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Research Article

IMMEDIATE RELEASE DOSAGE FORMS: THRUST AREAS AND CHALLENGES

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A B S T R A C T

Oral dosage forms are most commonly used and old existing dosage forms because of their advantages like easy manufacturing, self-administration, compactness and painless. But in many cases quick onset of action is require and conventional dosage forms are not able to give quick action. To overcome this problem, immediate release dosage forms are used. Immediate release dosage forms are the novel types of dosage forms that act very quickly after administration. In the immediate release dosage forms various superdisintegrants are used like croscarmellose, sodium starch glycolate, crospovidone etc which provide quick breakage/disintegration of tablet after administration. Other excipients like bulking agents, lubricants, flavours, emulsifying agents etc are also used. In this article, focus is on the various advantages/benefits of immediate release dosage form, excipients used in immediate release dosage form, various technologies for immediate release tablets, potential therapeutical area where immediate release dosage form used. This article also covers various marketed products of immediate release dosage forms.

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INTRODUCTION

Oral drug delivery system is the most successful and popular route for systemic effects. The oral administration provides ease of ingestion, pain avoidance, patient compliance and versatility. The immediate release solid dosage form enhances the release rate of the drugs and this system is very useful for the delivery of poorly soluble drugs, high molecular weight proteins and peptides. Most of the patients require fast onset of action so immediate release of medicament is required. [1,2]
Immediate release dosage forms are those which disintegrate rapidly and dissolve fastly to release the active constituents. Immediate release is provided by using various carriers and diluents which does not extent or prolongs the absorption and release of the drug. [3, 4, 5]

Advantages of Immediate Release Solid Dosage Forms [6, 7, 8, 9]

- Immediate release dosage forms are cost effective and improve patient compliance.
- Immediate release dosage form improves solubility of the pharmaceutical composition.
- Immediate release dosage form improves bioavailability and stability.
- Immediate release dosage forms are painless and show versatility.
- Immediate release dosage forms reduce disintegration and dissolution timing.
- Immediate release dosage forms have the ability to provide effect of liquid preparation in the form of solid preparation.
- High drug loading is possible in immediate release dosage form.
- Immediate release dosage forms offer accurate dosing as compared to liquid dosage forms.
- Ease of swallowing is possible in immediate release dosage form.
- In case of immediate release system, drug is released completely in one shot.

Need For Immediate Release Dosage Form *[10, 11, 12]*

❖ In case, when we expect that drug must dissolve or disintegrate in the stomach within very short time.
❖ In case, when we expect pleasing mouth feel.
❖ In case, when we expect no residue of drug in the mouth after oral administration.
❖ In case of liquid preparation immediate release dosage form should be compatible with taste masking.
❖ Produce rapid onset of action due to rapid dissolution and absorption of drug.

Other Excipients Used In the Immediate Release Dosage Forms [13, 14, 15]

Super disintegrants
Bulking materials
Emulsifying agents

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Flavours and sweeteners
Lubricants

Super Disintegrant [16, 17, 18, 19, 20]

A disintegrant is an excipient, which is added to most tablet formulation to facilitate a breakup or disintegration of the tablet when it comes in contact with water in gastrointestinal tract. The disintegrating agent may be mixed at two stages -; 1) During the formation of granules (intragranular). 2) At the second mixing stage during compaction of granules into tablets (extragranular).

Recently "super disintegrating agents" have been introduced and shows lots of advantages like reduced tablet disintegration time, effective in lower concentrations and more effective intragranularly.

Super Disintegrants Includes

Natural superdisintegrant
Synthetic superdisintegrant

Natural Super Disintegrants

Natural super disintegrating agents are natural in origin and mostly used over synthetic because of non-irritating, cheaper and non-toxic in nature. Natural superdisintegrant includes-;

- Gum karaya
- Mango Peel Pectin
- Dehydrated banana powder
- Plantago Ovata Seed Mucilage (Isapgula)
- Cassia fistula gum

Synthetic Superdisintegrants

- Sodium starch glycolate (primogel), [2-8%]
- Cross – linked povidone or crospovidone (kollidone), [2-5%]
- Cross linked carboxy methyl cellulose sodium (Ac-Di-Sol) croscarmellose sodium,
- [1-3%]
- Low – substituted – hydroxyl propyl cellulose,[1-5%]
- Polacrilin potassium

Bulking Materials

Bulking materials are used in the formulation of fast – melting tablets. The bulking materials show all the functions of diluent, filler and also cost reducer. Bulking agents enhance the disintegration in the mouth. Mostly used bulking agents are sugar-based such as mannitol, directly compressible lactose (DCL), lactitol, starch hydrolystate etc. Bulking agents are used in the range of 10% to about 90% by weight of the final composition.

