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An overview of Immediate Release Tablets

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ABSTRACT-
Tablet is the greater among the all of the dosage forms survive today because of it gives satisfaction of self administration, compactness and easy manufacturing; although in more cases immediate onset of action is mandtory than conventional therapy. In immediate release tablet formulation of the tablet is the use of superdisintegrants such as croscarmellose, sodium starch glycolate, and crospovidone, etc. These superdisintegrants gives instantaneous disintegration of the tablet after administration in the stomach. There are novel types of dosage forms that act very rapidly after the administration.. Immediate release liquid dosage forms and parenteral dosage form have also been used for treatment. These progress of immediate release system also brings an opportunity for increase in the marketplace, A different type of drugs (e.g., neuroleptics, cardiovascular drugs, analgesics, antihistamines, and drugs can be considered contender for this immediate release dosage form. These review provides a significant detail about these immediate release tablet and its mechanism of action and Preparation technique, excipients and evaluation of these dosage form.

KeyWords- Immediate release tablet, Oral dosage form, disintegrants, evaluation, Pharmacodynamics study, Pharmacokinetic study.

I. INTRODUCTION-

Immediate release drug delivery systemsaredescribed as immediate release tablets that are manufactured to disintegrate and release thedrugwithout special rate controlling features such as special coatings or alternative technologies,hencethetraditionaltypeofdrugdelivery .It'salsoasystem. Oral administration is one of the most popularroutesofadministration for systemic effects due to its ease of ingestion, simplicity,safety,convenience,non-invasiveness,versatility, and most importantly, patient compliance. Solid oral administration systems are inexpensivetomanufacture because they do not require sterile conditions [1].

Although the field of controlled-release and targeted drug delivery systemshasreceivedincreasingattentionandinterest in recent years, solid dosage forms designed to be swallowed disintegrate, releasingdrugsrapidly and violentlyin the gastrointestinal tract. The ideal dosing regimen for drug therapy achieves the desired therapeutic plasma (or site of action) drugconcentrationimmediately and maintains it constantthroughout the courseof treatment. Recently, scientists have turned their attention toimmediatereleasetabletformulations [2].

Attemptstodevelop rapidly disintegrating tabletsareachievedthroughtheuseof suitable diluents and superdisintegrants. Immediate release tablets are invented to matchdosetypewithoutspecialratecontroloptions.B. Specialcoatingsandvarioustechniquestodecomposeandrelease.Immediate-releasetabletsaretabletsthatrapidly disintegrate and dissolve to release the drug.Abilitytorapidlyrelease drug inresponseto disintegration, dissolution, and many physiological factors [3].

Immediate release dosage formshelpmanufacturers diversify theirmarkets and provide patients with convenient dosage forms or schedules. Excipients correspondto the properties of the activeingredient in the immediate release dosage form. This requires a thorough understanding of the chemistry of these excipients to prevent themfrominteracting with the activeingredient. The role of these excipients is important in the formulation of fast-dissolving tablets. These inert, food-grade ingredients, when incorporated intoformulations, impart desired organoleptic properties and product efficacy [4].

Ideal Properties

Animmediate release dosage form isrequired.Afixeddose should dissolve or breakdown in the stomach within a short period.Itshould show initial absorption and dissolution of the drug. Arapid onset of action is always observed with fast-acting tablets. Must be compatible with taste masking. Youcancarryitaround without

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worryingaboutitsfragility.There should be minimal residue in the mouth after oral administration. Itguaranteesapleasantmouthfeel.Low sensitivity to environmental conditionssuch as humidity and temperature. Itcanbe manufacturedatlowcost using conventional processing and packaging equipment [5, 6].

