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ONE STEP DRY COATED TABLETS (OSDRC) - A REVIEW

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ABSTRACT

Drug delivery has metamorphosed from the concept of pill to molecular medicine in the past 100 years. Better appreciation and integration of pharmacokinetic and pharmacodynamic principles in the design of drug delivery system has been developed a lead to improve therapeutic efficacy. This review focused on problems faced in preparation of compression coated tablet and inlay tablet and those can be overcome by a novel One Step Dry Coated Tablet.

Keywords: OSDRC, Inlay tablet, Compression Coated Tablet, Core in Cup Tablet.

INTRODUCTION

Drug therapy has a profound influence on the health statistics all over the world. The effective and rational use of the drug constitutes one of the most important of the health programs. Today all the world allopathic systems of medicine dominates the "Traditional medicine and healing art" due to its strong link with modern sciences & technology. Drug delivery has metamorphosed from the concept of pill to molecular medicine in the past 100 years. Better appreciation and integration of pharmacokinetic and pharmacodynamic principles in the design of drug delivery system has been developed a lead to improve therapeutic efficacy. Drug research has evolved and matured through phases beginning from pill to pharmaceutical dosage form [1].

Oral Administration

Oral route is the most convenient and usually the safest and least expensive, it is the one most often used.

Advantages

- Convenient - portable, no pain, easy to take.
- Cheap - no need to sterilize (but must be hygienic of course), compact, multi-dose bottles, automated machines produce tablets in large quantities.
- Variety - fast release tablets, capsules, enteric coated, layered tablets, slow release, suspensions, mixtures.

Mechanism of Absorption

- By passive diffusion through the lipid bilayer, neutral, liposoluble molecules but not those completely insoluble in

water.

- By secondary active transport, amino acids and sugars, certain peptides.

By complex mechanisms, elements in the form of ions, cations and anions, such as sodium, potassium, calcium, chlorine.

The Oral Route can be used for A Local or General Treatment

- Local treatment: gastrointestinal protectants of the digestive tract itself, treatment of an intestinal infection or a parasitosis. In this case, one wishes, in general, that the drug will not be absorbed or only poorly absorbed.
- General treatment: it is the usual route of administration of drugs and digestive absorption is followed of their diffusion in the body.

Tablet as a Dosage Form:

- Tablet is a solid dosage forms each containing a unit dose of one or more medicaments with or without suitable excipients.
- Tablets may be swallowed whole or being chewed. Some are dissolved or dispersed in water before administration. Some are put in oral cavity, where the active ingredient is liberated at a predetermined rate. Implants or passeries may also be presented in form of tablet. Tablet may vary in shape and differ greatly in size and weight depending on the amount of medicinal substance and the intended mode of administration [2].

Advantages

- Large scale manufacturing is feasible in comparison to other dosage forms. Therefore, economy can be achieved.
- Accuracy of dose is maintained since tablet is a solid unit dosage form. Tailor made release profile can be achieved.
- Longer expiry period and minimum microbial spillage owing to lower moisture content.
- As tablet is not a sterile dosage form, stringent environmental conditions are not required in the tablet department.
- Ease of packaging (blister or strip) and easy handling over liquid dosage form.
- Easy to transport in bulk. Emergency supply supplies can be carried by patients.
- Organoleptic properties (taste, appearance and odour) are best improved by coating of tablet.
- Product identification is easy and markings done with the help of grooved punches and printing with edible ink.
- Different types of tablets are available like buccal, floating, colon targeting, effervescent, dispersible, soluble, and chewable, etc.
- In composition to parenterals dosage form, a doctor or a nurse is not required for administration. i.e. self administration is possible.
- In comparison to capsules, tablets are more tamperproof.

Disadvantages

- It is difficult to convert a high dose poorly compressible API into a tablet of suitable size for human use.
- Difficult to formulate a drug with poor wettability, slow dissolution into a tablet.
- Slow onset of action as compared to parenterals, liquid orals and capsules.
- The amount of liquid drug (e.g. Vitamin E, Simethicone) that can be trapped into a tablet is very less.
- Difficult to swallow for kids, terminally ill and geriatric patients.
- Patients undergoing radiotherapy cannot swallow tablet [3].

