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A Review on Immediate Release Drug Delivery System

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Abstract: *Among the dosage forms, tablets are the most popular dosage form today due to their convenience, compactness and ease of preparation; Immediate effect is required in many cases compared conventional therapy. So much so that to overcome these drawbacks, the immediate release ganic form has positioned itself as an alternative to the oral ganic form immediate-release dosage forms disintegrate rapidly after administration with an increased dissolution rate. The basic method used in tablet development is the use of super dissolves such as cross-linked polyvinylpyrrolidonecrospovidone (Polyplasdone),sodium starch glycolate (Primogel, Explotab), carboxymethyl cellulose (Croscarmellose), etc.These super disintegrators allow the tablet to disintegrate immediately after administration in the stomach. In this area, immediate-release liquid dosage forms of and parenteral dosage forms have also been introduced to treat patients. In liquid dosage form, can be a suspension with typical dispersants such as hydroxypropyl methylcellulose,AOT (dioctylsulfosuccinate), etc. cardiovascular drugs, analgesics, antihistamines and other drugs can be considered as candidates for this dosage form. When a pharmaceutical entity is nearing the end of its patent term, it is common for pharmaceutical manufacturers to develop a certain pharmaceutical entity in a new and improved dosage form. The new dosage form allows the manufacturer to exclusively expand the market of the, while providing its patients with a more convenient dosage form or regimen.*

Keywords: Immediate release, polymers, super disintegrant.

I. INTRODUCTION

This research develops systems to expand markets/features, extend product life cycles and create opportunities. Oral administration is themost popular route to achieve systemic effects due to ease of ingestion, painlessness, avoidance, versatility, and most importantly, patient compliance. In these solid formulations do not require sterile conditions and are therefore cheaper to manufacture. Patient compliance, high precision dosing and manufacturing efficiency make tablets a popular solid dosage. The choice of excipients and devices will be significantly influenced by how solid dosage forms change as technologies change in response to unprecedented changes in drug development, such as genomics. The development of advanced oral protein delivery technology, along with immediate release tablets that can release drugs at an accelerated rate, hold great promise for the delivery of poorly soluble drugs, high molecular weight proteins and peptides. The oral route remains the perfect route for administration of therapeutic agents, as low treatment costs, manufacturing and ease of administration ensure high patient compliance. Many patients require rapid action in a defined therapeutic setting, and therefore immediate release of the drug is necessary. This problem is estimated to affect 50% of the population, often resulting in ineffective treatment.

1.1 Definition

Immediate release tablets are those which disintegrate rapidly and get dissolved to release the medicaments.
Immediate release may be provided for by way of an appropriate pharmaceutically acceptable diluent or carrier, which diluent or carrier does not prolong, to an appreciable extent, the rate of drug release and/or absorption. This term excludes formulations which are adapted to provide for “modified”, “controlled”, “sustained”, “prolonged”, “extended” or “delayed” release of drug

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Release time period consists of the provision (or presentation) of drug from the system to the gastrointestinal tract to frame tissues and/or into systemic circulation. For gastrointestinal tract launch, the discharge is below pH situations inclusive of pH=1 to three, mainly at, or about,pH=1. In one issue of the discovery a system defined herein with a compound of formula (I), or anacid addition salt thereof, in crystalline shape releases drug
below a number pH situations. In any other issue of theinvention a system as defined herein with a
compound of formula (I), or an acid addition salt thereof,releases drug below pH situations inclusive of pH=1 to three,mainly at, or about, pH=1. Thus, formulations of the invention can also additionally launch as a minimum 70% (ideally 80%) of lively factor inside four hours, inclusive of inside three hours,ideally 2 hours, greater ideally inside 1.five hours, andmainly inside an hour (inclusive of inside 30 minutes), of administration, whether or not this be oral or parenteral.

