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A REVIEW ON IMMEDIATE RELEASE SOLID ORAL DOSAGE FORMS AND STABILITY MONITORING OF FINISHED PRODUCT

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ABSTRACT
Among all the different routes of administration, Oral route of administration has been the preferred and the most widespread route of drug delivery system around the globe. The attractiveness of this dosage form is due to its easy of manufacturing, simplicity of administration, avoidance of pain and good patient compliance. From the perspective of the drug development and formulations, solid dosage form offers better stability as compared to suspension and liquid dosage forms. Hence, most of the NCEs under the development are preferred to formulate into solid dosage forms, which can produce an effective and reproducible *in vivo* plasma concentration after oral administration. Sometimes immediate onset of action is considered necessary for which immediate release tablets / capsules are the ultimate option. In the present review, it is focused on Ideal Properties Immediate release dosage forms, disadvantages, salient features, Unsuitable drug characteristics, common manufacturing methods, commonly used raw materials, evaluation of powder blend, tablets and capsules, tests in specifications, storage conditions and stability monitoring.

INTRODUCTION
Oral route of administration has been the preferred and the most widespread route of drug delivery system around the globe. The attractiveness of this dosage form is due to its simplicity of administration and good patient compliance.[1-3] From the perspective of the drug development and formulations, solid dosage form offers better stability as compared to suspension and liquid dosage forms.[4] Solid oral delivery systems (especially tablets and capsules) is system of choice among all drug delivery system and they do not require special treatment and are therefore less expensive to manufacture, likewise immediate release tablets are more acceptable among all the tablets. Based on their drug-release characteristics, tablets / capsules can be classified into three types, immediate release, extended release / prolonged release and, delayed release solid oral dosage forms. For immediate release tablets the drug is intended to be released rapidly after administration, or the tablet is dissolved and administered as a solution. In case of tablet dosage forms, this is the most common type of tablet and includes orally disintegrating, chewable, effervescent, sublingual and buccal tablets. They design to disintegrate and release their medication with no special rate controlling features. Immediate Release Tablets are those tablets which are designed to disintegrate and release their medication with no special rate controlling features, such as special coatings and other techniques. In pharmaceutical industries, manufactures of generic solid oral dosage forms are usually focused on the optimization of the concentration of functional excipients, manufacturing process to obtain a product that meet established standard**.** The aim of the generic formulation development was to develop stable, robust and bioequivalent Test product to marketed Innovator product with acceptable physiochemical properties, stability and ease of manufacture with reference product.

The therapeutic effect of an API depends on the concentration of an active constituent / or an active metabolite at the site of action. The absorption of an active pharmaceutical ingredient (API) into the systemic circulation is prerequisite to reach the site of action for all APIs, except those that are applied at the site of action, or intravenously injected.[5] An ideal dosage regimen in the drug therapy of any disease or the goal of any drug delivery system is the one, which immediately attains the desired therapeutic concentration of drug in plasma (or at the site of action) and maintains it constant for the entire duration treatment. Immediate release drug delivery systems are designed to provide immediate drug levels in short period of time. In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms considering quality of life, most of these efforts have been focused on ease of medication. Recently immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to

administer, has quick onset of action is economical and lead to better patient compliance.

Superdisintegrants, solubilizer (surfactants) are first choice of excipients which are extensively used for the formulation development of the immediate release tablets as they effectively result into the immediate disintegration, release and absorption of the drug after oral administration. Crosscarmellose sodium, Sodium starch glycolate and Crospovidone, which are commonly used super disintegrants in the immediate release solid oral dosage forms.[6]

Ideal Properties Immediate release dosage forms[7]

1. Be portable with no fragility concern.
2. It should dissolve or disintegrate in the stomach within a short period of time.
3. Rapid onset of action always seen with immediate release tablets / capsules.
4. It should not leave minimal or no residue in the mouth after oral administration. 7. No bitter taste and Provides pleasing mouth feel.
5. Exhibit low sensitivity to environmental condition as humidity and temperature.
6. Be manufactured using conventional processing and packaging equipment at low cost.

Advantages - An immediate release pharmaceutical preparation offers

- Improved patient compliance/added convenience
- Improved solubility of the pharmaceutical composition
- Improved stability, bioavailability.
- Decreased disintegration and dissolution times for immediate release oral dosage forms.
- Suitable for controlled/sustained release formulations
- Allows high drug loading.
- Bilayer tablet is possible for sequential release of two drugs in combination and separate two incompatible substance.
- Ability to formulate liquid medication in the form of solid dosage form.
- Involve fewer manufacturing steps
- Cost- effective.