Salient Features

Drugs should have long biological half-lives for immediate release drug delivery. The drug is released quickly and completely in one shot. High bioavailability expected inan immediate release dosage form. Lower clearance and elimination half-life are also requirements for immediate release drug delivery systems.However,the main criteria for immediate release dosage formsarethelow solubility of the drug and the need forimmediateeffectof the drug to treat theundesirable defect or disease. Promptpharmacotherapeutic intervention is possible. New business opportunities suchas product differentiation, line expansion and lifecycle management, excluding product promotion [7,8].

Mechanism of Action-

Watertransport,expansion,andpossiblydeformationrecovery.Itdispersesandswellsquicklyinwater,butdoesnotgelevenafterlongexposure.Maximumswellingratecomparedtootherexplosives.Largersurfaceareatovolumeratiothanotherexplosives.Water-insolublelow-substitutedhydroxypropylcellulose.Swellsrapidlyinwater.GradesLH-11andLH-21showthegreatestdegreeofswelling.Certaingradescanalsoprovidesomebondingpropertieswhilemaintainingdisintegrationcapabilities.Recommendedconcentration1-5%.Conventionalrapid-releasetabletmanufacturingtechnology [9, 10]

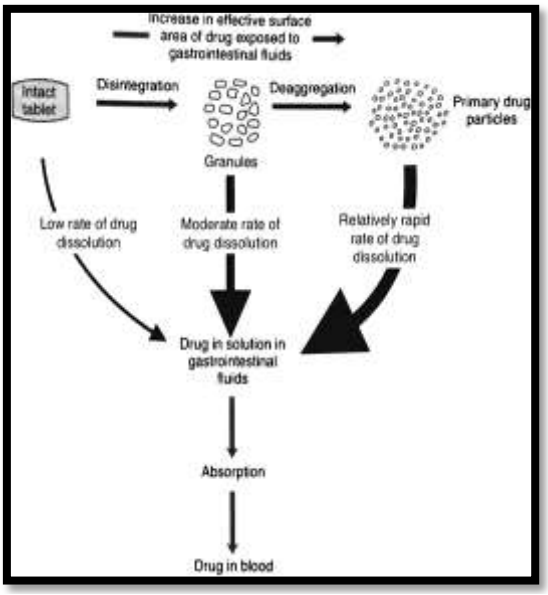

Figure Number- The flow of mechanism of Immediate Release Tablets

Conventional Techniques Used for Preparation of Immediate Release Tablets-

Several technologies are available to manufacture immediate-release tablets. The most common preparation methods are molding, lyophilization or freeze drying, direct compression, spray drying and sublimation.

Tablet Molding Technique-

This technology uses water-soluble chemicals to dissolve and break down the tablet more quickly. Utilizing moistened powder mixtures and compression pressure that is lower than that of traditional tablets, hydroalcoholic solvents are employed to form the tablets. Afterward, air drying is used to remove the solvent. The porous design of moulded tablets improves dissolution [11].

Direct Compression-

A method known as direct compression is one in which tablet formulations are made directly from a powder mixture of acceptable excipients and API. It is not essential to first granulate the mixed powder using a dry or wet process. Its benefits mostly relate to quick manufacturing because it uses less equipment, fewer workers, less unit activities, and processing time while also improving product stability [12].

Granulation Technique-

Small particles expand in size and become physically stronger through a process called size

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enlargement. Avoiding product component segregation, improving powder flow and handling, and reducing dustiness are all advantageous. It is perfectly spherical, and the smaller particles effectively cover the gaps between the granules. This approach falls into two categories as well [13].

Wet Granulation: The manufacture of severity-feed drugs is made simple by the wet granulation technique. An aqueous solution of a binding polymer is often added to fine particles of a granulated quick release formulation. Granulated formulation for controlled release with added binder polymer solution [14].

Dry Granulation: The powder combination is compacted during the dry granulation process without the use of heat or solvent. The two fundamental steps are to compress the material into a compact, and then to mill the compact to produce granules. Two techniques are shown below for dry granulation [15].

