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IMMEDIATE DRUG RELEASE TABLET DOSAGE FORM: A COMPREHENSIVE REVIEW

Ajay Kumar Saini*[1], Dr Vishal Garg[2], Dr Alok Upadhyay[3]

[1]Ph.D Research Scholar, Sunrise University, Alwar (Rajasthan), India

[2]Jaipur School of Pharmacy, Maharaj Vinayak Global University, Jaipur.

[3]Director Mascot College of Pharmacy, Bareilly

ABSTRACT:

Although there are lots of oral dosage forms available for drug administration still tablet is the best among the all of the other dosage forms survive today because it is easy to self administration, lightest and compact in nature, easy to swallow and easy to manufacture; although in conventional tablet there is major drawback is in delayed onset of action. In today's medication therapy sometimes immediate onset of action is mandatory. So that to overcome these drawbacks, immediate release dosage form has emerged as alternative oral dosage forms. Immediate drug release dosage forms disintegrate rapidly in stomach after administration with improve rate of dissolution. The basic approach used in development of tablets is the use of superdisintegrants like carboxy methyl cellulose (Croscarmellose), Cross linked Poly-vinyl pyrrolidone or crospovidone (Polyplasdone), Sodium starch glycolate (Primogel, Explotab) etc. Recently immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to administer and lead to better patient compliance.

IndexTerms: Immediate release dosage form, Superdisintegrants, Onset of action and polymers

INTRODUCTION:

Oral drug administration is the most popular route for systemic effects because of easy administration, ease of ingestion, easy to self-administration, most convenient, pain avoidance, versatility and most importantly patient compliance. Also oral dosage forms like tablet does not need sterile conditions and are therefore, less expensive to manufacture compare to other dosage forms, likewise immediate release tablets are more acceptable among all the other modified tablets. In solid dosage form tablet is preferred because it has batter patient compliance, high precision dosing, and manufacturing efficiency compare to other dosage forms. Many patients require quick onset of action in particular therapeutic condition and consequently immediate release of medicament is required. It is estimated that 50% of the population is affected by this problem which results in a high incidence of ineffective therapy.[1-3]

On the basis of drug-release profile, tablets can be divided into three types, immediate release, extended release and delayed release tablet. In case of immediate release tablets the content is intended to be released rapidly after drug administration, or the tablet is dissolved and administered as a solution.[4,5] This is the most common type of tablet and includes disintegrating, chewable, effervescent, sublingual and buccal tablets. The developments of enhanced oral protein delivery technology by immediate release tablets which may release the content at an enhanced rate are very promising for the absorption of poorly soluble drugs as high molecular weight protein and peptide. They design to disintegrate and release their medication without any special rate controlling features.[6] In pharmaceutical industries,

manufactures of generic tablets are usually focused on the optimization of the excipients mixture composition to obtain a product that meet established standard. [7]

These types of dosage form allow a producer to extend market exclusivity, while offering patients a convenient dosage form or dosage regimen. [8] Currently immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to administer, has quick onset of action, economical and have improved patient compliance. This is also a way for expanding markets; enhance drug life and generating opportunities. In development of immediate release tablets superdisintegrants are main choice of excipients because they effectively results into the immediate disintegration, release and absorption of the medication after administration into the body. [2,9] Cross carmellose sodium which is commonly known as Ac-di-sol is cross linked carboxy methyl cellulose sodium, Cross linked Poly-vinyl pyrrolidone or crospovidone (Polyplasdone) and sodium starch glycolate or carboxy methyl starch are majorly used superdisintegrants. [4,10]

Immediate release drug delivery system:

Dosage form which disintegrates and dissolve quickly to release the drug content. Immediate release of medication may be provided by way of an appropriate diluents or carrier, in which diluent or carrier does not prolong, to an appreciable extent, the rate of drug release and/or absorption. Immediate release excludes formulations which are adapted to provide for "controlled", "modified", "extended", "prolonged", "sustained" or "delayed" release of drug. [11,12]

