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# Formulation Development and Evaluation of Immediate Release Dosage Form

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**Abstract:** Among all dosage forms, capsule is the most popular dosage form existing today because of its convenience of self administration, compactness and easy manufacturing. Immediate release dosage form are those where greater than or equal to 85% of labelled amount dissolves within 30 min. The basic approach used in development of capsule is the use of different disintegrants like Croscarmellose sodium, Sodium starch glycolate and Plantago Ovata and evaluate impact of different disintegrants on dissolution study. These disintegrants provide rapid disintegration of capsule after administration in stomach.

**Keywords:** Immediate release, Polymers, Disintegrant, Plantago Ovata

## I. INTRODUCTION

To get fast onset of action, drug should be released immediately or as quickly as possible after administrations. Immediate release dosage forms release the drug at first-order kinetics profile i.e, the drug is released initially very quickly with highest plasma level (Cmax) in a short time ($t_{max}$) followed by distribution of drug throughout the body and elimination of the drug occurs following first-order kinetics. Oral drug delivery system includes conventional dosage form and immediate release dosage form. For last so many decade's, conventional dosage forms like tablets, capsules, pills, powders, solutions, emulsions, suspensions and aerosols are used in the treatment of acute or chronic diseases.

Lumateperone is a newly approved second generation antipsychotic drug currently indicated for the treatment of schizophrenia[1]. It has a unique receptor binding profile and differs from other antipsychotics in that it modulates glutamate, serotonin and dopamine which are all neurotransmitters that contribute to the pathophysiology of schizophrenia.

## II. MATERIAL & METHODS

In the present study, Lumateperone tosylate used as active pharmaceutical ingredients along with excipients listed in Table 1 and capsule filling machine used to fill the formulation in the capsule along with other instruments listed in Table 2.

**Table 1: List of Ingredients**

| Sr. No. | Ingredient |
|---|---|
| 1. | Lumateperone Tosylate |
| 2. | Mannitol |
| 3. | Sodium Starch Glycolate |
| 4. | Isabgol Powder (Plantago Ovata) |
| 5. | Crosscarmellose Sodium |
| 6. | Colloidal Silicon Dioxide (Aerosil 200) |

**Table 2: List of Instruments**

| Sr. No. | Instuments | It's Use |
|---|---|---|
| 1. | **Sieve** | The sieves are used to get uniform particle size of drug |

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| | | |
|---|---|---|
| | | substance and excipients used in formulation |
| 2. | **Electronic Weighing Balance** | Electronic balance is an instrument used in the accurate measurement of weight of materials |
| 3. | **Ultra-Sonicator** | Sonicators are vital lab tools used for a wide range of applications, such as degassing, mixing, cleaning, cell disruption and dissolution |
| 4. | **UV Visible Spectrophotometer** | UV visible spectrophotometer measures the intensity of the light that passes through the sample. UV-Visible spectroscopy is a well-established analytical technique used in the development of active pharmaceutical ingredients, quantification of impurities, dissolution testing in pharmaceutical development. |
| 5. | **Dissolution Apparatus** | The tablet or capsule is placed in a stainless steel cylindrical mesh basket. The basket is placed in a vessel kept at a constant temperature. The basket is rotated at a constant speed (between 25 and 150 revolutions per minute). Samples are withdrawn for analysis from the same position each time. |
| 6. | **Capsule Filling Machine** | A capsule filling machine is always used for filling the powder in capsules. |
| 7 | **Density Apparatus** | Density apparatus is used to measure the tapped density of powders, granules as well as flaked materials by standardized and repeatable procedures in powder flowability studies. |

**Development of Formulation:**

**Table 3: Composition of F1 to F3 Formulation**

| Sr. No. | Ingredients | | F 1 | F 2 | F 3 |
|---|---|---|---|---|---|
| | | | mg/capsule | | |
| 1. | Lumateperone Tosylate | | 60.38 | 60.38 | 60.38 |
| 2. | Mannitol | | 218.12 | 218.12 | 218.12 |
| 3. | Crosscarmellose Sodium | *Disintegrant* | 16.00 | - | - |
| 4. | Sodium Starch Glycolate | | - | 16.00 | - |
| 5. | Plantago Ovata | | - | - | 16.00 |
| 6. | Aerosil 200 | | 1.50 | 1.50 | 1.50 |
| | **Total Quantity** | | **296.00** | **296.00** | **296.00** |

**Procedure:**

1. Weigh accurately 60.38 mg of Lumateperone tosylate equivalent to 42.00 mg of Lumateperone.
2. Dispense the excipients as per table 2 in sealed polythene bag.
3. Take half quantity of drug and half quantity of mannitol and mix them properly & pass through 60 mesh.
4. Take remaining quantity of drug & remaining half quantity of mannitol and half quantity of *disintegrant* mix properly & pass through 60#.
5. Mix the prelubricated blend of step 3 & 4 in polybag.
6. Take Aerosil & remaining half quantity of *disintegrant* in polybag. Mix them properly & pass through 60#
7. Add step 5 to step 6 & blend for 5 minutes.
8. Blend of step 7, filled in yellow coloured capsule size ‘0

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## III. RESULT AND DISCUSSION:

