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Review Article

An Overview on Emerging Trends in Immediate Release Tablet Technologies

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Abstract

Tablet is the most popular among all dosage forms existing today because of its convenience of self-administration, compactness and easy manufacturing; however in many cases immediate onset of action is required than conventional therapy. To overcome these drawbacks, immediate release pharmaceutical dosage form has emerged as alternative oral dosage forms. The basic approach used in development tablets is the use of superdisintegrant, Tablet molding technique, Direct compression technique, Granulation technique, Mass extrusion technique which provide instantaneous disintegration of tablet after administration. The recent development in immediate release tablets such as Novel granulation technologies, electrostatic dry powder coating process, Novel Hole Technology in Fast Dissolving Tablets, Hot-Melt Extrusion and Injection Molding also provides an opportunity for a line extension in the market place. Now a day, immediate release formulations are similar to many sustained release formulations that are now commonly available.

Keywords: Immediate release; Granulation; Excipients; Drug Delivery

Introduction

Oral route of administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance. Also solid oral delivery systems does not need sterile conditions and are therefore, less expensive to manufacture. Patient compliance, high precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice. There is requirement for new oral drug delivery system because of poor patient acceptance for invasive methods, requirement for investigation of new market for drugs and combined with high cost of disease management. Developing new drug delivery techniques and that utilizing in product development is critical for pharma companies to survive this century [1,2].

The term 'immediate release' pharmaceutical formulation is the formulation in which the rate of release of drug and/or the absorption of drug from the formulation, is neither appreciably, nor intentionally, retarded by galenic manipulations. Immediate release dosage form is those which break down quickly and get dissolved to release the medicaments. In the present case, immediate release may be provided of an appropriate pharmaceutically acceptable diluent or carrier, which diluent or carrier does not delay, to an appreciable extent, the rate of drug release and/or absorption [3-5].

Immediate release drug delivery is suitable for drugs having long biological half-life, high bioavailability, lower clearance and lower elimination half-life. But main requirement for immediate release dosage form is poor solubility of the drug and need the immediate action of drug to treat undesirable imperfection or disease [6] (Table 1,2).

Excipients used in Immediate Release Tablets

Excipients require a thorough knowledge of the chemistry to prevent interaction with the actives. Deciding the expense of these ingredients is another issue that needs to be addressed by formulators. The part of Excipients is imperative in the definition of quick dissolving tablets. These inactive food-grade ingredients, when added in the formulation, impart the desired organoleptic properties and product efficacy. Excipients are general and can be utilized for a broad range of actives, aside from actives that need masking agents.

Bulking agents

Bulking agents are significant used in the formulation of fast-melting tablets. The material contributes elements of a diluents, filler and cost reducer. Bulking agents enhance the textural characteristics that in turn improve the disintegration in the mouth, other than; adding bulk also lessen the concentration of the active in the

Table 1: Advantages and Disadvantage [7-11].

Advantages	Disadvantages
Unit dose system and Long shelf life	Frequent dosing is required for those drugs which having short half-life
Cost effective	Swallowing difficulties with pediatrics and geriatrics
Stability, bioavailability is increased with immediate release	For drugs with bitter taste, bad odour or drugs that are sensitive to oxygen may require encapsulation or coating of tablet for minimizing Bioavailability problems
Maximum drug loading is possible	Chance of GI irritation for high concentrations medicaments
Effective in lower concentrations	Drug release at a time may produce high plasma concentration which leads to toxicity

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Table 2: Types and classes of tablets [12-16].

Oral Tablets for Ingestion	Tablets Used in the Oral Cavity	Tablets Administered by Other Routes	Tablets Used to Prepare Solutions
1. Single compressed tablets 2. Multiple compressed tablets 3. Layered or multilayered tablets 4. Film coated, Sugar coated and chocolate-coated tablets 5. Delayed release and enteric-coated tablets 6. Compression-coated tablets 7. Chewable tablets	1. Buccal tablets 2. Sublingual tablets 3. Lozenges 4. Dental cones	1. Implantable tablets 2. Vaginal tablets	1. Effervescent tablets 2. Dispersible tablets 3. Hypodermic tablets 4. Tablet triturates

composition. The suggested bulking agents for this delivery system should be more sugar-based, e.g. mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch for higher aqueous solubility and good sensory perception.