Immediate release means the content of drug from the formulation reached quickly to the GIT, to body tissues and/or into systemic circulation.[13] Drug release in GIT is controlled by pH conditions such as pH=1 to 3, means acidic pH. In one aspect of the development of a formulation as described herein with a compound of formula (I), or an acid addition salt thereof, in crystalline form releases drug under a range of pH conditions. In another aspect of the development a dosage form as described herein with a compound of formula (I), or an acid addition salt thereof, releases the content under pH conditions such as pH=1 to 3, especially at, or about, pH=1. Thus, formulations of the invention should release at least 70% of active constituents within an hour of administration, whether this be oral or parenteral. [14-15]

Salient Features of Immediate release drug delivery system [12, 14, 16]

- ✓ For immediate release delivery system, drugs should have longer half life.
- ✓ Content release should be quick and complete in one shot.
- ✓ From immediate release dosage form high bioavailability is expected.
- ✓ Low clearance and low elimination half life are also requred for immediate release drug delivery system.
- ✓ Major criteria for selection of drug is that drug should be poorly soluble and need the immediate action of drug to treat unwanted defect or disease Rapid drug therapy intervention is possible.
- ✓ New business opportunities like product differentiation, line extension and lifecycle management, exclusively of product promotion.

Difficulties with Existing Oral Dosage Form: [17-18]

- It is difficult to take powder and liquids dosage form if patient is suffering from tremors. Gastrointestinal ulcer may occur in case of dysphasia physical obstacles.
- Swallowing of solid dosage forms like tablet and capsules produce difficulty for young adult of incomplete development of muscular and nervous system and elderly patients suffer from dysphasia.
- Liquid dose like syrup, suspension and emulsion are packed in multi dose container; so to achieve uniformity in the drug content of each dose may be difficult.
- Buccal and sublingual formulation may cause irritation to oral cavity, so patients avoid using such medications.
- Cost of formulation is also a factor as parenteral formulations are most costly and cause discomfort also.

Desired Criteria for Selection of Immediate Release Drug: [19-22]

Immediate release formulation should disintegrate or dissolve in the stomach within a very less period after drug administration.

- If drug is solid it should disintegrate in the stomach in short time.
- In the case of liquid medicament it should be compatible with taste masking.
- Exhibit low sensitivity to environmental factors such as humidity, temperature etc.
- Drug should have pleasant mouth feel.
- It should not left minimal or no residue in the oral cavity after administration.
- It should be manufactured easily by using conventional processing technique at low production cost.
- Rapid dissolution and absorption of drug, which may produce desired rapid onset of action.
- Drug should be in micronized form in an amount of 20 mg to 400 mg which is sufficient to provide the desired daily dose.
- Be portable without fragility concern.

Merits of Immediate Release Drug Delivery System: [12, 23, 24]

- ✓ Immediate Release medication improves patient compliance
- ✓ This drug delivery system enhances stability and bioavailability of drug.
- ✓ Suitable system for modified drug release like controlled/sustained release system.
- ✓ Its mechanism allows high drug loading so dose dumping problem avoided.
- ✓ This system has ability to produce benefits of liquid drug in the form of solid formulation.
- ✓ More flexibility for adjusting the dose
- ✓ Adaptable and amenable to existing production and packaging tools so system is cost- effective
- ✓ Improved solubility of the pharmaceutical composition;
- ✓ Decreased disintegration and dissolution times for immediate release oral dosage forms.
- ✓ This system gives rapid onset of action.

Disintegrants Used in Immediate Release Drug Delivery System: [12, 20]

Excipients such as **disintegrants** are added to a tablet or capsule blend to help in separation of the compacted mass when it is put into a liquid media. Disintegrant are used in immediate release formulations to improve dissolution and hence bioavailability of any drug. Disintegration is one of most important process. This demands a detailed knowledge about the chemistry of such excipients to prevent interaction with the active ingredients. The role of such excipients is important in the development of fast-dissolving tablets. Excipients are used to produce dosage forms that can reduce the number of doses by modifying the rate of drug release or improve drug delivery by targeting drug release in a specific region in the gastrointestinal tract where drug absorption is the highest. These inactive food-grade ingredients, when incorporated in the formulation, impart the required organoleptic properties and product efficacy.

Determining the cost of these ingredients is another issue that needs to be addressed by formulators. Excipients are general and can be used for a broad range of actives, except some actives that require masking agents.