Mass-Extrusion-

In this technology, methanol, polyethylene glycol, and a mixture of the active medicine are softened before being added to a cylinder-shaped product and sliced using a hot blade to create a dosage form known as tablets [16].

Solid Dispersions-

Solid products containing at least two different components, mainly hydrophilic matrix and a hydrophobic drug. The matrix can be either crystalline or amorphous. This method deal with the challenge of mixing a matrix and drug, preferably on a molecular level, while matrix and drug are generally poorly miscible. When formulating immediate release solid dosage forms from solid amorphous dispersion for oral administration to effective use in an environment such as the GI tract of a human, it is often desirable to increase the amount of dispersion occurs in the dosage form [17].

Lyophilization-

It depends on simple principle i.e. sublimation. The sublimation is processed in which conversion of a substance from a solid state to vapor state, without changing in the liquid phase. Lyophilisationis performed at temperature and pressure conditions below the triple point. The whole process is performed at low temperature and pressure by applying vacuum; hence it is suitable for drying of thermolabile compounds [18].

Pneumatic Dry Granulation (PDG)-

It is a novel technique of dry method in which the formulation of granules is carried out by automatically or semi-automatically. This techniques granule has excellent properties as compared to dry granulation, direct compression, wet granulation and granules are showing high compressibility and flowabilityThe outcome can be attained without utilizing exotic and high-cost excipients [19].

Freeze Granulation Technology (FGT)-

Integrated Biosystems, Inc. (California, USA) had patented freeze GT that results in spherical and free flowing granules with ideal homogeneity. Its require spraying of a suspension containing powder into liquid nitrogen where the drops were swiftly frozen to form granules which upon subsequent freeze-drying yields dry granules [20].

Spray Drying Granulation-

This technology facilitated to improved flow, homogeneous distribution of colors, drug and required less lubricant as compared to wet massed products. It can be co-precipitate an active pharmaceutical ingredient with a suitable polymer to form a stable amorphous solid dispersion and promote improved bioavailability and dissolution rate of many drug products [21]

Thermal Adhesion Granulation Process-

Agglomeration is created using a little amount of binder liquid, heat, and an alternative to moist granulation. Heat is sometimes used to facilitate the granulation process. To create the agglomeration process that results in the powder particle, the excipient and API mixture is heated at 30-130 °C temperature in a closed chamber that is configured for tumble rotation. Because less liquid is needed and consumed during the aggregation of powder particles, this method stops the drying process. Granules can be obtained in the necessary particle size after chilling and sifting [22].

Granurex Technology-

This technology consistently and precisely accomplishes the powder layering processes, single coating, and multiple coating processes and powder layers that manifest the accuracy and better drug release mechanism [23]

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Mechanism of Disintegration-

Disintegrants are substances that are added to tablet and different encapsulated formulations to speed up the breakdown of the tablet and capsule "slugs" into tiny pieces in an aqueous environment, increasing the accessible surface area and encouraging a quicker release of the medicinal component. They cause the tablet matrix to disperse and absorb moisture. Tablet disintegration has drawn a lot of interest as a crucial stage in obtaining rapid medication release. The following list identifies the four main mechanisms of tablet disintegration:

Swelling-

The most commonly accepted general mechanism of action for tablet disintegration is swelling. Tablets with high porosity show weak disintegration due to lack of adequate swelling force. On the flip side, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is not able to penetrate in the tablet and disintegration is again slows down [24].

Capillary Action / Wicking-

Those disintegrating agents do not get swells so they acted by the mechanism of capillary action and porosity. Tablet's porosity provides a direction to penetrate the fluid into the dosage form. The disintegrating particles those having low compressibility and cohesiveness they facilitate the high porosity and provide a pathway to wicked and drawn up liquid in the tablets drawn through capillary action and break the bonding of inter particles which leads the tablet to break apart [25].