Emulsifying Agents

Emulsifying agents are very important for immediate release tablets because these aid in rapid drug release and disintegration. Emulsifying agents are also used as stabilizing the immiscible blends and improve bioavailability. The emulsifying agents used in the range of 0.05% to about 15% by weight of the final composition. The emulsifying agents used are sucrose esters, lecithin, alkyl sulfates, and propylene glycol esters.

Colours, Flavours and Sweetening Agents

The colours are used to improve the elegance of the tablet. The colours are added to the solution of the granulating agent or mixed with other ingredients before granulation.

Flavours are used to taste masking and also make product more pleasing for patients. Flavours are usually limited to effervescent tablets, lozenges and chewable tablets. Flavours are volatile oils in nature so added into the granules just before compression of tablets.

The sweetening agents are added to get pleasant taste and increase bulk of the composition. The commonly used sweetening agents are sucrose, lactose, mannitol etc. Artificial agents like saccharin and cyclamates are not used now. Sweetening agents also used in chewable tablets and lozenges.

Lubricants

The lubricants are used to improve the appearance of tablets, flow properties of granules and prevent the sticking of the materials to the dies and punches. Lubricants reduce interparticular friction during compression and friction between tablet and die wall during the ejection of tablet. The most widely used lubricant is stearic acid, various stearic acid salts and derivatives. Talc is the second most commonly used tablet lubricant. Calcium and magnesium stearate are the most common salts employed.

Technologies Used For Immediate Release Tablets [21, 22, 23, 24,25, 26, 27]

Conventional technique used in the preparation of immediate release tablets-;

- Tablet molding technique
- Direct compression technique
- Granulation technique
- Mass extrusion technique
- Lyophilisation

Tablet Molding Technique

Water soluble ingredients are used in this technique for the rapid tablet dissolve and disintegration. By using the hydro alcoholic solvent, the powder blend is moist and molded in to tablet using compression pressure. By using air drying, the solvent is removed. Dissolution of molded tablets enhanced due to the porous structure. The mechanical strength of the tablet is increased by using various binding agents such as acacia, sucrose, poly vinyl pyrollidone etc. mechanical strength and poor taste masking both the problems are solved by using this technique.

Direct Compression Method

The mixture of the drug and excipients are compressed directly without any preliminary treatment to form tablets. There are few drugs which can be directly compressed into tablets. Some crystalline substances, such as sodium chloride, sodium bromide and potassium chloride that may be compressed directly. The materials used for the direct compression must possess good flow and compressibility. The most important advantage of the direct compression process is its simplicity, low labor input and economy.

Advantages of Direct Compression Method

- Direct compression is the most advanced technology among all tablet preparing techniques.
- Direct compression is an economical process and more efficient because it requires only dry blending of active pharmaceutical ingredient (API) and excipients.
- Direct compression reduces labor costs, processing time and consumption of power.
- Less manufacturing steps, less number of equipments and less process validation is required in direct compression technique.
- Stability and suitability of the thermolabile and moisture sensitive active pharmaceutical ingredients are increasing by eliminating heat and moisture.
- Batch to batch variation does not occur in direct compression method.
- Provide chemical stability for the excipient and API.
- Direct compression method shows particle size uniformity.

Wet Granulation Method

Immediate release tablets are prepared by two granulation techniques i.e wet granulation and dry granulation. Wet granulation is more popular method as compare to dry granulation to prepare a tablet. The mixtures of drug with excipients such as diluent, binding agents, disintegrating agents are moistened with sufficient quantity of liquid binder or granulating agent in order to make a coherent mass. The liquid plays a key role in the granulation process. Liquid bridges are developed between particles, and the tensile strength of these bonds increases as the amount of liquid added is increased. The amount of liquid binder has to be properly controlled, because if we add more, then it will cause the granules to be too hard and if we add less, then it will cause them to be too soft and friable.

Various important steps involved in wet granulation method-;

- Mixing drug with excipients.
- Preparation of binder solution and mixed with powder to form wet mass.
- This wet or coherent mass is then passed through sieve no. 10.
- Drying of moist granules at 60^0c in a hot air oven.
- The dried granules are passed through sieve number 20 to collect the uniform size granules.
- These granules are then ready for the compression.

Mass Extrusion Technique

The wet mass is metered by special feeder into the extruder where it continuously formed into cylindrical extrudates of uniform shape and size. For the bitter drugs, dried cylinder is used to coat granules to overcome this problem.

