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AN OVERVIEW OF FAST DISSOLVING TABLETS

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Abstract

Fast dissolving tablets are solid dosage forms containing drugs that get disintegrated within one minute without need of water. In order to overcome the swallowing problems in paediatric and geriatric patients by conventional dosage forms, these fast dissolving tablets are formulated. This article overview the salient features, mechanisms of superdisintegrants, technologies and evaluation parameters in the fast dissolving drug delivery systems.

Keywords: Conventional technologies, Evaluation tests, Fast Dissolving Tablets (FDT's), Patented technologies, Superdisintegrants.

1. Introduction

USFDA Center for Drug Evaluation and Research (CDER) defined Oral Disintegrating Tablets (ODT) as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue"².

Orally Disintegrating Tablet (ODT) is a solid unit dosage form containing drugs that disintegrates rapidly and dissolves in the mouth without taking water within 60 seconds or less².

When this tablet is placed into the mouth, the saliva will serve rapidly to dissolve the tablet. They are also known as oro-dissolving, mouth dissolving, rapid dissolve orodispersible; melt in mouth, rapimelt, quick dissolving, fast melts and porous tablets¹.

Recently, the European Pharmacopoeia adopted the term orodispersible tablet for a tablet that disperses or disintegrates in less than 3 minutes in the mouth before swallowing³. Such a tablet disintegrates into smaller granules or melts in the mouth from a hard solid to a gel-like structure, allowing easy swallowing by patients.

Dysphagia or difficulty in swallowing is common in paediatric, geriatric and bedridden patients¹⁶. In order to assist those patients who feel difficulty in swallowing or chewing solid dosage forms, several FDT systems have been developed¹.

The main objective of fast dissolving drug delivery is to improve performance, convenience and compliance. It is suited for tablets undergoing high first pass metabolism and is improving bioavailability with reducing dosing frequency to minimize side effect^{1,4}.

1.1 Salient features of fast dissolving tablets

- Ease of administration in elderly, stroke victims, bed ridden and renal failure patients who feels difficulty in swallowing and also in case of paediatric, geriatric, psychiatric patients who refuse to swallow^{1, 5, 6}. Can be administered at any time without need of water for the patients during travelling period and get disintegrated and dissolved in the oral cavity within seconds so on set of action is rapid^{1,7,8}.
- Should leave less or no residue in the mouth after the administration by the patient¹. Good mouth feel property of FDT helps to change the perception of medications bitter pill particularly in paediatric patients^{1, 10}. In case of insoluble or hydrophobic drugs, increased bioavailability is achieved due to faster disintegration or dissolution of the tablets and should be compatible with taste masking and should give pleasant mouth feel^{1,7,8}.
- Exhibit low sensitive to environmental condition as temperature and humidity. It is cost effective, accurate dosing as compared to liquids, should be harder and less friable. Exhibit low sensitivity to environmental conditions (temperature and humidity) and new business opportunity like product differentiation, product promotion, patent extension and life cycle management^{1,9}.
- The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety^{1,10}.

1.2 Limitations of Fast dissolving tablets

- Fast dissolving tablets are hygroscopic in nature which cannot maintain physical integrity under normal condition from humidity in such cases they requires special packaging system for safety of stabilized product^{1, 11}.
- For proper disintegration or dissolution of FDT's in the mouth, they should be made of either very porous and soft-melted matrices or compressed into tablets with very low compression force, which makes the tablets

friable and brittle which are difficult to handle, in such cases they requires specialized peel-off blister packaging¹.

- As most drugs are unpalatable, FDT's systems usually contain the medicament in taste masked form. Delivery systems dissolve or disintegrate in patient's mouth, thus releasing the active ingredients which come in contact with the taste buds and hence, taste masking of the drugs becomes critical to patient compliance. The tablets usually have insufficient mechanical strength hence, careful handling is required. The tablets may leave unpleasant taste and grittiness in mouth if not formulated properly^{1,11}.

2. Mechanisms of tablet disintegration

The tablet disintegration takes place by following mechanisms and was listed in Figure 1.

2.1 Swelling

It's a common step involved in tablet disintegration. Tablets with low porosity shows rapid disintegration as swelling force is exerted and tablets with high porosity shows poor disintegration due to lack of swelling force¹².

2.2 Porosity and capillary action (Wicking)

The first step involves the disintegration by capillary action. When a tablet is placed into an aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles; the intermolecular bond gets weakened resulting in the breaking of tablet into fine particles. Water uptake by tablet depends upon both hydrophilicity of drug or excipient and tableting conditions. Maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary for these types of disintegrants which helps in disintegration by creating a hydrophilic network around the drug particles¹³.