Classification of tablets

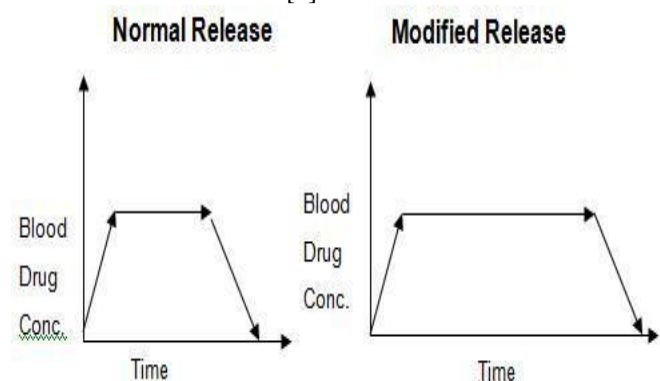
To understand each dosage form, tablets here are classified by their route of administration and by the type of drug delivery system they represent within that route.

Benefits of Modified Release Tablets

The novel system of drug delivery offer a means of improving the therapeutic effectiveness of incorporated drugs by providing sustained, controlled delivery and / or targeting the drug to desired site.

- Decreased in dosing frequency.
- Reduced peak to trough ratio of drug in systemic circulation.
- Reduced rate of rise of drug concentration in blood.

- Sustained & Consistent blood level with in the therapeutic window.
- Enhanced bioavailability.
- Customized delivery profiles.
- Reduced side effects [4].



INLAY TABLETS

- A type of layered tablet in which instead the core tablet being completely surrounded by coating, top surface is completely exposed.
- Tablet compressing was done with core rod tooling in which only one surface of core is expose to outside and other drug is incorporated in cup portion.
- While preparation, only the bottom of the die cavity is filled with coating material and core is placed upon it [1].
- The main body portion may consist of an uncoated granulation which is compressed around the enteric coated inlay portion. In this modification the main body portion of the tablet is first released and assimilated in the gastrointestinal tract while the enteric coating protects the inlay portion for a predetermined period of time so as to provide time delayed or sustained medication.
- Atoz is offering Inlay tablets with combinations like Metformin 500 mg sustained release (Outer coat) and Pioglitazone 15 mg (core tablet) which has a very unique advantage.
- Ursinos is the marketed inlay tablets containing aspirin.

Advantages of inlay tablets

- Dosage form comprising of an active ingredient as modified release and an active ingredient as immediate release can be prepared.
- Plasma level can be maintained constant and within the therapeutic window throughout the period of treatment.
- Adverse effects due to sub therapeutic plasma concentration can be avoided.
- The burst effect, namely, large release within a short period of time, is common in highly soluble drugs, and shall be avoided, as it may lead to high concentration of active ingredients in the blood stream.
- Has the ability to release soluble and insoluble drugs at a zero-order rate of release in dissolution media. Dosage frequency of highly water soluble drugs can be reduced providing same efficacy

- Tablets of different shape such as triangular, rectangular, or capsule shaped tablets can be manufactured.

Advantages of Inlay Tablets over Other Compressed Tablets

- Less coating material is required.
- Core is visible, so coreless tablets can be easily detected.
- Reduction in coating forms a thinner tablet and thus freedom from capping of top coating.
- The layered tablet is preferred over compression coated tablet as the surface contact is less and the production is simple and more rapid [1].