Super Disintegrants [20,25]

A disintegrant is an excipient, which is added to a tablet blend to aid in the break-sup of the compacted mass when it is put into a fluid environment.

Advantages:

1. These are effective even in low concentrations.
2. These have very less effect on compressibility and flow property
3. Such disintegrants are more effective intragranularly.

Most commonly used Super disintegrates are Sodium Starch Glycolate (Explotab, primogel) used in concentration of 2-8 % and optimum is 4%. Following are some super disintegrants which is used in immediate release formulation:

1) Sodium Starch Glycolate (Explotab, primogel) used in concentration of 2-8 % & optimum is 4%. It acts by rapid and extensive swelling with minimal gelling of drug. Microcrystalline cellulose (Synonym: Avicel, celex) used in concentration of 2-5% of tablet weight.

2) Cross-linked Povidone (crospovidone) (Kollidone) used in concentration of 2-5% of weight of tablet. Kollidone is insoluble in water completely. It works by water wicking, swelling and possibly some deformation recovery. It rapidly disperses and swells in water, but does not form gel even after prolonged exposure. Swelling rate is more compared to other disintegrants. Surface area to volume ratio is also more than other disintegrants.

3) Low-substituted hydroxyl propyl cellulose, which is insoluble in water. This is also 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. It is used in concentration 1-5%.

4) Cross linked carboxy methyl cellulose sodium (**Ac-Di-sol**) Croscarmellose sodium: It acts by wicking due to fibrous structure, swelling with minimal gelling. Effective Concentrations is 1-3% in Direct Compression method while 2-4% in Wet Granulation method.

Candidate for Immediate Release Oral Dosage Form: [15, 16]

Anxiolytic, Sedatives, Hypnotics and Neuroleptics:

Alprazolam, barbitone, bentazepam, amylobarbitone, bromazepam, bromperidol, brotizolam, butobarbitone, carbromal, chlordiazepoxide chlormethiazole, chlorpromazine, clobazam, clotiazepam,clozapine, diazepam, droperidol,ethinamate, flunanisone, flunitrazepam, fluopromazine, flupenthixol decanoate, fluphenazine decanoate, flurazepam, haloperidol.

Anti-fungal Agents: Amphotericin, butoconazolenitrate, clotrimazole, econazolenitrate, fluconazole, flucytosine,griseofulvin, itraconazole,ketoconazole, miconazole, natamycin, nystatin, sulconazole nitrate, terbinafine HCl, terconazole, tioconazole, undecenoic acid.

Anti-bacterial Agents:

Benethamine penicillin, cinoxacin, ciprofloxacin HCl, clarithromycin, clofazimine, cloxacillin, demeclocycline, doxycycline, erythromycin, ethionamide, Imipenem ,nalidixic acid, nitrofurantoin, rifampicin, spiramycin, sulphabenzamide, sulphadoxine , sulphamerazine ,sulphacetamide, sulphadiazine, sulphafurazole, sulphamethoxazole, sulphapyridine, tetracycline, trimethoprim.

Analgesics and Anti-inflammatory Agents:

Aloxiprin, auranofin,azapropazone, benorylate, diflunisal, etodolac, fenbufen, fenoprofen calcim, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamic acid, mefenamicacid, nabumetone, naproxen, oxaprozin,oxyphenbutazone, phenylbutazone,piroxicam, sulindac.

Anti-depressants:

Amoxapine, ciclazindol, maprotiline HCl, mianserin HCl, nortriptyline HCl, trazodone HCl, trimipramine maleate.

Anti-diabetics:

Acetohexamide, chlorpropamide, glibenclamide, gliclazide, glipizide, tolazamide, tolbutamide.

Anthelmintics:

Albendazole , bephenium, hydroxynaphthoate , cambendazole, dichlorophen,ivermectin, mebendazole, oxamniquine, oxfendazole, oxantel embonate, praziquantel, pyrantel embonate, thiabendazole.

Anti-Arrhythmic Agents:

Amiodarone HCl, Disopyramide, flecainide acetate,quinidine sulphate.

Anti-hypertensive Agents:

Amlodipine, carvedilol, benidipine, darodipine, dilitazem HCl, diazoxide, felodipine, guanabenz acetate, indoramin, isradipine, minoxidil, nicardipine HCl, nifedipine, nimodipine, phenoxybenzamine HCl, prazosin HCL, reserpine, terazosin HCl.