2.3 By disintegrating particles or particle repulsive forces

The particle repulsion theory proposed by Guyot-Hermann states that non-swellable particles also cause disintegration of tablets. Water is drawn into the pore as result of electric forces, particles repel each other¹⁴.

2.4 Deformation

During tablet compression, disintegrated particles get deformed. When these deformed particles come in contact with water turns to their normal structure. Generally, the swelling capacity of starch was increased when granules were deformed during compression. The increase in size of the deformed particles resulting in tablet disintegrating. This may be a mechanism of starch and has begun to be studied¹⁵.

2.5 By heat of wetting or air expansion

When disintegrants with exothermic properties gets wetted, localized stress is generated due to capillary air expansion, results in tablet disintegration. It is limited to some disintegrants and cannot describe the action of most modern disintegrating agents ¹⁶.

2.6 Due to release of gases

Due to interaction between bicarbonate and carbonate with citric acid or tartaric acid, carbon dioxide released within tablets on wetting. Pressure gets generated within tablet resulting in tablet disintegration. This effervescent mixture mostly used in formulating fast dissolving tablet and proper conditions need to be followed during manufacturing ¹⁷.

2.7 By enzymatic reaction

Enzymes present in the body acts as disintegrants by destroying binder action and helps in tablet disintegration ¹⁷.

3. Excipients used to prepare fast dissolving tablets ^{4,8}

3.1 Fillers/diluents: Lactose, magnesium carbonate, calcium sulphate, magnesium trisilicate, calcium phosphate, aluminium hydroxide, Mannitol, Sorbitol, xylitol, calcium carbonate

3.2 Superdisintegrants: Sodium carboxy methyl cellulose, calcium carboxy methyl cellulose, sodium starch glycolate, crosspovidone, cross carmellose sodium and modified starches.

3.3 Flavouring agents: Peppermint oil, clove oil, anise oil, eucalyptus oil, thyme oil, oil of bitter almonds, vanilla, citrus oil

3.4 Sweetners: Aspartame, sucrose, mannitol, sorbitol, xylitol, maltose, erythriol, fructose and other sugar derivatives

3.5 Surface active agents: Tweens, spans, sodiumlaurylsulfate, polyoxyethylene stearates.

3.6 Binders: Polyvinylpyrrolidone, Hydroxypropylmethylcellulose, Polyvinylalcohol

3.7 Colouring agents: Sunset yellow, Amaranth, Eosin

3.8 Lubricants: Magnesium stearate, Stearic acid, Magnesium lauryl sulphate

4. Drug selection for FDT

4.1 Suitable drug characteristics ^{2, 15, 18}

The ideal characteristics of a drug for *in vivo* dissolution from FDT are as follows.

- Should have no bitter taste

- Dose should be <20 mg
- Molecular weight should range from small to moderate
- Should show good stability in water and saliva
- At the site of oral cavities pH, should be partially nonionized
- Should undergo diffusion and partition into the upper GIT epithelium ($\log p >1$ or > 2)
- Should undergo permeation towards oral mucosal tissue

4.2 Unsuitable drug characteristics ²

- Drugs having shorter half-life
- Drugs with frequent dosing
- Drugs having bitter taste

5. Conventional technologies for fast dissolving tablets

5.1 Freeze-drying

ZYDIS[®] is a freeze drying process by R.P. Scherer, Swindon, UK. It involves drug in water soluble matrix, which is further transferred to the preformed blister with peelable foil, as the zydis units are sensitive to withstand being pushed through the lidding foil of a conventional blister. It is then done to remove water by sublimation.

Incorporation of lyophilization is a pharmaceutical technology allowing dried heat sensitive drugs at low temperature conditions and allowing removal of water by sublimation. The preparations formed are highly porous, with larger specific surface area that dissolve quickly within few seconds thus showing improved absorption and bioavailability. Special packing is required in some cases ^{1, 19}.

5.2 Tablet molding

Molded tablets can be prepared by using water-soluble ingredients so that the tablets undergo complete dissolution. The powder blend is moistened with a hydro-alcoholic solvent and under lower pressure they are molded into tablets. Finally, the solvent is then removed by air-drying. These molded tablets less compacted containing porous structure and enhances dissolution than compressed tablets ^{1, 19}.