Sustained Release Oral Drug Delivery

- There is a continuously growing interest in the pharmaceutical industry for sustained release oral drug delivery systems. There is also a high interest for design a dosage formulation that allows high drug loading, particularly for actives with high water solubility.
- This type of tablets are also called prolonged action tablet, repeat action tablet.
- In this type of dosage forms, a sufficient amount of drug is initially made available to the body to cause a desired pharmacological response. The remaining fraction is released periodically and is required to maintain the maximum initial pharmacological activity for some desirable period of time in excess of time expected from usual single dose.
- The basic rationale of a sustained drug delivery system is to optimize the Biopharmaceutic, Pharmacokinetic and Pharmacodynamic properties of a drug in such a way that its utility is maximized through reduction in side effects and cure or control of condition in the shortest possible time by using smallest quantity of drug, administered by the most suitable route.
- Sustained release tablets and capsules are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect.
- The sustained plasma drug levels provide by sustained release products often times eliminates the need for night dosing, which benefits not only the patients but the care given as well.. The goal of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the body to achieve promptly and then maintain the desired drug concentration.
- Oral route has been the most popular and successfully used for sustained delivery of drugs because of convenience and ease of administration, greater flexibility in dosage form design and ease of production and low cost of such a system.
- The sustained release systems for oral use are mostly solid and based on dissolution, diffusion or a combination of both mechanisms in the control of release of drugs.

- They can often be taken less frequently than instant-release formulations of the same drug, and that they keep steadier levels of the drug in the bloodstream.

Advantages

- Reduce the frequency of dosing or to increase effectiveness of the drug by localization at the site of action, reducing the dose required, or providing uniform drug delivery.
- It would be a single dose for the duration of treatment whether it is for days or weeks, as with infection, or for the life time of the patient, as in hypertension or diabetes.
- It should deliver the active entity directly to the site of action, minimizing or eliminating side effects.
- This may necessitate delivery to specific receptors or to localization to cells or to specific areas of the body.
- The safety margin of high potency drug can be increase and the incidence of both local and systemic adverse side effects can be reduced in sensitive patient [1].

Considerations for Formulation of Sustained Release Formulation

- If the active compound has a long half-life (over 6 hours), it is sustained on its own.
- If the pharmacological activity of the active compound is not related to its blood levels, time releasing has no purpose.
- If the absorption of the active compound involves an active transport, the development of a time-release product may be problematic.
- Finally, if the active compound has a short half-life, it would require a large amount to maintain a prolonged effective dose. In this case, a broad therapeutic window is necessary to avoid toxicity; otherwise, the risk is unwarranted and another mode of administration would be recommended [1].

Problems

- More complicated formulation may be more erratic in result. A sustained release product may contain a larger dose, i.e. the dose for two or three (or more) 'normal' dosing intervals. A failure of the controlled release mechanism may result in release of a large toxic dose.
- More expensive technology.

Immediate Release Oral Drug Delivery

- Immediate release formulations are designed to disintegrate and release the drug in absence of any controlling features such as coatings or other formulation techniques.
- Despite a rising interest in controlled-release drug delivery systems, the most common tablets are those intended to be swallowed whole, disintegrating and releasing their medicaments rapidly in the gastrointestinal tract.

- A disintegrant is a substance in a tablet formulation that enables the tablet to break up into smaller fragments upon contact with gastrointestinal fluids.
- Such a rapid rupture of the tablet matrix increases the surface area of the tablet particles, thereby increasing the rate of absorption of the active ingredient and producing the desired therapeutic action.
- The proper choice of disintegrant and its consistency of performance are critical to formulation development of immediate release tablets. In the past, starch was one of the most widely used, inexpensive, and effective tablet disintegrants.
- A high concentration of starch is required to bring about effective disintegration. Scientists search for disintegrating agents with efficient disintegrating properties at relatively low concentrations has led to the development of some new compounds with excellent disintegrating properties [1].

Preparation of Inlay Tablets

Preparation of inlay tablets can be done in three steps. They include

- Preparation of core Tablet.
- Preparation of cup portion.
- Preparation of inlay tablet.

Problem Faced During Manufacturing of Compression Coated and Inlay Tablets

Here preparation of core tablet can be done in similar manner as that of for other immediate release tablet after compression of core tablet, one has to place this core tablet in to middle of the outer layer powder blend or granules (cup portion) at the time of final compression manually or by use of mechanical device that can place a core tablet and them compression will carry out to prepare inlay or core in cup tablet. In this procedure there are certain drawbacks which are discussed below:

- By any of above two methods placing of core tablet at exact centre of the outer layer is quite difficult, Thus misalignment of core tablet is quite often.
- Uniform thickness of outer layer at every side of core tablet can't be maintained.
- If core tablet has to place manually, so it is time consuming and also required skilled personal.
- As tablet has to place manually by hand; there may a chance of accidental hazards.
- Hardness of core tablet is difficult to maintain.
- Incorporation of poor compressible material as core tablet can't be possible.
- Preparation of inlay tablet or compression coated tablet with more than one core tablet is quite difficult or not possible.
- Due to such manufacturing problems there may be a cost effective.