Lubricants

Lubricants, however not key Excipients, can assist help with making these tablets more acceptable after they disintegrate in the mouth. Lubricants remove grittiness and help the drug transport mechanism from the mouth down into the stomach. e.g. Magnesium stearate, Stearic acid.

Super disintegrants

A disintegrant is an Excipients, which is included to a tablet or capsule blend to aid in the breakup of the compacted mass when it is put into a fluid environment e.g. cross carmallose sodium, sodium starch glycolate, ludiflash.

Advantages:

- Effective in lower concentrations
- Less effect on compressibility and flow ability
- More effective intragranularly

Some super disintegrants are:

a) Sodium Starch Glycolate (Explotab, primogel) utilized in concentration of 2-8% & optimum is 4%.

Mechanism of Action: Quick and extensive swelling with minimal gelling. Microcrystalline cellulose (Synonym: Avicel, celex) utilized in concentration of 2- 15% of tablet weight.

b) Cross-linked Povidone (crospovidone) (Kollidone) utilized in concentration of 2-5% of weight of tablet, that completely insoluble in water.

Mechanism of Action: Water wicking, swelling and possibly some deformation recovery. Quickly disperses and swells in water, but does not gel even after prolonged exposure. The rate of swelling is high as compare to other disintegrants.

c) Low-substituted hydroxyl propyl cellulose, which is insoluble in water. Quickly swells in water. Grades LH-11 and LH-21 shows the greatest degree of swelling. Many grades can also provide some binding properties while retaining disintegration capacity. It used in concentration 1-5%.

d) Cross linked carboxy methyl cellulose sodium (i.e. Ac-Di-sol) Croscarmellose sodium: Mechanism of Action: Wicking occurs due to fibrous structure, swelling with minimal gelling. Recommended Concentrations: 1-3% Direct Compression, 2-4% Wet Granulation [17-21].

Conventional Techniques for Immediate Release Tablets

Conventional technique used in the preparation of immediate release tablets

Tablet molding technique

Direct compression technique

Granulation technique

Mass extrusion technique

Immediate release solid dosage forms prepared by solid dispersions

Disintegrants addition

Many technologies are available to manufacture immediate release tablets. The most widely used preparation methods are moulding, lyophilisation or freeze drying, direct compression, spray drying and sublimation.

Tablet molding technique

Water-soluble ingredients are utilized in tablet molding technique which facilitate tablet to broken down and disintegrate quickly. A hydro alcoholic solvent use to soak powder mix and is molded in to tablet utilizing compression pressure lower than utilized in conventional tablets compression. The solvent is then evacuated via air drying. Two issues generally experienced are mechanical strength and poor taste masking characteristics in this technique.

Direct compression method

In this procedure tablets are compressed specifically from powder blend. No uncommon treatment is required for the powder mix. Amongst all tablets preparing strategies, direct compression is the most developed technology.

Granulation technique

Immediate release tablets are manufactured by granulation technique. In this technique generally two methods are utilize, one is wet granulation another is dry granulation. Among this wet granulation is most widely used method to prepare a tablet.

Mass-extrusion

Here softening of active mix done with solvent mixture of water-soluble polyethylene glycol and methanol and then expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments utilizing heated blade to make tablets. In case of bitter drug granules may be coated with the use of dried cylinder to achieve taste masking.

Immediate release solid dosage forms prepared by solid dispersions

When formulating immediate release solid dosage forms from solid amorphous dispersion for oral administration to a utilize environment such as the GI tract of an animal such as a human, it is often desirable to maximize the amount of dispersion present in the dosage form.