5.3 Direct compression

The simplest method for manufacturing of tablets is done by direct compression. Directly compressed tablet's disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agents. It includes limited number of processing steps, cost effectiveness and easy to

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implement at industrial level. Super disintegrants are added in formulation of fast dissolving tablets to achieve rapid disintegration along with good mouth feel.

Gas evolving disintegrants are also used to formulate fast dissolving tablets. CO₂ as a disintegration mechanism in OROSOLV and DURASOLV patented technologies by CIMA lab^{1,19}.

5.4 Spray drying

Both hydrolyzed and unhydrolyzed gelatin is used as supporting agent for the matrix, mannitol as a bulking agent and sodium starch glycolate or croscarmellose as a disintegrant in the formulation process. By the addition of acid (citric acid) or alkali (sodium bicarbonate) disintegration and dissolution can be enhanced. The suspension of excipients was spray-dried to yield a porous powder and compressed finally into tablets. Tablets manufactured by this method disintegrated in < 20 sec in water^{1,19}.

5.5 Mass-Extrusion

This method involves softening of active blend by 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 tablet. This dried cylinder can also be used to coat granules for bitter drugs and taste masking can be achieved^{1,19}.

5.6 Sublimation

Sublimation is used to produce FDTs with high porosity. A porous matrix is formed by compressing the volatile ingredients along with other excipients into tablets, which are finally subjected to a process of sublimation. Inert solid ingredients with high volatility like ammonium bicarbonate, benzoic acid, camphor, naphthalene, phthalic anhydride and urea can be used in this process. Solvents like cyclohexane and benzene were also meant for generating the porosity in the matrix^{1,19}. The steps involved in sublimation process are given in Figure2.

6. Patented technologies for fast dissolving tablets

6.1 Zydis Technology

Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast dissolving carrier material. This product is made to dissolve on the tongue in 2 to 3 seconds. Zydis products are packed in blister packs to protect the formulation from moisture in the environment^{1,20}.

6.2 Durasolv Technology

Durasolv is the patented technology of CIMA labs. The tablet preparation by conventional tableting equipment includes drug, fillers and a lubricant. Tablets prepared will be with good rigidity and can be packed into blisters. This technology can be applied for low amount of active ingredients required by the product ^{1,20,21}.

6.3 Orasolv Technology

This technology was also developed by CIMA labs. The tablets are prepared by direct compression technique. The active medicament used in this method is taste masked and also contains effervescent disintegrating agent ^{1,20}.

6.4 Wowtab Technology

This technology is developed by Yamanouchi Pharmaceutical Co.WOW means "Without Water ". Both low mouldability saccharides and high mouldability saccharides are combinely used to obtain a rapidly melting strong tablet in this process. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet ^{1,21}.

6.5 Flash Dose Technology

This technology has been patented by Fuisz. The flash dose tablets consist of self binding shearform matrix termed as "floss". Shearform matrices are prepared by flash heat processing ^{1,20,21}.

6.5 Flashtab Technology

The Flashtab technology was patented by prographarm. The active ingredient in the form of microcrystals was used for tablet preparation. Drug microgranules may also be prepared by using conventional techniques like coacervation, microencapsulation and extrusion- spheronisation. All the processing utilizes conventional tableting technology ^{1,20,21,22}.

6.6 Oraquick Technology

The tablet formulation utilizes patented taste masking technology. KV Pharmaceutical claims its microsphere technology, known as Micro Mask. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable ^{1,20,21,22}.

6.7 Nanocrystal Technology

NanoCrystal particles are small particles of drug substance <1000 nm in diameter, are produced by milling the drug substance by using wet milling technique. Decreasing particle size increases the surface area, which leads to an

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increase in dissolution rate. NanoCrystal colloidal dispersions of drug substance are combined with water-soluble ingredients, filled into blisters and lyophilized. The resultant wafers are remarkably robust, dissolve in very small quantities of water in seconds ^{1, 20, 21, 22}.