Types of Extruders

Screw extruders-;

- Axial type
- Radial type

1. Sieve extruder
2. Basket extruder
3. Roll extruders

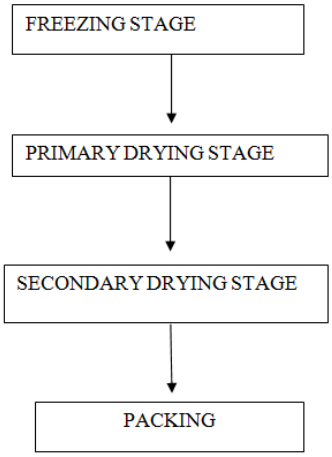
Extrusion Process Includes

1. Preparation of wet mass (Mixing)
2. Shaping the wet mass into cylinders (Extrusion)
3. Breaking up the extrudates and rounding of the particles into spheres (Spheronization)
4. Drying of the pellets

Lyophilization

Lyophilisation is depending on a simple principle i.e sublimation. The sublimation is the transition of a substance from the solid to the vapour state, without passing through an intermediate liquid phase. Lyophilisation is performed at temperature and pressure conditions below the triple point. The whole process is performed at low temperature and pressure by applying vacuum, hence is suited for drying of thermolabile compounds.

Steps Involved In Lyophilization



Potential Therapeutical Area Where Immediate Release Dosage Forms Are Used *[28, 29, 30]*

Table 1 Thrust areas where immediate release dosage forms are used

Therapeutical area	Drugs
Analgesics and Anti-inflammatory agents	Ibuprofen, Indomethacin, Ketoprofen, Meclofenamic acid, Mefenamic acid, Nabumetone, Oxyphenbutazone, Auranofin, Azapropazone, Diflunisal, Fenbufen, Fenoprofen calcium, Aloxiprin, Naproxen, oxaprozin, phenylbutazone, piroxicam, sulindac.
Anthelmintics	Albendazole, bephenium, hydroxynaphthoate, cambendazole, dichlorophen, mebendazole, oxamniquine, oxfendazole, oxantel embonate, praziquantel, pyrantel embonate, thiabendazole.
Anti – hypertensive agents	Amlodipine, carvedilol, benidipine, darodipine, diltiazem HCI, diazoxide, felodipine, guanabenz acetate, indoramin, isradipine, minoxidil, nicardipine HCI, nifedipine, nimodipine, phenoxybenzamine HCI, prazosin HCI, reserpine, terazosin HCI.
Anti – fungal agents	Amphotericin, butoconazolenitrate, clotrimazole, econazolenitrate, fluconazole, flucytosine, griseofulvin, itraconazole, ketoconazole, miconazole, natamycin, nystatin, sulconazole nitrate, terbinafine HCI, terconazole, tioconazole, undecenoic acid.
Anti- neoplastic agents and immunosuppressant	Aminoglutethimide, amsacrine, azathioprine, busulphan, chlorambucil, cyclosporine, dacarbazine, estramustine, etoposide, lomustine, melphalan, mercaptopurine, methotrexate, mitomycin, mitotane, mitozantrone, procarbazine HCI, tamoxifen citrate, testolactone.
Corticosteroids	Beclomethasone, betamethasone, budesonide, cortisone acetate, desoxymethasone, dexamethasone, fludrocortisoneacetate, flunisolide, flucortolone,

	fluticasone propionate, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone.
Proteins, peptides and recombinant drugs	Insulin, glucagon, growth hormone, polypeptides or their derivatives, calcitonins, enkephalins, interferons, ACTH analogues, insulin like growth factors, erythropoietin, granulocyte-colony stimulating factor (G-CSF)
Histamine H_1 receptor antagonists	Acrivastine, astemizole, cinnarizine, cyclizine, cyproheptadine HCl, dimenhydrinate, flunarizine HCl, loratadine, meclizine HCl, oxatomide, terfenadine, triprolidine.
Nitrates and other anti-anginal agents	Amyl nitrate, glyceryltrinitrate, isosorbide dinitrate, isosorbide mononitrate.
Gastro-intestinal agents	Bisacodyl, cimetidine, cisapride, diphenoxylate HCl, domperidone, famotidine, loperamide, mesalazine, nizatidine, omeprazole, ondansetron HCl, sulphasalazine.
Oral vaccines	Influenza, tuberculosis, meningitis, hepatitis, whooping cough, polio, tetanus, diphtheria, malaria, cholera, herpes, typhoid, HIV, AIDS, foot and mouth disease, swine.
Anxiolytic, sedatives, hypnotics and neuroleptics	Alprazolam, amylobarbitone, barbitone, bentazepam, bromazepam, bromperidol, brotizolam, butobarbitone, carbromal, chlorpromazine, clobazam, diazepam, droperidol, ethinamate, flunanisone, fluopromazine, flurazepam, haloperidol.
Anti- epileptics	Beclamide, carbamazepine, clonazepam, ethotoin, methoin, methsuximide, methylphenobarbitone, oxcarbazepine, paramethadione, phenacemide, phenobarbitone, phenytoin, primidone, sulthiame, valproic acid.
Diuretics	Acetazolamideamiloride, bendrofluazide, bumetanide, chlorothiazide, Chlorthalidone, ethacrynic acid, frusemide, metolazone, spironolactone, triamterene.
Anti – protazoal agents	Benznidazole, clioquinol, decoquinate, diiodohydroxyquinoline, diloxanide furoate, dinitolmide, furzolidone, metronidazole, nimorazole, nitrofurazone, omidazole, tinidazole.
Anti-muscarinic agents	Atropine, benzhexol HCl, biperiden, ethopropazine HCl, hyoscine butyl bromide, hyoscyamine, mepenzolate bromide, orphenadrine, oxyphencylcimine HCl, tropicamide.
Anti- migraine agents	Dihydroergotamine mesylate, ergotamine tartrate, methysergidemaleate, pizotifen maleate, sumatriptan succinate.
Anti- diabetics	Acetohexamide, chlorpropamide, glibenclamide, gliclazide, glipizide, tolazamide, tolbutamide, sitagliptin.
Anti – bacterial agents	Imipenem, nalidixic acid, nitro furantoin, rifampicin, spiramycin, sulphabenzamide, sulphadoxine, sulphamerazine, sulphafurazole, sulphamethoxazole, sulphapyridine, tetracycline, trimethoprim, benethamine, penicillin, cloxacillin, demeclocycline, doxycycline, erythromycin.
Anti- malarials	Amodiaquine, chloroquine, chlorproguanil HCl, mefloquine HCl, proguanil HCl, pyrimethamine, quinine sulphate.