Disadvantages

1. Frequent dosing is necessary for drug with short biological half-life.
2. Drug release at a time / burst release may produce high plasma concentration which may produce toxicity.

Salient Features[7]

1. Drugs should possessing long biological half-life for immediate release drug delivery.
2. High bioavailability expected with immediate release dosage form.
3. Lower clearance and lower elimination half-life are also requirement for immediate release drug delivery system.
4. Rapid drug therapy intervention is possible.
5. Carrier materials for immediate release compositions preferably are selected to provide a disintegration time less than about 15 minutes, preferably about 10 minutes or less.

Unsuitable drug characteristic for immediate release tablets[7]

1. Drug are not suitable for immediate release tablets which having short biological half-life.
2. Drug with low bioavailability are also not desirable candidate for immediate release tablets.
3. Drug with higher clearance and higher elimination half-life are also not desirable candidate for immediate release tablets.

Solid oral dosage forms (Tablets) are commonly **manufactured** by wet granulation (aqueous / non-aqueous / together), dry granulation (Roller compaction / Slugging) and Direct compression. Direct compression / Direct filling.[8]

A. Wet granulation process[8]: Wet granulation is a process of using a liquid binder (binder in solvent) or binder in dry mix portion to lightly agglomerate the powder mixture. The amount of liquid has to be properly controlled, the binder solution should be pourable. Over-wetting will cause the granules to be too hard and under-wetting will cause them to be too soft and friable. Aqueous solutions have the advantage of being safer to deal with than solvent-based systems but may not be suitable for drugs which are degraded by hydrolysis It considered to consist of a series of steps (unit processes) – weighing, sifting, mixing, granulation, drying, blending / lubrication, filling into hard gelatin capsules (Capsules dosage form) / compression into tablets (tablet dosage form) followed by coating (film coated tablets) and packaging. The commonly used excipients in the immediate release tablets / capsules dosage forms are diluent (s), Binder, Disintegrant (s), Anti-adherent, Lubricant..etc.

Limitation of wet granulation[8]: 1. The main disadvantage of wet granulation is its cost. It is an expensive process, involves number of steps, more labour and time is required, equipment, energy and space requirements. 2. Loss of material during various stages of processing. 3. Stability may be a major concern for moisture sensitive or thermo labile drugs. 4. An inherent limitation of wet granulation is that any incompatibility between formulation components is aggravated.

B. Direct Compression / Filling Method[8]: In this method, the mixture / blend of the drug and excipients (without any preliminary treatment) will be compressed into tablets with suitable toolings by using suitable compression machine in case of tablet dosage forms / fill into suitable hard gelatin capsules by using suitable capsule filling machine in case of capsule dosage forms. The mixture to be compressed / filled must have adequate flow properties and cohere under pressure thus

making pre-treatment as wet granulation unnecessary. Few drugs can be directly compressed into tablets of acceptable quality. A type of disintegrant and its proportion are of prime importance. The other factors to be considered are particle size distribution, contact angle, flowability. All these factors determine the disintegration. The disintegrant addition technology is cost effective and easy to implement at industrial level.

Limitations in Direct compression / filling[8]: 1. Problems in the uniform distribution of low dose drugs. 2. High dose drugs having high bulk volume, poor compressibility and poor flowability are not suitable for direct compression. 3. The choice of excipients for direct compression is extremely critical. Direct compression diluents and binders must possess both good compressibility and good flowability. 4. Many active ingredients are not compressible either in crystalline or amorphous forms. 5. Capping, lamination, splitting, or layering of tablets is sometimes related to air entrapment during direct compression. When air is trapped, the resulting tablets expand when the pressure of tablet is released, resulting in splits or layers in the tablet.

C. Dry granulation[8]: The manufacture of tablets / capsules by dry granulation method eliminates a number of unit operations but still include weighing, mixing, compaction / slugging, milling or sizing of flakes / coarser granules, dry screening, lubrication, and compression or filling of granules into tablets or capsules. Dry granulation is a method where no moisture and heat is used to process powders into granules. There are two types of dry granulation: **slugging** – where a blend of API and excipients is compressed into large tablets or slugs, and **roller compaction** - process in which uniformly mixed blend of API and excipients are compressed between two counter rotating rolls to form a compact flakes. In both cases these intermediate products, slugs and flakes are sized using suitable milling technique to produce granular material which is then sieved to separate desired particle size.