1.2 Pharmacokinetics

In this aspect, study has done on absorption,distribution, metabolism and excretion. Afterabsorption, drug attains healing stage and therefore produces pharmacological response, therefore each rate and increase of absorption important. In conventional drug remedy there may be put off in disintegration and therefore dissolution. While instantaneously dosage shape is rapidly disintegrating in oral hollow space and dissolution is fast. Due to disintegration of RDT in mouth absorption in commenced from mouth, pharynx and esophagus. Someelement like age, GI pH, and blood go with the drift through GI are taken into consideration, due to the fact elders can be denoted as wonderful specific Medicare population. Drug distribution performed through tissue permeability, perfusion rate, binding of drug to tissue, ailment state, drug interplay etc. In geriatric patients, lower in frame mass and general frame water bring about reduced extent of distribution of water-soluble pills and increase exent of distribution (Vd) of lipid soluble pills excretion through renal clearance is slowed, for this reason half-life of renal excreted pills increase

1.3 Pharmacodynamics

Decreased capability of the frame to react baro reflexive stimuli, cardiac output, and orthostatic hypotension might also additionally see in taking antihypertensive like prazosindecreased sensitivity of the CVS to b-adrenergic agonist and antagonist. Immunity is much less and brought into attention whilst administered antibiotics different response to drug treatment-aged indicate decreased bronchodilator impact of theophylline showsextended sensitivity to barbiturates.

Desired Criteria for Immediate Release Drug Delivery System:

Immediate release dosage form should-
In the case of solid dosage it should dissolve or disintegrate in the stomach within a short period.
In the case of liquid dosage form it should be compatible with taste masking.
Be portable without fragility concern.
Have a pleasing mouth feel.
It should not leave minimal or no residue in the mouth after oral administration.
Exhibit low sensitivity to environmental condition as humidity and temperature.
Be manufactured using conventional processing and packaging equipment at low cost.
Rapid dissolution and absorption of drug, which may produce rapid onset of action.

Advantages of Immediate Release

Economical and cost effective.
Quick onset of action.
Suitable for commercial production.
Improved balance and bioavailability.
Provides a few benefits of liquid dosage forms
Adaptable and amendable to existing processing and packaging machinery.
Unique product differentiation

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Disadvantages of Immediate Release

Rapid drug therapy intervention is not possible.
Sometimes may require more frequency of administration.
Dose dumping may occur.
Reduced potential for accurate dose adjustment.

Problems with Existing Oral Dosage Form

Patient might also additionally be afflicted by tremors consequently they have issue to take powder and liquids. In dysphasia bodily boundaries and adherence to an oesophagus might also additionally reason gastrointestinal ulceration.
Swallowing of strong dosage bureaucracy like pill and pills bring issue for younger grownup of incomplete improvement of muscular and nervous gadget and aged sufferers be afflicted by dysphasia.
Liquid medicaments (suspension and emulsion) are packed in multidose container; consequently achievement of uniformity withinside the content material of every dose might also additionally be
difficult.
Buccal and sublingual formation might also additionally reason irritation to oral mucosa, so sufferers refused to apply such medications.
Cost of merchandise is important thing as parenteral formulations are maximum expensive and discomfort.

Excipients used in immediate release dosage form:

Excipients balance the active ingredient properties inimmediate-release dosage forms. This requires a thorough understanding of the chemistry of these excipients to avoid any interactions with the active ingredients. Determining the cost of these ingredients is another issue that formulators have to deal with. the role of excipient is important in the formulation of quick-dissolving tablets. These food-grade inactive ingredients, when incorporated into the formula, provide the desired performance and organoleptic properties of the product. Excipients are generic and can be used for a wide range of active ingredients, with the exception of some that require a coating agent.

1. Bulking Materials

Bulking materials are significant in the formulation of fast melting tablets. The material contributes functions of a diluent, filler and cost reducer. Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides; adding bulk also reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolystate for higher aqueous solubility and good sensory perception. Mannitol in particular has high
aqueous solubility and good sensory perception. Bulking agents are added in the range of 10 percent to about 90 percent by weight of the final composition.

2. Lubricants

Lubricants, although it is not crucial excipients, can further help in building these tablets more edible after they disintegrate in the mouth. Lubricants eliminate grittiness and help in the drug transport mechanism from the mouth down into the stomach.

3. Emulsifying Agents

Emulsifying agents are important excipients for formulating immediate release tablets they aid in rapid
disintegration and drug release. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and enhancing bioavailability. A wide range of emulsifiers is recommended for fast-tablet formulation, including alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents can be incorporated in the range of 0.05 percent to about 15 percent by weight of the final composition

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4. Flavors and Sweeteners

The product with flavors and taste masking agents should prepare product most palatable and pleasing for patients. The incorporation of these agents supports in overcoming bitterness and undesirable tastes of some active ingredients. For immediate release tablet to enhance the organoleptic characteristic, both synthetic and natural flavors can be used. Ex. Sugar, dextrose, mannitol. Incorporation of sweeteners contribute to pleasant taste as well as bulk to the composition.