Evaluation of Immediate Release Dosage Form (Tablets) [31, 32]

Evaluation of powder blend -;

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

Table 2 Flow properties according to angle of repose

FLOW PROPERTY	Angle of repose (θ)
Excellent	25-30
Good	31-35
Fair	36-40
Passable	41-45
Poor	46-55
Very poor	>56

Table 3 Flow properties according to compressibility index

Flow property	Compressibility index
Excellent	<10
Good	11-15
Fair	16-20
Passable	21-25
Poor	26-31
Very poor	32-37
Very very poor	>38

Table 4 Flow properties according to hausner's ratio

Flow Property	Hausner Ratio
Excellent	1-1.11
Good	1.12-1.18
Fair	1.19-1.25
Passable	1.26-1.34
Poor	1.35-1.45
Very poor	1.46-1.59
Very very poor	>1.60

Evaluation of Tablets [33, 34, 35]

- Appearance
- Thickness
- Weight variation
- Hardness
- Friability
- Disintegration
- Wetting time
- Water absorption ratio
- Drug content
- *In vitro* dissolution
- Stability studies

Marketed Products of Immediate Release Tablets [36, 37]

Table 5 List of marketed products

Brand name	Active ingredient	Applications
Diltiazem	Diltiazem	Treating high blood pressure and chronic stable angina
Calan	Verapamil	Treating high blood pressure and chronic stable angina
Isoptin	Verapamil hydrochloride	Treating high blood pressure and angina
Cataflam	Diclofenac potassium	Treating pain and inflammation
Voltaren	Diclofenac potassium	Treating pain and inflammation
Nucynta	Tapentadol	Treating moderate and severe chronic pain

Difficulties/Challenges With Immediate Release Dosage Forms [38,39]

There are various difficulties in immediate release tablets. The drugs having short biological half-life are not suitable for immediate release. The drugs having higher clearance and higher elimination half-life are also not suitable candidate for immediate release dosage form. In case of immediate release dosage forms, high concentration of medicaments may cause GI irritation. The drug release at a time may produce high plasma concentration which leads to toxicity.

Current Scenario /Recent Development in Immediate Release Tablets [38, 40, 41]

Novel granulation technologies-;

- Pneumatic dry granulation (PDG)

- Freeze granulation technology (FGT)
- Foamed binder technologies (FBT)
- Melt granulation technology (MGT)
- Steam granulation technology (SGT)
- Moisture activated by dry granulation (MADG)
- Thermal adhesion granulation process (TAGP)

- Hot – melt extrusion and injection molding for continuous manufacturing of immediate release tablets.
- Novel hole technology
- A novel electrostatic dry powder coating process.

CONCLUSION

The immediate release dosage form shows lots of advantages like ease of dosing, painless, patients comfort etc. In case of immediate release dosage form rate of drug release is enhanced. Most of the patients required quick therapeutic action of drug, so the conventional drug therapy gives the poor patients compliance and leads to reduced overall therapy effectivencess. For the high effective therapy, immediate release dosage forms are the best options. Most of the prescripted drugs, neutraceuticals, over the counter (OTC) products can be incorporated into this innovative immediate release dosage form. Thus, immediate release dosage forms are new enhanced oral product which covers wide range of therapeutic agents.

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