Slugging involves the use of circulating dies to produce a large compact / tablet, often 20 mm or larger in diameter. In this process, round, flat – faced punches should be used in order to avoid trapped air within the slug, which may be trapped with concave punches. To get better feeding and high production rate the maximum diameter should be used. Slugging tends to be more limiting in terms of uniformity and capacity than roller compaction system. The advances of roller compaction over slugging are: greater production capacity, more control over operating parameters, simplifier and continuous processing.

Limitations in dry granulation[8]: 1. It requires a specialized tablet press to form slug. 2. It does not permit uniform colour distribution as can be achieved with wet granulation where the dye can be incorporated into binder liquid. 3. The process tends to create more dust than wet granulation, increasing the potential contamination.

The list of commonly used fillers / diluents in Immediate release solid oral dosage forms[9]: Lactose monohydrate, Lactose anhydrous, Microcrystalline cellulose, Maize starch, Pregelatinized starch, Dicalcium Phosphate, Mannitol, Sorbitol, Dextrose, etc.

The list of commonly used binders in Immediate release solid oral dosage forms[9]: Povidone, Copovidone, Hydroxypropyl cellulose, Hydroxypropyl methyl cellulose, Ethyl cellulose, Maize starch, Carbomers, Alginic acid, Polyethylene Oxide, Acacia, etc.

The list of commonly used disintegrants in Immediate release solid oral dosage forms[9]
Crosscarmellose sodium, Crospovidone, Sodium starch glycolate, Pregelatinized starch, Microcrystalline cellulose, Low substituted hydroxypropyl cellulose (L-HPC), Polacrillin Potassium, etc.

The list of commonly used surfactants in Immediate release solid oral dosage forms[9]
Sodium lauryl sulphate (anionic surfactant), Poloxamer (non-ionic surfactant), Polysorbates (non-ionic surfact), Polyoxyethylene castor oil derivate, Polyoxyethylene stearates, Vitamin-E polyethylene glycol, etc.

The list of commonly used Glidants in Immediate release solid oral dosage forms[9]
Colloidal silicon dioxide, Talc, etc.

The list of commonly used Lubricants in Immediate release solid oral dosage forms[9]
Magnesium stearate, Sodium stearyl fumarate, Calcium stearate, Hydrogenated castor oil, Stearic acid, etc.

An excipient called disintegrant are added to a tablet or capsule blend to aid in the breakup of the compacted mass when it is put into a fluid environment. Disintegrant are used in immediate release tablets to enhance dissolution and hence bioavailability of any drug. Disintegration is one of important process. “Superdisintegrants” newer substances are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength. Few Super-disintegrants are available commercially as Croscarmellose sodium, Crospovidone and Sodium starch glycolate. In the present investigation, we tried to judge the disintegration efficiency of disintegrants by comparing various parameters such as disintegration time, wetting time, maximal water uptake capacity and dissolution study of tablet. Disintegrants powder properties like swelling and hydration capacity was compared.

Evaluation of powder blend[10-11]: The prepared blend is evaluated by following tests.

1. Angle of repose
2. Bulk density
3. Tapped density
4. Hauser's ratio
5. Carr's index

1. Angle of repose: Angle of repose was determined by using fixed funnel method. The fixed funnel method employ a funnel that was secured with its tip at a given height (2cm), above the graph paper that was placed on a flat horizontal surface. Granules or blend to be compressed / filled is carefully poured through the funnel until the apex of the conical pile just touches the tip of the funnel. Thus, with **'r'** being the radius of the base of the conical pile. Angle of repose was calculated using the following equation.

$\theta = \tan^{-1}$ (h/r), where h = Height of pile; r = Radius of pile; θ = Angle of repose.

2. Bulk density: Bulk density was determined by pouring a weighed quantity of Granules or blend to be compressed / filled into graduated cylinder and measuring the height. Bulk density is the ratio of mass of tablet blend to bulk volume.
Bulk density = m / v; where m = weight of powder or granules (gm); v = Bulk Volume (cm^3).