7. Evaluation tests

7.1 Tests for powder blends ^{1, 11}

a) Bulk Density (D_B)

It is determined by pouring the weighed powder (passed through standard sieve # 20) into a measuring cylinder and initial weight was noted and the initial volume of powder is called bulk volume. The bulk density is expressed in terms of g/ml and calculated by formula,

$$D_B = W / V_B$$

Where, W is the weight of the powder

V_B is the bulk volume of the powder

b) Tapped Density (D_T)

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume is measured by tapping the powder for 750 times and the tapped volume is noted if the difference between these two volumes is <2%. If it is >2%, tapping is done for 1250 times and tapped volume is noted. Tapping should be done until the difference between successive volumes is < 2 %. It is expressed in terms of g/ml and is calculated by formula,

$$D_T = W / V_T$$

Where, W is the weight of powder

V_T is the tapped volume of the powder

c) Hausner's ratio

Hausner's ratio is an indirect index of ease of powder flow and is calculated by the formula.

$$\text{Hausner's ratio} = D_T / D_B$$

Where, D_T is the tapped density

D_B is the bulk density

Hausner's ratio value <1.25 shows better flow property.

d) Angle of repose

It determines the flow property of the powder. It is defined as maximum angle formed between the surface of the pile of powder and the horizontal plane. The powder is allowed to flow through the funnel fixed to a stand at definite height (h). By measuring the height and radius of the heap of powder formed (r), angle of repose can be calculated by using formula,

$$\tan \theta = h / r, \theta = \tan^{-1} (h / r)$$

Where, θ is the angle of repose

h is the height in cm

r is the radius in cm

The relation between angle of repose and flow property were given in table-1.

e) % Compressibility

It indicates the powder flow properties and expressed in terms of percentage.

$$\% \text{ Compressibility } C = \frac{D_T - D_B}{D_T} \times 100$$

Where, D_T is the tapped density of the powder

D_B is the bulk density of the powder

The relation between % compressibility and flow ability were given in table-2.

7.2 Tests for tablets^{1,11}

a) Hardness

Hardness or Tablet crushing strength (T_{cs}) is the force required to break the tablet. It can be measured by using Monsanto or Pfizer hardness tester. It is expressed in kg/cm^2 .

b) Weight variation

20 tablets selected randomly should be weighed individually to check for weight variation. The I.P specifications for weight variation limits were given in table-3.

c) Friability (F)

Friability of tablet can be determined by using Roche friabilator. The tablets are subjected into a plastic chamber revolving at 25 rpm by dropping a tablet at height of 6 inches in each revolution. The preweighed tablets should be

placed in the friabilator and subjected for 100 revolutions. Tablets were dusted using a muslin cloth and again reweighed and can be calculated by the formula.

$$\% F = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

d) Wetting time

Washburn E.W equation states that the water penetration rate into the powder bed is proportional to the pore radius and is affected by the hydrophilicity of the powders.

$$dl/dt = \frac{r w \cos \alpha}{4vl}$$

Where l is the length of penetration

r is the capillary radius

w is the surface tension

v is the liquid viscosity

t is the time

α is the contact angle

A double folded tissue paper should be placed in a petri dish containing 6ml of water. The tablet was kept on the paper and the time for complete wetting of the tablet was measured in units of seconds. This method can be slightly modified by maintaining water at 37°.

e) *In vitro* drug release

In vitro drug release can be determined by using dissolution test apparatus.

Dissolution test:

Apparatus- USP type2 apparatus (paddle)

Rpm - 50

Dissolution medium - 900ml of phosphate buffer pH 6.8

Temperature - 37±0.5°C

f) Modified disintegration test

The standard procedure for performing disintegration test for these dosage forms has several limitations and cannot suffice measurement of short disintegration times. The disintegration time for FDT needs to be modified without requirement of water, thus the test should show similar disintegration in salivary contents. For this test, the tablet

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should kept in the centre of petridish (10cm diameter) containing 10ml of water and the time for complete disintegration of tablet into fine particles was noted.

g) Water absorption Ratio

A double folded tissue paper is placed in a petri dish containing 6 ml of water. A tablet is kept on that paper & the time required for complete wetting is measured. The wetted tablet is taken and weighed. Water absorption ratio(R) can be determined by equation,

$$R = (W_A - W_B) / W_B \times 100$$

Where, W_B is weight of tablet before water absorption

W_A is weight of tablet after water absorption

h) In vitro dispersion time

Time required for complete dispersion of a tablet can be determined by adding of tablet to 10 ml of phosphate buffer solution, pH 6.8 at $37 \pm 0.5^\circ\text{C}$.

i) Stability studies (Temperature Dependent)

The fast dissolving tablets should be packed and stored for accelerated studies as per ICH guidelines at conditions like $40 \pm 1^\circ\text{C}$, $50 \pm 1^\circ\text{C}$, $37 \pm 1^\circ\text{C}$ and RH $75\% \pm 5\%$. After 15 days, tablets should be withdrawn were tested and analysed for visual defects, hardness, friability, disintegration, dissolution and drug content. The data obtained is fitted in first order equations to determine the kinetics of degradation. Accelerated stability data plotted according Arrhenius equation to determine the shelf life at 25°C .