Some super disintegrants are:

Sodium Starch Glycolate (Explotab, primogel)

Used in concentration of 2-8 % & optimum is 4%

Mechanism of Action: Rapid and extensive swelling with minimal gelling. Microcrystalline cellulose (Synonym: Avicel, celex) used in concentration of 2-15% of tablet weight. And Water wicking

Cross-linked Povidone or crospovidone

(Kollidone) used in concentration of 2-5% of weight of tablet. Completely insoluble in water.

Mechanism of Action: Water wicking, swelling and possibly some deformation recovery. Rapidly and swells in water, but does not gel even after prolonged exposure. Greatest rate of swelling to other disintegrants. Greater surface area to volume ratio than other disintegrants.

Low-substituted hydroxyl propyl cellulose, which is insoluble in water. Rapidly 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 sodium

(Ac-Di-sol) Croscarmellose sodium:

Mechanism of Action: Wicking due to fibrous structure, swelling with minimal gelling. Effective concentrations: 1-3% Direct Compression, 2-4% wet Granulation.

Conventional Technique Used in the Preparation of Immediate Release Tablets:

- Tablet molding technique
- Direct compression technique
- Wet granulation technique
- Mass extrusion technique

Tablet molding technique

In this technology, water-soluble components are used so that pill fall apart and dissolve rapidly. The powder combo is moistened with a hydro alcoholic solvent and is molded in to pill the usage of compression strain decrease than utilized in traditional drugs compression. The solvent is then eliminated via way of means of air-drying. Molded drugs have a porous shape that complements dissolution. Two problems generally encountered are mechanical power and negative flavor covering characteristics. Using binding retailers such as sucrose, acacia or poly vinyl pyrrolidone can growth the mechanical power of the pill. To conquer negative flavor covering feature Van Scoik integrated drug containing discrete particles, which had been fashioned via way of means of spray congealing a molten aggregate of hydrogenated cottonseed oil, sodium bicarbonate, lecithin, polyethylene glycol and energetic element right into a lactose primarily based totally pill triturate form.

Directcompression method

In this method, drugs are compressed directly from the aggregate of the drug and excipients with none initial treatment. The aggregate to be compressed need to have good enough flow houses and cohere beneathneath stress thus making pretreatment as moist granulation unnecessary. Few pills may be directly compressed into drugs of ideal quality. A

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form of disintegrant and its percentage are of top importance. The different elements to be taken into consideration are particle length distribution, contact angle, pore length distribution, pill hardness and water absorption capacity. All those elements decide the disintegration. The disintegrates addition generation is fee powerful and clean to enforce at commercial level.

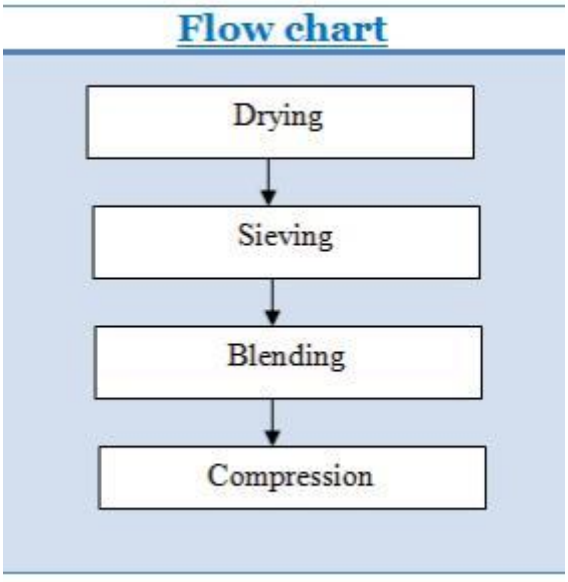

Figure 1: Direct compression technique

Advantages:

- Low labour input
- A dry process up
- Fewest processing steps

Disadvantages:

- Stratification might also additionally arise because of variations in particlelength and bulk density which ends poor content material uniformity.
- A huge dose drug might also additionally motive hassle in direct compression. It calls for diluents. The tablet
- turns into huge in length that is hard to swallow and additionally costly.
- During coping with of dry substances static charge might also additionally shape which might also additionally gift uniform distribution of drug.