3. Tapped Density: Tapped density is ratio of mass of Granules or blend to be compressed / filled to tapped volume of tablet blend. Accurately weighed amount of Granules or blend to be compressed / filled poured in graduated cylinder and height is measured. As per USP<616>, there are two methods for determination tapped density of individual raw material / granules / blend, *i.e.*, Method-I and Method-II.

Method-I Procedure
Apparatus—the apparatus consists of the following
- A 250-mL graduated cylinder (readable to 2 mL)
- A settling apparatus capable of producing, in 1 min, either nominally 250 ± 15 taps from a height of 3 ± 0.2 mm, or nominally 300 ± 15 taps from a height of 14 ± 2 mm.

Proceed as described above for the determination of the bulk volume (V_0). Secure the cylinder in the holder. Carry out 10, 500, and 1250 taps on the same Change to read: powder sample and read the corresponding volumes V_{10}, V_{500}, and V_{1250} to the nearest graduated unit. If the difference between V_{500} and V_{1250} is less than or equal to 2 mL, V_{1250} is the tapped volume. If the difference between V_{500} and V_{1250} exceeds 2 mL, repeat in increments such as 1250 taps, until the difference between succeeding measurements is less than or equal to 2 mL. Fewer taps may be appropriate for some powders, Calculate the tapped density (g/mL) using the formula m/V_F, in which calculate V_F is the final tapped volume.

Method-II Apparatus and Procedure - proceed as directed under Method I except that the mechanical tester provides a fixed drop of 3 ± 0.2 mm at a nominal rate of 250 taps per min.

4. Hausner's Ratio: Hausner's ratio indicates the flow properties of powder and measured by the ratio of tapped density to bulk density. Hausner's ratio was determined by the given formula
Hausner's ratio = Tapped density / Bulk density.

5. Carr's Index (Compressibility Index): Compressibility is the ability of powder to decrease in volume under pressure. The percentage compressibility of powder is determined using bulk density and tapped density, which is given as carr's compressibility index. It is indirectly related to the relative flow rate. Carr's compressibility index was determined by the given formula
Carr's Index = [(Tapped density – Bulk density) / Tapped density] x 100 / or
Carr's Index = $[(V_0 - V_F)/ V_F]$ x 100; where V_0 = unsettled apparent volume; V_F = final tapped volume

Table. 1.1: Relation between flow properties with Compressibility index (Carr's index) and Hausner ratio.[11]

Flow Properties	Angle of repose (^{0})	CI (%)	HR
Excellent	25-30	<10	1.00-1.11
Good	31-35	11-15	1.12-1.18
Fair	36-40	16-20	1.19-1.25
Passable	41-45	21-25	1.26-1.34
Poor	46-55	26-31	1.35-1.45
Very poor	56-65	32-37	1.45-1.59
Very very poor	>66	>38	>1.60

Where, CI is The Carr's index an HR is Hausner ratio.

Evaluation of Tablets / Capsules[12]
In-process tests during compression of tablets: - 1. Appearance / Description, 2. Weight variation / Weight of 10 tablets (gm), 3. Individual weight (mg) 3. Thickness (mm), 4. Hardness (kilo ponds / newton), 5. Friability (%w/w), 6. Disintegration time (min),

In-process tests during filling of Hard gelatin capsules - 1. Appearance / Description, 2. Average weight of empty capsule shell (mg), 3. Average weight of filled capsule (mg), 4. Weight variation of 10 filled capsules (gm), 5. Individual weight variation of filled capsules (mg), 6. Individual weight variation of fill content (mg), 7. Lock length (mm), 8. Disintegration time (min).

The tests for finished product (tablets) at release and stability testing.[13]

Table 1.2: The tests for finished product (tablets) at release and stability testing.

S. No	Tests	At release (Initial)	At stability stage
1	Description	Yes	Yes
2.	Identification by A) UV; B)HPLC	Yes	No
3	Water content (By KF)	Yes	Yes
4	Average weight	Yes	No
5	Dissolution (By HPLC / UV)	Yes	Yes
6	Uniformity of dosage units (by weight variation / Content uniformity)	Yes	No
7	Assay	Yes	Yes
8	Related substances / Impurities	Yes	Yes
9	Microbiological examination	Yes	Yes
10	Residual solvents	Yes	No

Table 1.3: The tests for finished product (capsules) at release and stability testing.[13]