Disintegrants addition

Excipients called disintegrant s are added to a tablet or capsule blend to help in separation of the compacted mass when it is put into a liquid domain. Disintegrant are utilized in immediate release tablets to improve dissolution and hence bioavailability of any drug. Disintegration is one of most important process. "Superdisintegrant" newer substances are more effective at lower concentrations with good disintegrating efficiency and mechanical strength. [10,22-24].

Recent Development in Immediate Release Tablets

Miniaturized approach for excipient selection

The miniaturized Approach is high-throughput stage to comprehend the impact the influence of Excipients on the performance of oral solid dosage forms during early drug advancements. For the fruitful manufacturing of tablets, different Excipients such as binders, diluents, disintegrants, and lubricants are required. Despite the fact that Excipients are considered as inactive ingredients and are added to enhance the functionality of the dosage forms, they may have harmful impact on the performance of the dosage forms at different stages during manufacturing, storage and/or dissolution. This may be attributed to different properties of Excipients, for e.g. water-sorbing potential, phase transformation behavior, hydrophobicity, solubility, microenvironment pH, crystallinity and chemical incompatibility with Active Pharmaceutical Ingredient (API). Thus, it is essential to investigate the impact of Excipients on the performance of oral solid dosage forms. A well-designed Excipients screening study during early advancement can help selecting suitable Excipients that enhance the usefulness of the API. Also, it can help in the elimination of Excipients having harmful impact on the performance of API. This approach can be used for Excipients selection and for early-stage activity testing of active pharmaceutical ingredient intended for oral solid dosage form.

Unexpectedly, one of the significant difficulties during early drug development is negligible accessibility of candidate drug compounds limiting the possible batch sizes and the number of studies that can be performed. Consequently, it is essential to create approaches that empower accomplishing the data about the candidate drug with minimal use of resources. The current study introduces a miniaturized approach for the combined examination of the impact of the Excipients and processing-induced stress (wet granulation and compression) on the activity of oral solid dosage forms (tablets) [25].

Novel granulation technologies

The current technologies utilized for granulation contain steam granulation; Moisture Activated Dry Granulation (MADG), Moist Granulation Technique (MGT), Thermal Adhesion Granulation Process (TAGP) and foam granulation etc. have their own advantages and overcome the disadvantages of conventional granulation process for e.g. dust generation or harmful impact of heat as drying step.

Pneumatic Dry Granulation (PDG): This is a new drug method for automatic or semi-automatic preparation of granules. It modifies the drug load along with disintegration time and tablet hardness.

The PDG Technology enables preparation of porous granules having excellent compressibility and flow ability characteristics. The pneumatic dry granulation process is fit for granulating virtually any pharmaceutical solid dosage ingredient. PDG Technology has been utilized with prevalent results in advancement of tablets having fast release, controlled release along with measured-dose, and orally disintegrating tablets. The technology can be utilizing for practically any solid dosage pharmaceutical product.

PDG technology can achieve:

- High drug loading, even with difficult APIs and combinations
- Taste masking
- Excellent stability

Nowadays, wet granulation is the most usually utilized. This process can granulate any pharmaceutical solid dosage ingredient. This technology is utilized for the development of tablets with quick and controlled-release along-with fixed dose and orally disintegrating tablets. PDG has replaced wet granulation technique.

Freeze Granulation Technology (FGT): This system has been received by Swedish Ceramic Institute (SCI) which empowers safeguarding of the homogeneity from suspension to dry granules. A powder suspension is sprayed into fluid nitrogen, the granules are frozen promptly. In a subsequent freeze-drying the granules are dried by utilizing sublimation of the ice without any segregation effects as in case of conventional drying in air. The subsequent granules will be spherical and free flowing with ideal homogeneity. This procedure helps in easy crushing to homogeneous and dense powder compacts in preparing operation.

Foamed Binder Technologies (FBT): FBT from the Dow Chemical company helps in accomplishing faster, simpler and more secure wet granulation. This method utilizes METHOCEL polymers and greatly enhanced binder distribution in the formulation blend and yields a remarkable array of processing advantages. It helps in decreasing water prerequisites, enhanced reproducibility. It helps in eliminating spray nozzles and their numerous variables in granulation preparing equipment.