8. Packaging ⁴

Special packaging care is required during manufacturing and storage to protect the dosage of some fast dissolving dosage forms. Unlike quick-dispersing or dissolving oral delivery systems, the systems can be packaged by using single pouch, blister card with multiple units, multiple unit dispenser and continuous roll dispenser depending on the application and marketing objectives.

9. Marketed fast dissolving tablets ^{1, 11, 23, 24}

Brand name	Active drug	Manufacturing company
Felden fast melt	Piroxicam	Pfizer, NY, USA

Febrectol	Paracetamol	Prographarm, Chateaufneuf, France
Zeplar TM	Selegiline	Amarin Corp., London, UK
Zoming-ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
Tempra quiclets	Acetaminophen	Bristol myers Squibb, NY, USA
Nimulid MDT	Nimesulide	Panacea Biotech, New delhi , India
Claritin redi Tab	Loratidine	Schering plough Corp., USA
Zyprexa	Olanzapine	Eli lilly, Indianapolis, USA,
Maxalt MLT	Rizatriptan	Merck and Co., NJ, USA
Olanex instab	Olanzapine	Ranbaxy lab.Ltd. New delhi, India
Torrox MT	Rofecoxib	Torrent pharmaceuticals, India
Benadryl fastmelt	Diphenhydramine, Pseudoephedramine	Warner Lambert, NY, USA
Calpol fastmelts	Paracetamol	McNeil, Healthcare
Pepcid RPD	Famotidine	Merck and Co., NJ, USA
Romilast	Montelukast	Ranbaxy lab.Ltd. New delhi, India
UNISOM sleepmelts	Diphenhydramine	Chattem
Cibalginadue FAST	Ibuprofen	Novartis consumer Health
Zotacet MD	Cetirizine Hcl	Zota pharma
Nulev	Hyoscyamine sulphate	Schwarz Pharma

10. Conclusion

Orally disintegrating tablets will have more patient acceptance, as they offer improved biopharmaceutical properties, improved efficacy and safety when compared to conventional oral dosage forms. In order to achieve rapid disintegration and dissolution of the tablet, the various technologies used in the formulation of FDT's involve the addition of super disintegrants in optimum concentrations along with good taste masking agents to get FDT's with excellent mechanical strength.