These problems can be overcome by novel One Step Dry Coating (OSDRC) technique.

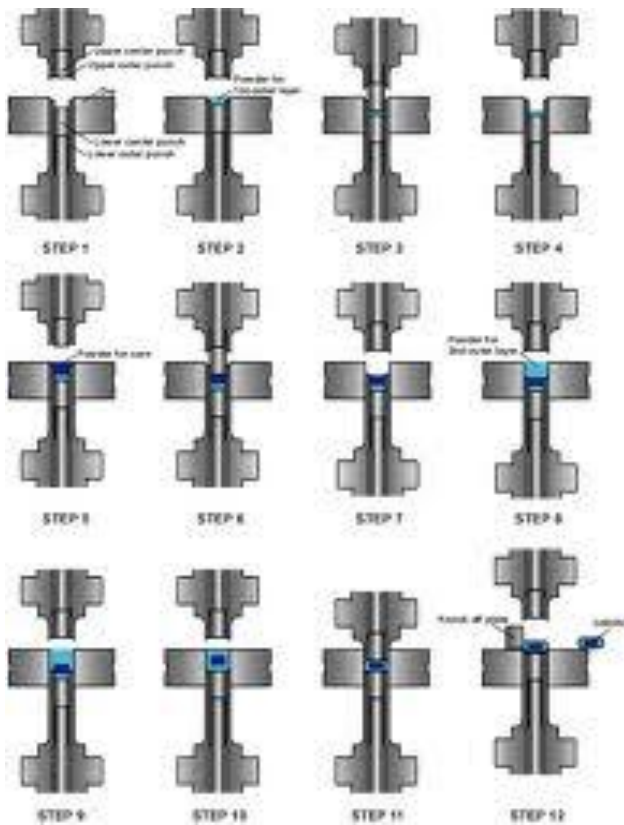
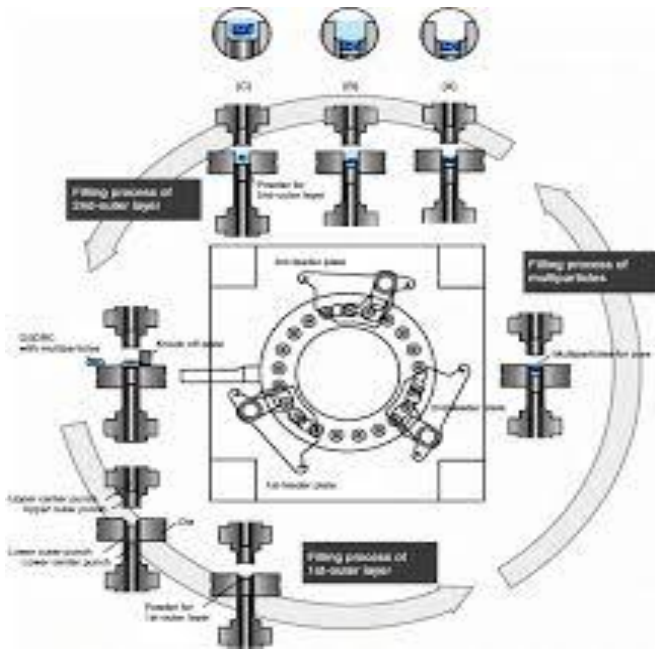
What is OSDRC?

OSDRC is one step dry coating technology that opens a door to a new world of pharmaceutical tablet manufacturing.

- OSDRC is the great innovation towards compression coated tablets and inlay tablets.
- OSDRC provides unique, high quality products at low cost.
- OSDRC is novel variable double punch tableting technology, simply by changing the punch of rotary tablet compression machine, product development scientists can create new formulations and tablet configurations that are not possible with current tablet manufacturing technology.