One can without much of a stretch use it with recognizable high shear, low shear, or fluid bed granulation equipment, in both laboratory and production scale settings. Our evaluation also demonstrates it yields well known metrics for particle size distributions, solid dose physical properties and dissolution profiles.

It gives advantage of tremendous increase in the liquid surface area and volume of polymeric binder foams to enhance the distribution of the water or binder system throughout the powder bed of pharmaceutical formulation of solid dose.

Melt Granulation Technology (MGT): This is method with the assistance of which granules are obtained through the incorporation

of either a molten binder or a solid binder which melts during the process. This technique is additionally called melt agglomeration and thermoplastic granulation.

Steam Granulation Technology (SGT): This method is a change of wet granulation. We utilize steam as binder rather than water. Pure steam is a transparent gas. At a standard temperature and pressure (mixed with air, but in equilibrium with liquid water) it involves around 1600 times volume of an equal mass of fluid water. The granulation of particles includes the injection of appropriate amount of fluid as steam. This steam injection strategy utilizes the utilization of steam at 150 0C and tends to deliver.

Moisture Activated by Dry Granulation (MADG): This technology is also called "Single pot granulation".

- Moisture is utilize in order to activate the granules formation but the granule drying process is not needed due to moisture absorbing material such as microcrystalline cellulose.
- This technique comprises of two stages, wet agglomeration of powder blend followed by moisture absorption stages.
- 1-4% water is added first keeping in mind the end goal to agglomerate the blend of API, a binder and excipients. Moisture absorbing material such as MCC alongside potato starch is added to absorb the excess amount of moisture.
- After the lubricant has been blended, the blend obtained can be compressed directly into the tablets. Hence, this process offers few advantages of wet granulation.

Advantages:

- Very little granulating fluid is utilized.
- Drying time is diminished and the granules created have good flow ability.
- Single production equipment such as high shear granulator is utilized.
- No equipment change and lower tablet capping.
- No over and under granulation.
- It is applicable for building up a controlled released formulation.

Thermal Adhesion Granulation Process (TAGP): It is useful in manufacturing tableting formulations. This procedure is performed under low moisture content or low content of pharmaceutically acceptable solvent by subjecting a blend including one or more diluents and active ingredients; a binder; alternatively a disintegrant to warm at a temperature ranging from 30°Cto 1300°C in a closed system under blending by tumble rotation until the formation of the granules happens.

It utilizes less water than the wet granulation strategy. It gives granules with very good flow properties and binding capacity to form tablets which have low friability with adequate hardness and have a high loading of active substances whose tableting is poor. It additionally minimize the generation of dust particles during the preparation. This method serves to contain fine- powder active ingredients whose spread or loss from system is not desirable because of their cost or biological activity.

TOPO (TOPO Granulator) Technology: HERMES PHARMA has built up a unique technology for doing single pot granulation. This procedure requires a little amount of fluid to begin the chain reaction. Pure water or water-ethanol blend are utilized.

TOPO Technology produces granules for tablets which in any event contains one solid crystalline, an organic acid and one alkaline or alkaline earth metal carbonate that reacts with the organic acid in aqueous solution to produce carbon dioxide. Therefore there are no solvent residues in the final products; granules have excellent hardness and stability. TOPO Granulator was utilized for creating for effervescent tablets following TOPO vacuum granulation technology, patented by Hermes Pharma. It includes granulation under vacuum to prevent uncontrolled chain reaction.

Continuous Flow Technology: This technology does not require any liquid to begin the chain reaction. For this situation granulation is done in slanted drum into which powder is fed at one end and granulate is removed at the other. The procedure produces granule with surface ensured by inactive component that do not harm the sensitive API. This technology can formulate upto12 tons of granules every day.

