as the concentrated fluid. At the end of 30 minutes, pick up the basket from the fluid and observed the tablets. All the tablets should disintegrate. Recorded the disintegration time in minute and seconds.

7. Wetting Time:
The wetting time of tablets was measured using a easy procedure. Five round tissue papers of 10cm width they located in a Petri dish containing 0.2% w/v solution of amaranth (10ml). One tablet was watchfully located on the surface of the tissue paper. The sometime required for develop the blue color due to amaranth water-soluble dye on the upper surface of the tablets was noted as the wetting time.

9. In- vitro Dissolution Profile:
Immediate release formulation are subjected to the in vitro drug release study in the pH 6.8 phosphate buffer or 0.1N HCl for 30 minutes times to access the capability of the formulation for provide immediate drug delivery. Drug release studies are carried out in dissolution test apparatus using specific volume 900ml of dissolution media maintain at 37±0.2˚C. The tablets or capsule are set aside in the cylindrical basket placed in medium with paddle then rotate at 100 rpm. 5ml of the sample from the dissolution medium are remote at each time interval (5, 10, 15 & 30 minutes) and 5ml of fresh or new medium was replaced each time. The samples were filtered and from the filtrate 1ml was taken and then diluted to the 10ml. These samples were analyzed by spectrophotometrically and further calculation was carried out to get drug release. The drug released information were plotted and tested with zero order, First order. The dissolution kinetic parameters, dissolution rate constants, correlation coefficient and dissolution effectiveness were calculated.

B. Capsule:(24)
1. Appearance: - The appearance as same as the evaluation of tablet.
2. Weight variation: - The weight variation test as same as the evaluation of tablet.
3. Lock Length: - Ten individual capsules are taken from formulation trial batch and lock length is measured using by hand using verniear caliper and average of 10 capsules was noted.
4. In vitro Dissolution: - The In vitro Dissolution study as same as the evaluation of tablet.
5. Disintegration: - The disintegration study of capsule study as same as the evaluation of tablet.
6. Content Uniformity: - Ten capsules were weighed and their contents were removed. An accurately weighed sample equivalent to 100mg of drug was taken in a volumetric flask (100ml). The content was dissolved in 0.1N HCL and volume made up to 100ml. This solution was filtered through Watt man filter paper No.41 The solution was diluted and the absorbance was measured. The drug content was measured.

C. Pellets: - (21,22)
1. Appearance: - The appearance of pellets as same as above tablet and capsule formulation.
2. Particle Size: - The size distribution of the manufacturing by pellets was investigate using laser light diffraction (Mastersizer Scirocco 2000, Malvern Instruments, Grove wood Road, UK). For a typical experiment, about pellets was fed into the sample micro feeder. All samples were analyzed five times

and average results were taken. The sizes below which 10% d(0.1)), (d(0.5)) and (d(0.9)) of the pellets were present were used to characterize the pellet size distribution. The mean diameter was taken as the average of d(0.1), d(0.5) and d(0.9) values.

3. Drug Content: - Drug content of the manufactured pellets was determined by the spectrophotometrically. Pellets were crushed in a porcelain mortar and about 25mg of crushed pellets was dispensed in a 20ml of distilled water under the sonication for 5min. The supernatant was filtered and measured spectrophotometrically. The drug content was calculate using a pre-constructed calibration curve.

4. In- vitro Dissolution: - in vitro dissolution study of pellets same as above as evaluation of tablet and capsule formulation.

CONCLUSION:

There is a clear chance for new improved oral products arising within this market segment. Approximately one-third of patients are require fast therapeutic action of drug, resultant in poor compliance with conventional drug therapy which leads to reduced overall therapy effectiveness. A new dosage format, the immediate release pharmaceutical formulation has been developed which offers the shared advantages of ease of dosing and convenience of dosing. These formulations are designed to discharge the medicaments with an better rate. Due to the constraints of the current technologies as tinted above, there is an unmet need for improved manufacturing processes for immediate release pharmaceutical form that are automatically strong, allowing ease of packaging, handling and with the manufacturing costs same to that of conventional tablets or capsules.

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