Wet Granulation Method

Wet granulation is a process of using a liquid binder to lightly agglomerate the powder mixture. The amount of liquid has to be properly controlled, as over-wetting will cause the granules to be too hard and under-wetting will cause them to be too soft and friable. Aqueous solutions have the advantage of being safer to deal with than solvent-based systems but may not be suitable for drugs which are degraded by hydrolysis.

Procedure:

Step 1: The energetic aspect and excipients are weighed and mixed

Step 2: The moist granulate is ready with the aid of using adding the liquid binder–adhesive to the powder blend and combining thoroughly. Examples of binders/adhesives consist of aqueous arrangements of cornstarch, herbal gums such as acacia, and cellulose derivatives such as methyl cellulose, gelatin, and povidone.

Step 3: Screening the damp mass through a mesh to shape pellets or granules.

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Step 4: Drying the granulation. A conventional tray-dryer or fluid-mattress dryer are most typically used.
Step 5: After the granules are dried, they are handed thru a display of smaller length than the one used for the moist mass to create granules of uniform length.

Low shear moist granulation techniques use very easy blending gadget, and may take a huge time to acquire a uniformly mixed state. High shear moist granulation techniques use gadget that combines the powder and liquid ata totally speedy rate, and consequently hastens the production process. If the granulation is over wetted the granules could be hard, if now no longer wetted sufficiently, theegranules could be too soft, breaking down in the course of lubrication. The moist mass is forced througha 6 or eight mesh (Mesh no. is the number of wires passing through an inch) display or numerous generators may be used.

Mass extrusion technique

This technology involves softening the energetic combination the use of the solvent combination of water-soluble polyethylene glycol and methanol and next expulsion of softened mass via the extruder or syringe to get a cylinder of theproduct into even segments the use of heated blade to form tablets. The dried cylinder also can be used to coat granules for sour tablets and thereby reap flavor masking.

II. PROBLEMS IN TABLET MANUFACTURING

An ideal tablet should be free from any visual defect or functional defect. The advancements and innovations in tablet manufacture have not decreased the problems, often encountered in the production, instead have increased the problems, mainly because of the complexities of tablet presses; and/or the greater demands of quality. An industrial pharmacist usually encounters number of problems during manufacturing. majority of visual defects are due to inadequate fines or inadequate moisture in the granules ready for compression or due to faulty machine setting. Functional defects are due to faulty formulation. Solving many of the manufacturing problems requires an in depth knowledge of granulation processing and tablet presses and is acquired only through an exhaustive study and a rich experience.

Following are the defects that are found during tablet manufacturing.

- Weight variation
- Capping
- Lamination / Laminating
- Cracking
- Chipping
- Sticking / Picking
- Mottling
- Double impression

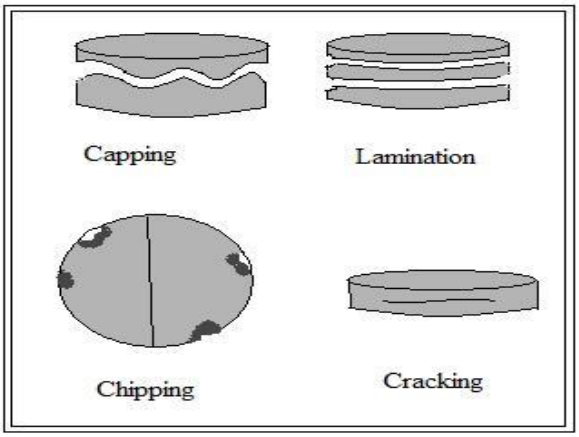

Figure 2:problems in tablet manufacturing

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Evaluation of powder blend

The prepared blend is evaluated by following tests.

- Angle of repose
- Bulk density
- Tapped density
- Hauser's ratio
- Carr's index

1. Angle of repose

Angle of repose changed into decided through the usage of constant funnel technique. The constant funnel technique hire a funnel that changed into secured with its tip at a given height (2cm), above the graph paper that changed into located on a flat horizontal surface. Granules or tablet blend were carefully poured through the funnel till the apex of the conical pile simply touches the tip of the funnel. Thus, with r being the radius of the bottom of
the conical pile. Angle of repose changed into calculated the usage of the following equation.