Advantages:

- Sensitive APIs are secured.
- Granules and effervescent become less sensitive to humidity and high temperature.
- Granules form greatly stable products.
- No solvent residues in the finished products.

Granulex technology: This technique performs both coating and powder layering process. Different coating and powder layers demonstrate the precision and control of a granulex rotor process, including the production of non-pareil.

Key-Features: Unique, Efficient granulation forms. Granules delivered are thick and spherical in shape. One Pot Processing: It has the capacity of drying the product in the same handling chamber. This strategy in blend with 12 bar development gives a true one pot system which is ideal for manufacturing of highly potent and costly pharmaceutical compounds [26,27].

Hot-melt extrusion and injection molding for continuous manufacturing of immediate-release tablets

In the most recent 10 years, the enthusiasm for the potential use of Continuous Manufacturing (CM) to the pharmaceutical field has been growing. 3-6cm comprises in creating/preparing, without interference, materials generally maintained in movement and experiencing chemical reactions or mechanical/heating treatments. As indicated by the US Food and Drug Administration (FDA), continuous processing has the potential for enhancing product quality, and the industry is encouraged to genuinely consider a shift in this direction.

Advantages related to CM are evident. It could lessen the time and expenses of development simply by avoiding the moving of

materials among facilities, constraining the put away amount of dangerous chemicals thus enhancing sustainability, overcoming the requirement for stopping, reconfiguration and testing between batches as well as that for scaling up. A model Immediate-Release (IR) tablet was accomplished by extruding and injecting an essential thermoplastic formulation, made up of an in situ synthesized model drug and Polyethylene Glycol (PEG), into appropriately formed mold. Hot-processing methods, such as Hot-Melt Extrusion (HME) and Injection Molding (IM), would particularly be suitable for satisfying the requirements of CM. HME has successfully been applied to improve the dissolution rate/bioavailability of drugs by advancing the formation of solid dispersions with thermoplastic carriers, and, again, a couple of products reached the marketplace. With respect to IR dosage forms, starch-based injection-molded shells were proposed as a different option to dip-molded gelatin capsules. Furthermore, powders or granules got from milling of extruded dispersions may be compressed to give IR tablets. The utilization of these processing methods would also result in the possibility of carrying out solvent-free processes, overcoming blending and/or compaction problems, patenting the obtained products and improving the relevant adaptability as far as size/shape [28].

Novel hole technology

The fundamental target of this technology is to design and development of Fast dissolving tablets by novel hole technology. It is a novel way to deal with lessening the disintegration time and build the patient compliance. By utilizing this technology total surface area of the tablet increment because of hole formation. Quick breaking of the tablet happens because of the liquid goes into the hole formed in the tablet.

A few technologies were developed to improve the disintegration time but the tablets manufactured by hole technology have expanded surface area due to formation of hole and expanded pore structure. The principle included in hole technology is sublimation. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride might be compressed along with different excipients into a tablet. This added volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets made by this technology have reported to usually disintegrate in 10-20 seconds. The tablets manufactured with hole technology demonstrated all the parameters like hardness, friability, weight variation inside the limits [29].

A novel electrostatic dry powder coating process

Polymer film coat is mostly applied in pharmaceutical dosage forms to accomplish aesthetic quality, taste masking, enhancement of stability, and modification of drug release. The coating procedure is generally based on the dissolution or dispersion of polymeric materials in organic or aqueous solvents. The utilization of organic solvent experiences the toxicological, environmental, expense and safety-related issues. These disadvantages have been solved by the introduction of aqueous-based coating technology. However, aqueous film coating need a slower drying process and high energy input because of the high heat of evaporating water (539.4cal/ g). Different issues experienced with aqueous film coating are lower solid content in the coating solution and risk of microbial contamination. The presence of water during the coating process and residual moisture in the film can influence stability of certain water sensitive drugs. Thus, eliminating solvents in the pharmaceutical film coating is thought to be a powerful approach to lessen production cost, improve process efficiency and enhance product quality.