Technology Attributes

- OSDRC includes variable double punches those can manufacture compression coated or inlay tablet in a single step and can go beyond the parameters of current tableting machines.
- This technology has ability to manufacture this compression coated and inlay tablet configuration at a rate of up to 100,000 tablets per hour with the avoidance of problem faced with conventional manufacturing process such as misalignment of cores, mass variability and cross contamination.
- This variable double punch rotary tableting machine has up to 54 double punches and two or three feeders.
- Because the tablet is prepared in a single step while the punches make one rotation on a turret there is no longer any need for separate step to deliver a core tablet. Because the core tablet is held in place by lower punch until the final compression, thus misalignment does not occur.
- There are many types of tablet configurations can be made with OSDRC, depending only on double punch variations.
- OSDRC allow the formulators to freely control the size, shape, thickness and position of core tablet as well as that of outer cup tablet.
- This facilitates the manufacturing of completely new types of drug products that were not possible with conventional technology.
- In addition of this one can include cameras, automation and advance in process control functions to provide precision, high speed tableting, also prevent cross contamination of powders, auto sampling and auto exclusion mechanism can meet Good Manufacturing Practice (GMP) standards.
- This technology not only produces higher quality cored tablets than previously possible, but also enables development of various new solid dosage forms; it also allows product development scientists to device new novel dosage forms.



OSDRC Tablets



Controlled Release Tablets

This technology facilitates the control of API by altering the thickness of outer coating. Capability to precisely position multiple cores allows the manufacture of tablet product with variety of pulsatile drug delivery profiles.

Divided Core Tablets

There also possible to make divided tablets with separate cores in one step operation, which is not possible with current technology. For example divided enteric coated tablets are the world's first dividable enteric coated tablets. Dividable core tablets so called because the core fully encased in the coating even when the tablet is divide, even though the release profile is remain unaffected by dividing the table.

Cored Tablets with Poorly Compressible Cores

By using this technology there is no need of separate manufacturing of core tablet even using of powders with poor compressibility as the core matrix.

As it possible to directly encase core pharmaceutical ingredients with the outer covering, these ingredients can be used in oral rapid disintegration tablets.

Pellets can also be used instead of powder as core material, drugs normally formulated as capsule dosage form can be formulated as tablet dosage form.

Sugar and Film Coating can be Replaced

Tablet with extremely thin coat can be produce in one step, thus sugar and film coating can be replaced which substantially reduce manufacturing steps and cost.

Core and Coat Shapes are also Variable

The shape, thickness and tablet configuration of core and coat can be varied simply by changing the punches.

Advantages of OSDRC

- The OSDRC is rotary tableting machine with variable double punch configuration facilitate single step manufacturing of pharmaceutical products.
- In addition to commercial production of compression coated and inlay tablet it is also ideal for manufacturing a variety of high quality pharmaceutical product at low cost.
- In addition to overcome of misalignment of core tablet this technology allows placement of any number of cores of any shape into the tablet just where they positioned for optimum drug delivery of API such as divide tablets with two cores, pulsatile tablets with three cores and other combination products.
- Core ingredients with poor compressibility, pellets as core material to replace conventional capsule dosage form, development of new oral rapid disintegrating tablet can be possible with OSDRC technology.
- Variety of pulsatile drug release profile can be achieved.

- Dividable enteric coated tablet with two cores can be formulated in such a way that after division of tablet each core is fully encased by coat material and release profile will be unaffected.
- By using this technology extremely thin coated tablet can be formulated so sugar coating and film coating can be replaced.
- Variety of core and coat tablet can formulate in single step just by changing double punches.
- By including cameras, automation technique and advanced in process control one can achieved GMP standards.

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CONCLUSION

Manufacturing problems that occur during formulation of compression coated and inlay tablet can be overcome by OSDRC technology. OSDRC is the one step dry coated technology where variety of dosage forms can be formulated preciously, with high quality and uniqueness in single steps those cannot possible with existing tableting technology so, it opens new era of tableting technology and manufacturing of novel solid dosage form can be formulated at low cost, with simple one step operation by just simply changing the double punches assembly.