S. No	Tests at release stage	At release (Initial)	Tests at stability
1	Description	Yes	Yes
2.	Identification by A) UV; B)HPLC	No	No
3	Water content (By KF)	Yes	Yes
4	Average weight of filled capsules	No	No
5	Average net of filled content	No	No
6	Lock length	No	No
5	Dissolution (By HPLC / UV)	Yes	Yes
6	Uniformity of dosage units (by weight variation / Content uniformity)	No	No
7	Assay	Yes	Yes
8	Related substances / Impurities	Yes	Yes
9	Microbiological examination	Yes	Yes
10	Residual solvents	No	No

Storage Conditions[14]

Climatic Zones

- Zone I: 21°C/45% RH
- Zone II: 25°C/60% RH (subtropical)
- Zone III: 30°C/35% RH (hot/ dry)
- Zone IVA: 30°C/65% RH (hot/ humid)
- Zone IVB: 30°C/75% RH (hot/ very humid)

Stability testing[14]

The storage conditions and the lengths of studies chosen should be sufficient to cover storage, shipment, and subsequent use. The long term testing should cover a minimum of 12 months duration on at least three primary batches at the time of submission and should be continued for a period of time sufficient to cover the proposed re-test period. Additional data accumulated during the assessment period of the registration application should be submitted to the authorities if requested. Data from the accelerated storage condition and, if appropriate, from the intermediate storage condition can be used to evaluate the effect of short term excursions outside the label storage conditions (such as might occur during shipping). Long term, accelerated, and, where appropriate, intermediate storage conditions for drug substances are detailed in the sections below. The general case applies if the drug substance is not specifically covered by a subsequent section. Alternative storage conditions can be used if justified.

Table. 1.4: Finished product Stability testing – General case.[14]

Study	Storage condition	Minimum time period covered by data at submission
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months
Intermediate*	30°C ± 2°C/65% RH ± 5% RH	6 months
Long term**	25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH	or 30°C ± 2°C/65% RH ± 5% RH 12 months

*If 30°C ± 2°C/65% RH ± 5% RH is the long-term condition, there is no intermediate condition.

**It is up to the applicant to decide whether long term stability studies are performed at 25 ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH.

If long-term studies are conducted at 25°C ± 2°C/60% RH ± 5% RH and "significant change" occurs at any time during 6 months' testing at the accelerated storage condition, additional testing at the intermediate storage

condition should be conducted and evaluated against significant change criteria. Testing at the intermediate storage condition should include all tests, unless otherwise justified. The initial application should include a minimum of 6 months' data from a 12-month study at the intermediate storage condition. "Significant change" for a drug substance is defined as failure to meet its specification.

Testing Frequency[14]

Accelerated stability: Minimum three points including t_0 and t_{final}, *i.e.*, 0 (initial), 3 months, 6 months. Long term stability: 0 (initial), 3, 6, 12, 18, 24, 36 months Intermediate stability: Four points including t_0 and t_{final}, *i.e.*, 0 (initial), 6, 9, 12 months.

Note: when long term condition is Zone IV, there is no intermediate condition.

Summarizing dissolution data[15]

Dissolution limits should be expressed as a Q value (amount of API expressed as % label content), in line with the harmonized chapters (USP, BP, JP)

Q value means three stage testing:

- Stage 1 (6 units): each unit ≥ Q+5%
- Stage 2 (6 units): average of 12 units (S1 + S2) ≥ Q, no unit < Q-15%
- Stage 3 (12 units): average of 24 units (S1 + S2 +S3) ≥ Q, not more than 2 units < Q-15%, No unit < Q-25%

Stage 1 is always tested. Stage 2 is tested only if stage 1 fails. Stage 3 is tested only if stage 2 fails.

Rationale for the Reporting and Control of Degradation Products:

Summarizing Related substances / Impurities of Finished product[16]**:** The specification for a new drug product should include a list of degradation products expected to occur during manufacture of the commercial product and under recommended storage conditions. Stability studies, knowledge of degradation pathways, product development studies, and laboratory studies should be used to characterise the degradation profile. The selection of degradation products in the new drug product specification should be based on the degradation products found in batches manufactured by the proposed commercial process.

Degradation Product: An impurity resulting from a chemical change in the drug substance brought about during manufacture and/or storage of the new drug product by the effect of, for example, light, temperature, pH, water, or by reaction with an excipient and/or the immediate container closure system. Degradation Profile: A description of the degradation products observed in the drug substance or drug product. Development Studies: Studies conducted to scale-up, optimise, and validate the manufacturing process for a drug product. Identification Threshold: A limit above (>) which a degradation product should be identified.