Chemical Reaction (Acid-Base Reaction)-

Due to the interaction of tartaric acid and citric acid (acids) with alkali metal carbonates or bicarbonates (bases) in the presence of water, the tablet soon breaks apart by the internal release of CO2 in water. The tablet disintegrates as a result of pressure generation. API's ability to dissolve in water and its ability to disguise flavours thanks to its release into CO2 gas. Because these disintegrants are extremely sensitive to even tiny changes in humidity level and temperature, a careful control environment is required during the manufacture of the tablets. The effervescent blend can be introduced either immediately before compression or in two separate formulation fractions [26].

Deformation-

Because of their elastic nature, starch granules can be easily bent under pressure before quickly resuming their original location and shape. However, when tableting forces are applied, these grains are permanently damaged and referred to as "energy-rich," and this is energy released when come into contact with water as seen in [27]

Pharmacokinetics [28-30]-

It is the research into nutrient uptake, distribution, metabolism, and excretion. Both the rate and the extent of absorption are crucial because after absorption, a drug reaches a therapeutic level and induces a pharmacological action. Since there is a delay in the disintegration process in conventional dosage forms, the dissolution is quick. Drug distribution is influenced by a variety of variables, including illness severity, drug interactions, tissue permeability, perfusion rate, and drug binding to tissue. The amount of time a drug remains in the body or how quickly it transforms at its site of action determines how strong and long its effects are. The biotransformation of drugs by oxidation, reduction, and hydrolysis is inhibited by a decrease in liver volume and regional blood flow to the liver. The half-life of medicines secreted by the kidneys extends as renal clearance is slowed.

Pharmacodynamics [31, 32]-

Due to improper organ development, drug reception interaction is hampered in both elderly and young adults. When taking an antihypertensive drug like prazosin, side effects include decreased cardiac output, orthostatic hypotension, and decreased reflex response may occur. decrease in the CVS's susceptibility to -adrenergic agonist and antagonist. When administering antibiotics, immunity is reduced and taken into account. Theophylline's bronchodilator function in older people is decreased, and they are more sensitive to barbiturates. Elderly patients frequently have concurrent ailments, which is taken into account when prescribing numerous pharmacological therapies. Clinical medication combinations for many kinds of cardiovascular medicines, diuretics, anti-hypertensive, etc. have been studied by researchers for rapid release dosage forms. The patient's illness state determines the combination that is used.

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Precompression study Studies [33-36]-

Angle of repose-

A cone-shaped pile of material created via various techniques assumes a three-dimensional angle (relative to the horizontal base) known as the angle of repose. In several scientific fields, the angle of repose has been employed to describe how solids flow. The literature has a number of ways for calculating angle of repose, but the constant height method is the most used. Use a funnel that was fastened with the tip at a specific height (2 cm) above the graph paper that was placed on a flat, horizontal surface for the fixed funnel method. The mixture of granules or tablets was gently poured through the funnel until the top of the conical pile barely touched the funnel's tip.

Tan θ = h / r

Where,

h = height of the powder pile

r = radius of pile circle

Bulk Density (ρB) -

Using a graduated cylinder and the constant mass method, bulk density is calculated. An apparent density is the bulk density. The mass-to-volume ratio of an untouched powder sample, taking into account the inter particulate void volume, is known as the bulk density of a powder. It is provided by and stated in gm/ml.

Bulk density (ρB) = M / Vo

Where,

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

Vo = Void volume (Untapped Volume in ml)

Tapped density

The powder's tapped density is determined by dividing its total mass by its tapped volume. A measuring cylinder is taped until the reading changes only slightly or not at all to determine the taped volume. It is provided by and is measured in gm/ml.

Tapped density (ρT) = M / Vf

Where,

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

Vf = Tapped Volume (Final bulk volume after tapped in ml)

Hausner ratio

Hausner ratio is an indirect index to predict of powder flow. It is calculated by the following formula.