Anti-epileptics:

Beclamide,carbamazepine,clonazepam,ethotoin, methoin, methsuximide, methyl phenol-barbitone, oxcarbazepine, paramethadione, phenacemide, phenoba rbitone, phenytoin, phensuximide, primidone, sulthiame, valproic acid.

Method Used In the Preparation of Immediate Release Tablets: [26-30]

- Tablet molding technique
- Direct Compression technique
- Wet granulation technique
- Mass extrusion technique
- By solid dispersions technique

Tablet Molding:

In this method, water-soluble excipients are utilized so that tablet disintegrate and dissolve rapidly. For this purpose powder mixture is moistened with a hydro alcoholic solvent and then it is molded in to tablet by using compression pressure which should be less than used in normal tablets compression. Finally solvent is seperated by air-drying. These tablets have a porous structure that increases dissolution. Less mechanical strength and poor taste masking characteristics are major problem with this method. This can be overcome by using sucrose, acacia or poly vinyl pyrrolidone as binding agents who increases mechanical strength. For poor taste masking characteristic Van Scoik may be incorporated.

Direct Compression Method:

In this technique, tablets are compressed directly from the mixture of the drug and excipients without any preliminary process. The mixtures necessarily have adequate flow characteristic and cohere under pressure thus making pretreatment as wet granulation unnecessary. Only few drugs can be compressed directly into desired quality tablets. Other parameters to be considered are particle size distribution, pore size, contact angle, tablet hardness and water absorption capacity. All these parameters decide the disintegration of tablet.

Wet Granulation Method:

Wet granulation method is the most commonly used unit operation within the pharmaceutical industry. Wet granulation is usually allotted out utilizing a high shear mixer. The high-shear granulation process is a quick method which is susceptible for over wetting. Thus, the liquid quantity added is essential and the optimal quantity is affected by the properties of the raw materials. The quantity of liquid should be adequate, as over-wetting may cause the granules 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:

- The main constituents and excipients are weighed and properly mixed.
- The wet granulate is prepared by adding the liquid binder–adhesive to the powder blend and mixing thoroughly. Examples of binders/adhesives include aqueous preparations of cornstarch, natural gums such as acacia, and cellulose derivatives such as methyl cellulose, gelatin, and povidone.
- Screening the dump mass through a mesh to form granules.
- Granules are dried by using tray-dryer or fluid-bed dryer.
- After the granules are dried, they are passed through a screen of smaller size than the one used for the wet mass to create granules of uniform size.

Mass-Extrusion (Mass-Extrusion) technique:

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.

By solid dispersions technique:

When formulating such solid amorphous dispersions into immediate release solid dosage forms for oral administration to a use 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. This minimizes the size of the solid dosage form required to achieve the desired dose. Depending on the drug dose, it is often desired that the solid amorphous dispersion comprise at least 30 wt %, preferably at least wt %, and more preferably at least 50 wt % or more of the solid dosage form. Such high drug loadings of dispersion in a solid dosage form minimize the dosage form's size, making it easier for the patient to swallow it and tending to improve patient compliance.

The immediate release formulations containing a solid dispersion which increases the solubility of a "less-soluble drug," meaning that the drug may be either "substantially 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 low to moderate aqueoussolubility, having an aqueous-solubility from about 1 mg/mL to as high as about 20 to 40 mg/mL.

Evaluation Parameters of Immediate Release Tablets: [31-42]

Pre-formulation Parameters:

Angle of repose:

Fixed funnel method used to determine angle of repose. The fixed funnel method employ a funnel that was secured with its tip at a given height (2cm), above the graph paper that was placed on a flat horizontal surface. The accurately weighed granule powder was taken in a funnel. The height of the funnel was adjusted in such a way that its tip just touches the top of the heap of blend. The drug excipient mixture was poured through funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

tanΘ = h/r

Θ = tan-1 (h/r)

Where h and r are the height and radius of the powder and θ = Angle of repose

Bulk density

Apparent bulk density was determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.

BD =Weight of the powder / Volume of the packing.