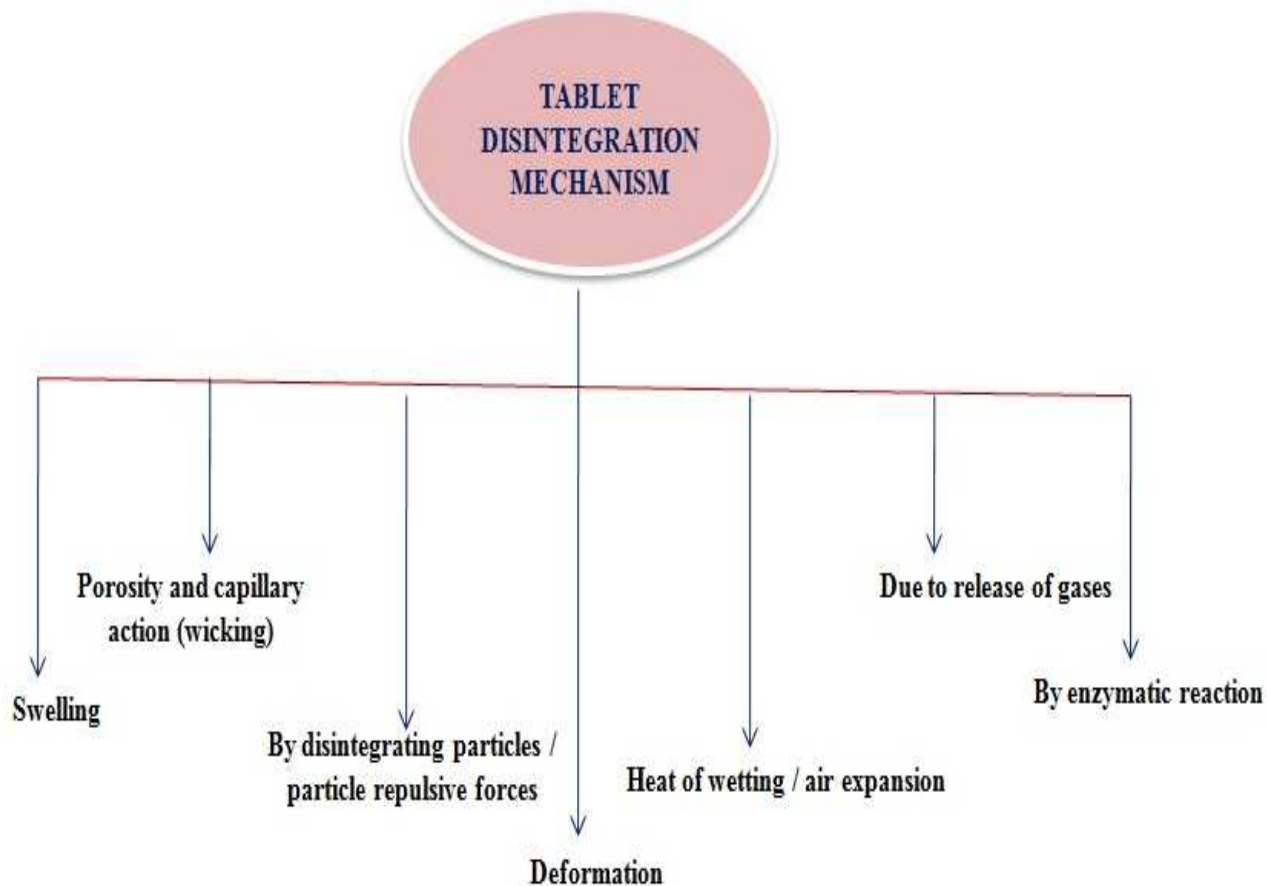


Figure-1: Mechanisms of tablet disintegration.

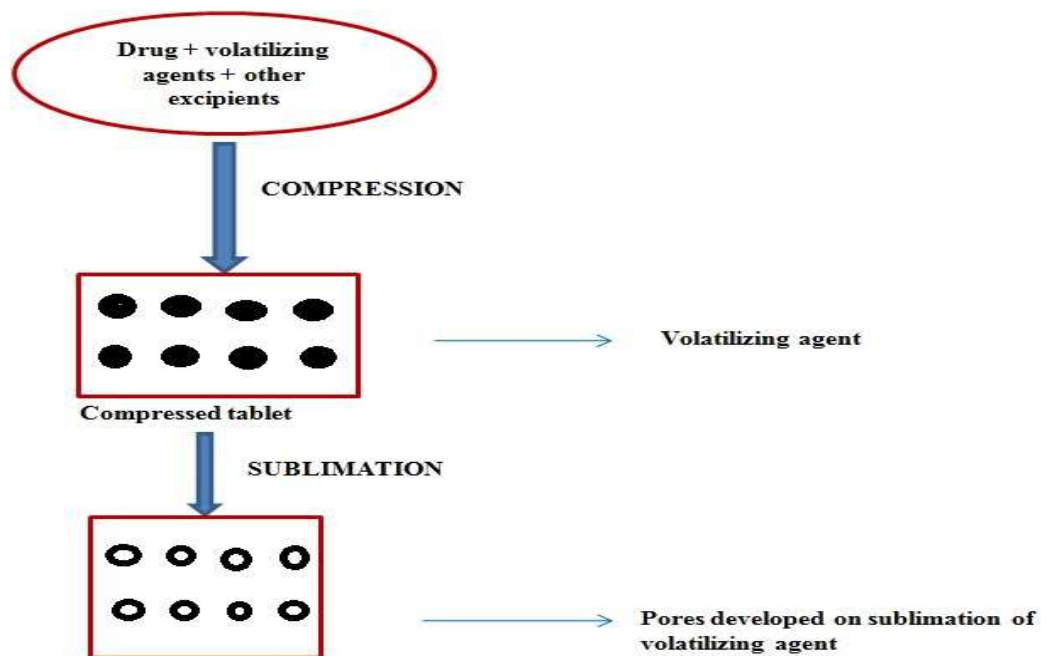


Figure-2: Sublimation process steps.

Table-1: Relation between Angle of repose and Flow property.

Angle of repose(°)	Flow property
<20	Excellent
20-30	Good
30-34	Passable
>34	Very poor

Table-2: Relation between % Compressibility and Flow ability.

% Compressibility	Flow ability
5-12	Excellent
12-16	Good
18-21	Fairly passable
23-35	Poor
33-38	Very poor
<40	Very very poor

Table-3: Weight variation limits specifications as per I.P.

Average weight of the tablet	% deviation
80mg or less	±10
More than 80mg but less than 250mg	±7.5
250mg or more	±5

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