Hausner ratio = Tapped density (ρT) / Bulk density (ρB)

Compressibility index (Carr's index)

Compressibility index (Carr's index) is an indirect parameter to assume flow property of powder. Compressibility index determined by measuring the initial volume (Vo) and final volume (Vf) after complete tapings of powder sample in a measuring cylinder.

It is calculate using an equation.

Compressibility index (CI) = (Vo – Vf X 100)/Vo

Post compression study [36-42]-

The appearance, thickness, diameter, hardness, friability, uniformity of weight, disintegration time, medication content, and in vitro dissolution studies are just a few of the factors that are analysed for each tablet.

Appearance-

A tablet's general appearance serves as its visual identity, and this may be determined simply by looking at tablets. Elegance, shape, colour, and surface textures are all components of appearance. Each of these criteria is necessary for suitability and consumer acceptance.

Dimensional Analysis-

Thickness and diameter of tablets are determined using Vernier Caliper. Randomly twenty tablets selecte from each batch are use and average values are calculated. Thickness is expressed in Mean ±SD and unit is mm.

Hardness-

The strength of a tablet's resistance to capping, abrasion, or breakage under conditions of storage, transportation, and handling prior to use is indicated by the tablet's hardness. The force necessary to break a tablet using a given tool is measured as hardness. 10 tablets are chosen at random from a batch to have their hardness tested by different hardness testers (Monsanto hardness tester, Pfizer hardness tester). Hardness expressed as kg/cm^2

Weight variation test-

Weight variation test is carried out in order to ensure uniformity in the weight of tablets in a batch. Individual weights of 20 tablets are taken randomly from whole batch. Individual weight is then compared with the average weight for the weight variations. USP 30-NF25 limits for weight variation in case of tablets weighting up to 130mg or less is ± 10%, 130 mg to 324 mg is ± 7.5% and more than 324 mg is ± 5%. IP limit for

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weight variation in case of tablets weighting up to 80mg or less is ± 10%, 80 mg to 250 mg is ± 7.5% and more than 250 mg is ± 5%

PD = [(W_{avg} – $W_{initial}$) / (W_{avg})] x 100
Where,
PD = Percentage deviation,
W_{avg} = Average weight of tablet,
$W_{initial}$ = Individual weight of tablet

Friability test-

Thetabletfriabilitytestisdeterminedoncompressed,uncoatedtabletscontainingagrindingagent.Tabletfriabilitymeasurementscomplementotherphysicalstrengthmeasurements.B.Tabletbreakingstrength. Fortabletswithaunitmassof650mgorless,samplethewholetabletascloseto6.5gaspossible.Fortabletswithaunitmassgreaterthan650mg,sampleall10tablets.Tabletsshouldbecarefullydustedbeforetesting.Accurately weighthetabletsampleandputthetabletsintothedrum. Rotatethedrum100timesandejectthetablets.Asbefore,removeloosedustfromtabletsandweighaccurately.Thedrumismountedonthehorizontalaxisofthemachine rotatingat25±1rpm.Therefore,witheachrotation,thetabletsrollorslideandfallontothewallofthedrumorontoeachother.Amaximumaveragemasslossof1.0%orlessfromtriplicatesamplesisconsideredacceptableformostproducts.

% friability = [(Initial weight - final weight) /Initial weight]× 100

Wetting time study -

Five circular tissue papers withadiameter of 10cmwere placed in a petridish containing a 0.2% w/v solution of amaranth (10ml).Gentlyplacethe tablet on the surface of the tissue paper. The time required for a blue color todevelop due to thewater-solubledye amaranth on the top surface of the tabletwas recorded as the wetting time.