An electrostatic dry powder coating process for pharmaceutical solid dosage forms was produced for the first time by electrostatic dry powder coating in a pan coater system. Two immediate release coating compositions with Opadry® AMB and Eudragit® EPO were effectively applied using this process. A fluid plasticizer was sprayed onto the surface of the tablet cores to expand the conductivity of tablet cores to improve particle deposition, electrical resistivity lessen from greater than 1×1013Ωm to less than 1×109Ωm, and to bring down the Glass Transition temperature (Tg) of the coating polymer for film forming in the pan coater. The utilization of fluid plasticizer was followed by spraying charged coating particles utilizing an electrostatic charging gun to improve the uniform deposition on tablet surface. The electrostatic powder coating technique can produce smooth and uniform coating film and has been exhibited as a promising different option to conventional aqueous-based coating process [30].

A flexible-dose dispenser for immediate 3D printed tablet

Personalized medicine provides patients with a superior treatment that thinks about their Pharmacogenomics, anatomical and physiological particulars. One major clinical part of personalised medicine is individualizing the dose to suit an individual patient's requirement. It is of significant importance to change standardized dose tablet regimes with a dynamic-dose dispenser, which gives fast and effective assembling to individual patient's needs. For a tablet preparation technique that meets the demands of personalised medicine, a safe and effectively adjustable dispensing station must be made. The station ought to be worked through a basic client interface with negligible operation preparing required and can be associated with the more extensive human service system. Clearly, such criteria cannot be satisfied by traditional tableting methods. The utilization of 3D printing as a adaptable option strategy to traditional tableting techniques was first created using powder based 3D printing technologies. Fused Deposition Modelling (FDM) is a broadly utilized and affordable bench top 3D printing technique. The capability of FDM-based 3D printers to consolidate drug molecules has already been investigated utilizing economically accessible PVA filaments. The capability of this printing technology to give a mini-dispensing dose controlling station by controlling the volume of the printed design through an order from computer software. Nevertheless, past endeavors with FDM-based 3D printing shows a few constraints, for example, limited drug loading, the utilization of non-pharmaceutical grade ingredients, high temperature and fundamental tablet designs [31].

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

Angle of repose

Angle of repose was measured by using funnel method. The precisely weighed blend was taken in a funnel. The height of the funnel was balanced in such a way that the tip of the funnel just touches the apex of the heap of blend. The drug (as solid dispersion)-excipient blend was permitted to flow through the funnel freely on to the surface. The diameter of the powder cone was determined and angle of repose was calculated using the following equation.

Tan θ = h/r

Angle of repose (θ) = tan-1 (h/r)

Where,

h = height of the powder pile

r = radius of pile circle

Bulk Density (BD)

Weigh accurately (M) 25g of granules, which was previously passed through #20 sieve and transferred in 100ml graduated cylinder. Carefully level the powder without compacting, and read the apparent volume (V_0).Calculate the apparent bulk density in gm/ml by the following formula- Bulk density (BD) = M/V_o

Tapped Density (TD)

Weigh accurately (M) 25g of granules, which was previously passed through #20 sieve and transfer in 100ml graduated cylinder. Then mechanically tap the cylinder containing the sample by raising the cylinder and allowing it to drop under its own weight utilizing mechanically tapped density tester that provides a fixed drop of 14±2mm at a nominal rate of 300 drops per minute. Tap the cylinder for 500 times initially and measure the tapped volume (V1) to the nearest graduated units, repeat the tapping an additional 750 times and measure the tapped volume (V2) to the nearest graduated units. If difference between two volumes is less than 2%, then volume (V2) is final volume. Calculate the tapped density in gm/ml by the following formula-

Tapped density (TD) = M/VT

Where, VT = Tapped volume or final volume

Carr's Index

The Compressibility Index of the powder blend was measured by Carr's compressibility index. It is easy test to evaluate the BD and TD of a powder and the rate at which it packed down. The formula for Carr's Index is as below-

Carr's Index= [(TD-BD)*100]/ TD

Hausner's Ratio

The Hausner's ratio is a number that is correlated to the flow ability of a powder or granular material.