Tan = h/r

Here h = Height of pile

R = Radius of pile

Θ = Angle of repose

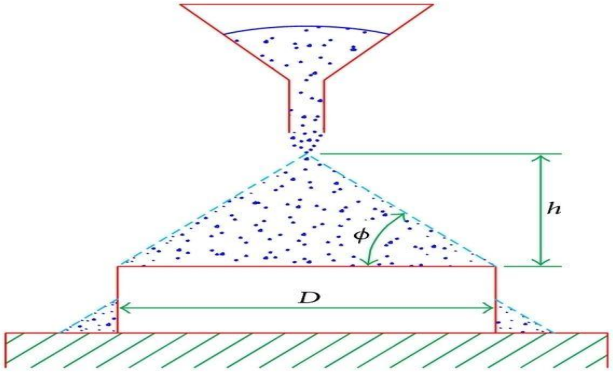

Figure 3: Measurement of angle of repose (Fixed funnel method).

2. Bulk density

Bulk density was determined by pouring a weighed quantity of tablet blend into graduated cylinder and measuring the height. Bulk density is the ratio of mass of tablet blend to bulk volume.

Bulk density (ρB) = M / Vo

Where,

M = mass of the powder (weight taken in g)

Vo = Void volume (Untapped Volume in ml)

3. Tapped Density

Tapped density is ratio of mass of pill combination to tapped extent of pill combination. Accurately weighed quantity of pill combination poured in graduated cylinder and peak is measured. Then cylinder changed into allowed to 100tap beneathneath its very own weight onto a tough surface. The tapping changed into endured till no in addition alternate in peak changed into noted.

Tapped Density (TD) = Weight of granules (m) /tapped volume of granules (v).

Here; m = weight of powder or granules (gm)

V = Tapped Volume (cm.3)

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4. Hausner's Ratio

Hausner's ratio indicates the flow properties of powder and measured by the ratio of tapped density to bulk density. Hausner's ratio was determined by the given formula.

Hausner's Ratio =Tapped density/ Poured density

Hausner's ratio <1.25 – Good flow = 20% Carr 1.25 –

Poor flow =33% Carr

5. Carr's Index (Compressibility Index)

Compressibility is the ability of powder to decrease in volume under pressure using bulk density and tapped density the percentage compressibility of powder were determined, which is given as carr's compressibility index. It is indirectly related to the relative flow rate. Carr's compressibility index was determined by the given formula

Carr's compressibility index (%) = [(TBD-LBD) X 100] / TBD

Evaluations of Immediate release Tablets

These tests are as following:-

- Appearance
- Thickness
- Hardness
- Weight variation
- Friability
- Disintegration
- Uniformity of dispersion
- Wetting Time
- Drug content
- In vitro Dissolution
- Stability studies

Appearance

The general appearance of tablet is its visual identity and all over elegance, shape, color, surface textures. These all parameters are essential for consumer acceptance.

Thickness

The thickness of the capsules turned into decided through using vernier calipers. Randomly 10 capsules decided on were used for dedication of thickness that expressed inMean± SD and unit is mm

Hardness

The hardness of tablet is an indication of its strength towards resistance of capsules to capping, abrasion or breakage under situations of storage, transportation and managing earlier than usage. Measuring the force required to interrupt the pill throughout assessments it. Hardness of10 capsules (randomly) from complete pill batch was decided through Monsanto hardness tester. Hardness measured in kg/cm2.

Weigh Variation

The weight variation test is carried out in order to make certain uniformity withinside the weight of capsules in a batch.The overall weight of 20 capsules randomly from wholebatch changed into decided and the common changed into calculated.The man or woman weights of the capsules have been also decided appropriately and the burden variation changed into calculated.

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Friability

Measurement of tablets friability enhancements other physical strength dimension, such as tablet crushing strength. Friability of tablet is determined for to ensure that tablets are stable to abrasion or not. Friability test can be done by using apparatus known as Roche Friabilator. Randomly weighed 20 tablets and are kept in plastic rotating drum attached to the device rotated for 100 revolution at 25 rpm. After that tablets are weighed again, % Friability is calculated as follow:

$\% \, Friability = (Wo - W)/ \, Wo * 100$

Where,

Wo = Initial weight of 20 tablets.

W = Weight after 100 revolution.

The weight loss would not be more than 1 percentage w/w.

Disintegration test:

The USP device to rest disintegration was six glass tubes that are "3 long, open at the top, and held against 10" screen at the bottom end of the basket rack assembly. One tablet is placed in each tube and the basket rack is poisoned in 1 liter beaker of distilled Water at 37± 20C, such that the tablets remain below the surface of the liquid on their upward movement and descend not closer than 2.5cm from the bottom of the breaker.