Water absorption ratio-

A small tissue paper folded inhalf was placed in a small Petridish containing 6mL of water. Priortorecording the initial weight of thetablet,the tablet wasplacedonpaper. The wettabletsare then weighed. Water absorption (R) is determined using theformula:

R = (Wa – Wb) / Wa × 100
Where,
Wa = weight of the tablet before absorption.
Wb = weight of the tablet after absorption

Disintegration test-

Adisintegration test is performedusinga disintegration apparatus. Place one unit ofmeasure in eachtube(6) of Pannetandusediscs if prescribed.Unlessotherwisespecified, use water as the immersion liquidandmaintain 37 ± 2 oC in the immersion liquid. Operate the deviceuntil each unit doseemerges from the basket. 15 minutes for uncoated tablets. 30 minutes for uncoated tablets, and 60 minutes for coated tablets and pills. If one or two tablets donot disintegrate completely, repeat the test with another 12 tablets.Atleast 16 outof18total tablets have disintegrated.

Drug content-

Ten tablets were powdered and 100mgof drug equivalent powder was dissolved in theappropriatemedium (buffer or 0.1N HCl). The volume of the solution up to 100mLinthismedium.Thesolution was filtered, diluted 100-fold, analyzed spectro-photometrically, and further calculated to determine the drug content in thetablets.

In- vitro drug release -

Studydrug release studies were performed in a dissolution tester using a specified volume of 900ml dissolution medium maintained at 37±0.5°C.Tablets are stored in a cylindrical basket or placed directly intothe medium and immediately run the device at the specified speed.Collectsamplesfrom the intermediate zone between the surface of the eluate and the top of the rotating basket or bladewithinthespecifiedtimeintervals(5,10,15,and30min)oratspecifiedtimeintervals.Keepatleast 10 mm away from the vessel wall and replacethe same amount of fresh medium each time. The sampleisfiltered and 1mlistaken from the filtrate and diluted to 10ml. These samples are analyzed and further calculationsareperformed to obtain drug release. Drugrelease data were plotted and tested for0th order (cumulative% drug released vs.time)and1st order (log % remainingvs. time). Invitro dissolution kinetic parameters, dissolution rate constants, correlation coefficients and dissolution efficiency were calculated. The currentQ6Aguidancefromthe International Conference on Harmonization (ICH) recommends theuseof single-point assays to measure the release of drug substances from immediate-release medicinalproducts.

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Table Number 01- Lists of different excipients used in the design of tablets [43-45]

Excipients	Functions	Examples
Diluents	Diluents are used as fillers designed to make up the required bulk of the tablet.	Lactose, starch, mannitol, sucrose, sorbitol,etc
Binders and Adhesives	These are used to produce cohesive compact,	Hydroxy propyl methyl cellulose, acacia, starch,
Disintegrants	Used to facilitate a breakup of the tablet.	Starch, clays, cellulose, alginate, povidone,etc
Colors, flavors, and sweeteners	Used to enhance the Organoleptic properties and acceptability of the product.	FD & C, D&C dyes and lakes, banana, bubble gum, strawberry, vanilla flavors,
Glidants or flow promoters	Used to promote the flow of the tablet granules or powder material by reducing friction within particles	Silica derivatives, talc, corn starch, etc.

II. CONCLUSION:

Most patients require rapid the rapeuticeffects of drugs, resulting in poor compliance with conventional pharmacotherapyandpoor overall therapeuticefficacy. Immediate-release tablets are designed to release the drugat an increased rate. As highlighted above for current technology, there is still an unmet need for improved manufacturing processes for immediate-releasepharmaceuticals that are mechanically robust,easytohandle and package, and competitivelypriced to manufacture conventional tablets.Theadditional market exclusivitythatcan be provided by theimmediate-release dosage formwilllead to increased revenue and target underserved and undertreated patient populations. A newer dosage form, the immediate release formulation, has been developed, which combinesthe advantages of ease of administration and convenience of administration. These tablets are made to release thedrug from the dosage form. To meetthis medical need, formulators have expended considerable effort to developnewtypes of tablet dosage forms that disintegraterapidly and dissolve with improved dissolution.

Conflicts of interest-

There are no conflicts of interest or disclosures regarding the manuscript.

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