Impurity Profile: A description of the identified and unidentified impurities present in a drug product. New Drug Substance:

Impurity: Any component of the new drug product that is not the drug substance or an excipient in the drug product.

Identified Degradation Product: A degradation product for which a structural characterisation has been achieved.

Qualification: The process of acquiring and evaluating data that establishes the biological safety of an individual degradation product or a given degradation profile at the level(s) specified.

Reporting Threshold: A limit above (>) which a degradation product should be reported.

Qualification Threshold: A limit above (>) which a degradation product should be qualified.

Specified Degradation Product: A degradation product that is individually listed and limited with a specific acceptance criterion in the new drug product specification. The formulator should summarise the degradation products observed during manufacture and/or stability studies of the new drug product. Any degradation product observed in stability studies conducted at the recommended storage condition should be identified when present at a level greater than (>) the identification thresholds. Degradation products present at a level of not more than (≤) the identification threshold generally would not need to be identified.

Table 1.5: Thresholds for Degradation Products in New Drug Products.[16]

A.Reporting Thresholds		B. Identification Thresholds		C. Qualification Thresholds	
Maximum Daily Dose	**Threshold**	**Maximum Daily Dose**	**Threshold**	**Maximum Daily Dose**	**Threshold**
≤ 1 g	0.1%	< 1 mg	1.0% or 5 µg TDI, whichever is lower	< 10 mg	1.0% or 50 µg TDI, whichever is lower
> 1 g	0.05%	1 mg - 10 mg	0.5% or 20 µg TDI, whichever is lower	10 mg - 100 mg	0.5% or 200 µg TDI, whichever is lower
		>10 mg - 2 g	0.2% or 2 mg TDI, whichever is lower	>100 mg - 2 g	0.2% or 3 mg TDI, whichever is lower
		> 2 g	0.10%	> 2 g	0.15%

The product is said to be passing the stability test criteria, if there is no significant change is any of[14]

1. Any degradation product exceeding its specified limit
2. Failure in tests of appearance, physical attributes and functionality test, e.g. colour, hardness, pH.
3. > 5% change in assay from initial, *i.e.* t_0.
4. Failure to pass dissolution testing for 12 dosage units (fail S2 criteria).

As per ICH, the shelf life of the product will be decided based on its accelerated and long term stability data.

Table 1.6: Shelf life of the product, if accelerated stability data till 6 months is within the pre-defined stability specifications.

	X	Y
Accelerated stability data for 6 months within the pre-defined stability specifications	Long term stability (till 9 months within the stability specifications)	Y=2X Shelf life is 18 months
	Long term stability (till 12 months within the stability specifications)	Y=2X Shelf life is 24 months
	Long term stability (till 18 months within the stability specifications)	Y=X+12 Shelf life is 30 months
	Long term stability (till 24 months within the stability specifications)	Y=X+12 Shelf life is 36 months
	Long term stability (till 36 months within the stability specifications)	Y=X Shelf life is 36 months (no extrapolation beyond 36 months)

Table. 1.6: Shelf life of the product, if accelerated stability data till 6 months is not within the pre-defined stability specifications.

	X	Y
Accelerated stability data for 6 months is not within the pre-defined stability specifications	Intermediate stability (till 12 months within the stability specifications)	Y=1.5X Shelf life is 18 months
	Intermediate stability (till 9 months within the stability specifications)	Y=1.5X Shelf life is 13.5 months
	Intermediate stability (till 9 months is not within the stability specifications & If long term 9 months stability is within stability specifications)	Y=X+3 Shelf life is 12 months

CONCLUSION

Immediate release solid oral dosage forms (tablets / capsules) are applicable to a wide range of therapeutic drug substances. Most of the patients need quick therapeutic action of drug. Sometime immediate onset of action is desirable, to fulfil these medical needs, formulators have to develop a novel type of tablet dosage form for oral administration, one that disintegrates and dissolves rapidly with enhanced dissolution. These tablets / capsules are designed to release the medicaments with an enhanced rate. An extension of market exclusivity, which can be provide by immediate release dosage form, leads to increased revenue, while also targeting underserve and undertreated patient populations. The finished product should meet the pre-determined specifications throughout the shelf life of the product in the marketed pack.

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