Tapped Density

Tapped density is ratio of mass of tablet blend to tapped volume of powder blend. It was measured by a graduated cylinder, having a known mass of drug-excipients blend. The cylinder was allowed to fall under its own weight onto a hard surface from the height of 10 cm at 2 second intervals upto 100 tap. The tapping was continued until no further change in volume was noted.

TBD =Weight of the powder / volume of the tapped packing.

Compressibility Index (Carr's index)

The Compressibility Index of the blends was measured by Carr's compressibility index. This parameter determines the flow characteristics of granules. The percentage compressibility of granules/blend is a direct measure of the potential powder arch and stability. The Carr's index can be calculated by the following formula.

%Carr's index= et - eb / et ×100.

Where et is the tapped density of granules and eb is bulk density of granules

Hauser's ratio = Tapped density/ Poured density:

Hausner's ratio also indicates the flow characteristics of granules. Hausner's ratio <1.25 – Good flow = 20% Carr 1.25 – Poor flow =33% Carr.

Post compression parameters: Evaluation of Tablets

Thickness

Vernier caliper used to determine the thickness of tablets. 10 random tablets used for determination of thickness in mm. The limit of the deviation of each tablet is 5%.

Hardness

Hardness of a tablet is associated with the resistance of the solid specimen towards fracturing, abrasion, breakage and attrition during storage, transportation and handling. The hardness of tablets can be measured by using Monsanto or Erweka hardness tester and measured in terms of kg/cm^2.

Friability

This is removal of fine particles from the surface during transportation or handling. Roche friabilator used to measure friability of the tablet. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at the height of 6 inches in each revolution. Pre weighted sample of tablets was placed in the friabilator and were subjected to the 100 round. Tablets were dusted using soft muslin cloth and reweighed.

The %friability (% F) is given by the formula

% Friability = (Initial weight – Final weight) / Initial weight× 100

Where, the weight of the tablets before (initially weight) and after (final weight) the test respectively.

Weight Variation

This test indicates uniformity in the weight of tablets in a batch. Test was performed by weighing 20 random tablets from whole batch individually, calculating the average weight and comparing the individual tablet weights to the average. The percentage weight deviation was calculated and then compared with USP specifications.

Disintegration test:

The disintegration time was measured using disintegration test apparatus. One tablet was placed in each tube of the basket. The basket with the bottom surface made of a stainless-steel screen (mesh no.10) was immersed in water bath a 37±2°C. The time required for complete disintegration of the tablet in each tube was determined using a stop watch. To be complied with the pharmacological standards, dispersible tablets must disintegrate within 3min when examine by the disintegration test for tablets.

In vitro dissolution studies:

In vitro dissolution studies for all the fabricated tablets was performed using USP paddle method at 100 rpm in 900 ml of HCl buffer pH 1.2 as dissolution media, maintained at 37±0.5°C. 5 ml aliquot was withdrawn at the specified time intervals, filtered through whatt-man filter paper and then equal volume of fresh medium, which was pre-warmed at 37°C, was replaced into the dissolution media after each sampling to maintain the constant volume throughout the test. The samples are then analyzed spectrophotometrically at 210 nm and the absorbance can be known.

Stability studies:

The formulation was subjected to accelerated stability studies as per ICH (The International Conference of Harmonization) guidelines. The packed tablets14 in air tight container were placed in stability chambers (Thermo lab scientific equipment Pvt.Ltd. Mumbai, India) maintained at 40±2ºC/75±5% RH for 3 months. Tablets were periodically removed and evaluated for physical characteristics, drug content, in- vitro drug release etc. At intervals of one week, the tablets were visually examined for any physical changes, and changes in drug content.

In vitro dispersion time:

Tablet was added to 10 ml of phosphate buffe r solution (pH 6.8) at 37 ± 0.5°C. Time required for complete dispersion of a tablet was measured.

Conclusion:

A new dosage format, the immediate release pharmaceutical form 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. These immediate release tablets having good patient compliance, and having much more advantages over another dosage form. Due to

the constraints of the current 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. This review was done with an aim to design an immediate release oral dosage forms and evaluation of the tablets, excipients used for immediate release tablets, mechanism of action and also various parameters including in vitro drug dissolution studies.

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