Uniformity of dispersion:

Two tablets were kept in 100ml water and gently stirred for 2 minutes. The dispersion was passed through 22 meshes. The tablets were considered to pass the test if no residue remained on the screen.

Wetting Time:

The wetting time of the tablets was measured using a simple procedure. Five circular tissue papers of 10cm diameter were placed in a petridish containing 0.2% w/v solution of amaranth (10ml). One tablet was carefully placed on the surface of the tissue paper. The time required for develop blue color due to amaranth water soluble dye on the upper surface of the tablets was noted as the wetting time.

Drug Content:

Powdered 10 tablets and 100mg drug equivalent Powder dissolved in appropriate media (buffer and 0.1N HCL). Volume make up to 100ml by this media, solution was filtered and diluted 100times and examined spectrophotometrically and further calculation carried out to detected drug content in 1 tablet.

In vitro drug release study:

In vitro drug release can be determine with the help of apparatus known as Dissolution apparatus. Contain dissolution media of volume 900ml and maintained at 37˚ ± 0.5˚C. Tablets are placed in cylindrical basket or directly kept in media and instantly run the device at appropriate rate. Within the time intermission specified (5, 10, 15 and 30min) or at each time interval withdraw the sample from midway of dissolution medium and top of the rotating basket, not less than 10mm from vessel wall and replace the same volume of fresh media. The samples are filter and from the filtrate 1ml is taken and dilute to 10ml. The sample was examined and then calculated to get a drug release. The drug released data were plotted and tested with zero order (Cumulative % drug released Vs time), first order (Log % Remained Vs time). The in-vitro dissolution kinetic parameters, dissolution rate constants, correlation coefficient and dissolution efficiency were calculated.

Stability study:

Stability is defined as the ability of a particular drug or dosage form in a specific container to remain within its physical, chemical, therapeutic, and toxicological specifications. Drug decomposition or degradation occurs during storage, because of chemical alteration of the active ingredients or due to product instability, lowering the concentration of the drug in the dosage form. Stability study of the dosage form must include a section for product characterization and

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another section to study the product stability during storage. Formulations are evaluated for their appearance, possible weight gain in drug content thickness, flatness, folding endurance, tensile strength, moisture content and moisture uptake, and invitro release study by keeping dosage form in different temperature and humidity condition after a specified time. The stability study indicates that the formulation is quite stable at different conditions of storage

Brand name	Generic name	Disease / indication	Dosage form
PROVACHOL®	Pravastatin	Cholesterol & Fast	Tablet
DIAVON®	Valsartan	Anti-hypertensive	Tablet
Advil®	Ibuprofen	NSAID	Tablet
Abilify Among®	Aripiprazole.	antipsychotic	Tablet
Albenza®	Albendazole	Anthelmintics	Tablet
Cipro XR®	Ciprofloxacin HCl	Anti-bacterial Agents	Tablet
COUMADIN®	Warfarin	Anti-coagulants	Tablet
Asendin	Amoxapine	Anti-depressants	Tablet/ Capsules
Valoid®	Cyclizine	Histamine H, Receptor Antagonists	Tablet
Daonil	Glibenclamide	Anti-diabetics	Tablet
Tagamet	Cimetidine	Gastro-intestinal Agents	Tablet
Trexall	Methotrexate	Antineoplastic agent	Tablet

Table 2: Various immediate release dosage form with marketed preparation

III. CONCLUSION

Immediate release of dosage form is applicable to a wide range of therapeutic agents involving generics, therefore adding value, i.e. 'supergenerics' for veterinary or human application. Almost one-third of the patients required rapid therapeutic action of drug, resulting in poor compliance with conventional drug treatment which leads to reduced overall treatment effectiveness. Sometime immediate onset of action is necessary, to accomplish these medical requirements, formulators have dedicate significant determination to improve a novel type of tablet dosage form for oral drug delivery, one that disintegrates and dissolves quickly with higher dissolution. The immediate release dosage form have combine benefits of easy administration of dosage form and compliance or convenience of dosing. These tablets are designed to release the medicaments with an enhanced rate. There are various techniques are developed above to improved manufacturing process for immediate release pharmaceutical product which are mechanically strong. An extension of market exclusivity, which can be provided by immediate release dosage form, leads to increased revenue, while so targeting underserved and under-treated patient population.

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