Hausner's ratio = TD/BD [32].

Evaluation of Immediate Release Tablets

Thickness

Hardness

Friability

Weight variation

Drug content

Disintegration time

In vitro Drug release study

Thickness

The thickness of the tablets was measured by using Vernier calipers. Randomly 10 tablets selected were used for measurement of thickness that shown in Mean±SD and unit is mm.

Hardness

The hardness of tablet is indicating its strength against resistance of tablets to capping, abrasion or breakage under conditions of storage, transportation and handling before utilized. Measuring the force needed to break the tablet across tests it. Hardness of 10 tablets (randomly) from whole tablet batch was measured by Monsanto hardness tester. Hardness unit is kg/cm^2.

Friability test

Friability is the loss of weight of tablet in the container due to removal of fine particles from the surface during transportation or handling. Roche friabilator was utilized for finding the friability of the tablets. For tablets having average weight of 0.65g or less take a sample about 6.5g of whole tablets and for tablets having average weight of more than 0.65g take a sample of 10 whole tablets. Roche friabilator is rotated at 25rpm for 4 minutes for 100 rounds. The tablets were dedusted and weighed again. The percentage of weight loss was calculated using the formula:

% f = (w0 – w1) x 100/w0

Here, % f = Percentage friability

W0 = Initial weight (Before test)

W1 = Final weight (After test).

Weight variation

The weight variation test is performed in order to ensure uniformity in the weight of tablets in a batch. The total weight of 20 tablets that selected randomly from whole batch was determined and the average was calculated. The individual weights of the tablets were also measured accurately and the weight variation was calculated.

Drug content

10 tablets were powdered and 100mg drug equivalent powder dissolved in suitable media buffer or 0.1N HCl. Volume of the solution made up to 100ml by that media. Solution was filtered and diluted 100times and analyzed spectrophotometrically and further calculation carried out to determine drug content in one tablet.

Disintegration time

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 placed in 1L beaker of distilled water at 37±2°C, such that the tablets remain below the surface of the fluid on their upward movement and descend not closer than 2.5cm from the bottom of the beaker.

In vitro drug release studies

The immediate release tablets are subjected to *in vitro* drug release studies in pH 6.8 phosphate buffer or 0.1N HCl for 30 minutes to get the capacity of the formulation for giving immediate drug delivery. Drug release studies were completed in dissolution test apparatus using specified volume 900ml of dissolution media kept up at 37±2°C. The tablets are kept in the cylindrical basket or directly placed in medium with paddle then rotated at 100rpm. 5ml of the sample from the dissolution medium are withdrawn at each time interval (5,10,15 & 30 minutes) and 5ml of fresh medium was supplanted every time. The samples were sifted and from the filtrate 1ml was taken and diluted to 10ml. These samples were analyzed spectrophotometrically and further calculation was completed to get 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 effectiveness were calculated [33-35].

Conclusion

Most of the patients need rapid therapeutic action of drug, resulting in poor compliance with conventional drug therapy which leads to minimize therapy effectiveness. A new approach i.e. immediate release has been developed which offers the combined advantages of ease of dosing and convenience of dosing. These tablets are designed to release the medicaments with an enhanced rate. Due to the problems of the conventional technologies as highlighted above, there is an unmet need for improved manufacturing processes for immediate release pharmaceutical form that are mechanically strong, allowing ease of handling and packaging and with production costs similar to that of conventional tablets. To fulfill these medical requirements, formulators have devoted considerable effort to developing a novel type of tablet dosage form prepared by novel techniques such as Novel granulation technologies, electrostatic dry powder coating process, Novel Hole Technology in Fast Dissolving Tablets, Hot-Melt Extrusion and Injection Molding for Continuous Manufacturing of Immediate-Release Tablets for oral administration, one that disintegrates and dissolves rapidly with improve dissolution and also for selection of Excipients novel Miniaturized approach is used.

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