**Evaluation Parameter:**

***In-process* Parameter:**

**Flowability parameters of Drug Substance:**

**Table 4: Flowability Parameters of Drug Substance**

| Parameter | Drug Substance |
|---|---|
| Bulk Density (g/ml) | 0.60 |
| Tapped Density (g/ml) | 0.73 |
| Compressibility Index (%) | 17.80 |
| Hausner's Ratio | 1.216 |

**Table 5: Flowability Parameters of Lubricated Blend**

| Parameter | Lubricated Blend |
|---|---|
| Bulk Density (g/ml) | 0.64 |
| Tapped Density (g/ml) | 0.72 |
| Compressibility Index (%) | 11.111 |
| Hausner's Ratio | 1.125 |

**Table 6: Finished Product Parameters of Capsule**

| Parameter | Capsule |
|---|---|
| **Description** | White to off-white colored powder filled in hard gelatine capsule size "0" having a yellow body and yellow cap. |
| **The average weight of 10 filled capsules (g)** | 3.88 |
| **The average weight of 10 empty capsules (g)** | 0.92 |
| **Color** | Yellow |
| **Capsule Size** | 0 |

**Preparation of Dissolution Medium (0.1 N Hydrochloric Acid):**

Dilute 85 mL of concentrated hydrochloric acid to 1000 mL purified water and degas by sonication.

**Dissolution Parameters**:

Quantity of Dissolution Medium: 500 mL

Apparatus: USP Type - I (Basket)

RPM: 50

Profile Time Point: 30 min or specified time interval

Temperature: $37^0$C

Preparation of Blank Solution: Use dissolution medium.

**Preparation of Standard Stock Solution:**

Weigh and transfer accurately about 50 mg of Lumateperone tosylate (Equivalent to 35mg Lumateperone) working standard/Reference standard to 100 mL volumetric flask, add 70 mL of dissolution media and sonicate for 5 minutes to dissolve. Make up the volume up to the mark with dissolution media and mix well.

**Preparation of Test Preparation:**

Transfer 500 ml of dissolution medium into the vessel carefully and allow the medium to equilibrate to a temperature of 37± $0.5^0$C. Place one capsule in each basket and operate the apparatus at 50 RPM for specified time interval. Withdraw 5 ml of the sample from each dissolution vessel through syringe and replace with equal volumes of dissolution media which is maintained at 37 ±$0.5^0$C.

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**Calibration Curve for Lumatoperone Tosylate:**

**Table 7: Standard Calibration Curve of Lumatoperone Tosylate in 0.1N HCl**

| Sr. No. | Concentration (ppm) | Absorbance (at 248 nm) |
|---|---|---|
| 1 | 4 | 0.213 |
| 2 | 8 | 0.378 |
| 3 | 10 | 0.468 |
| 4 | 12 | 0.616 |
| 5 | 16 | 0.800 |
| 6 | 20 | 1.064 |

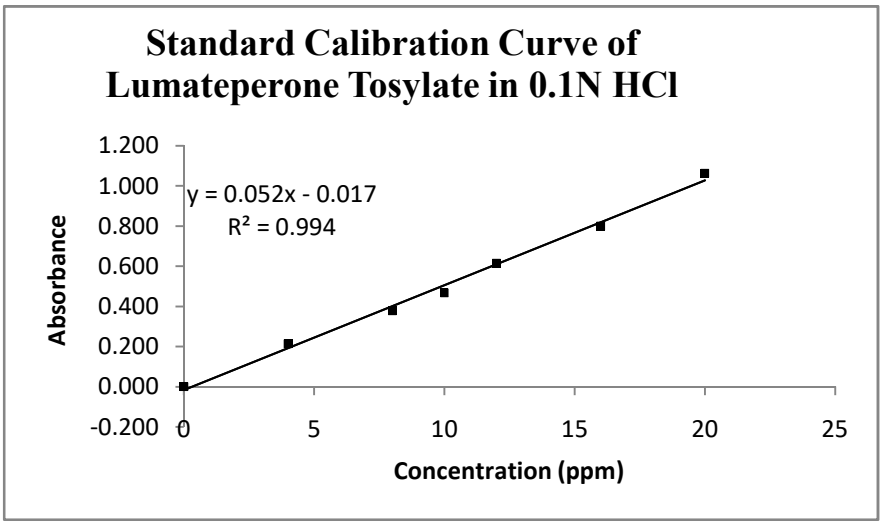


**Figure 1: Standard Calibration Curve of Lumateperone Tosylate in 0.1N HCl**

The caliberation curves of Lumateperone Tosylate were measured in 0.1N HCl which showed good linearity with the regression coefficient ($R^2$) as 0.9943.

During the development of formulation, different synthetic disintegants were used like crosscarmellose sodium and sodium starch glycolate. The main objective of current research work is to check efficiency of plantago ovata as a disintegrant and it's impact on dissolution profile. Below table 8 shows comparative dissolution profile of F1 to F3 formulation.

**Table 8: Comparative Dissolution Profile of F1 to F3 Formulation**

| Time (Min) | %Drug Release | | |
|---|---|---|---|
| | F1 | F2 | F3 |
| 0 | 0.00 | 0.00 | 0.00 |
| 5 | 9.11 | 8.97 | 8.31 |
| 10 | 23.24 | 22.87 | 21.96 |
| 15 | 40.57 | 39.97 | 38.80 |
| 20 | 58.36 | 57.53 | 56.55 |
| 25 | 76.74 | 75.78 | 74.68 |
| 30 | 96.22 | 94.28 | 93.15 |

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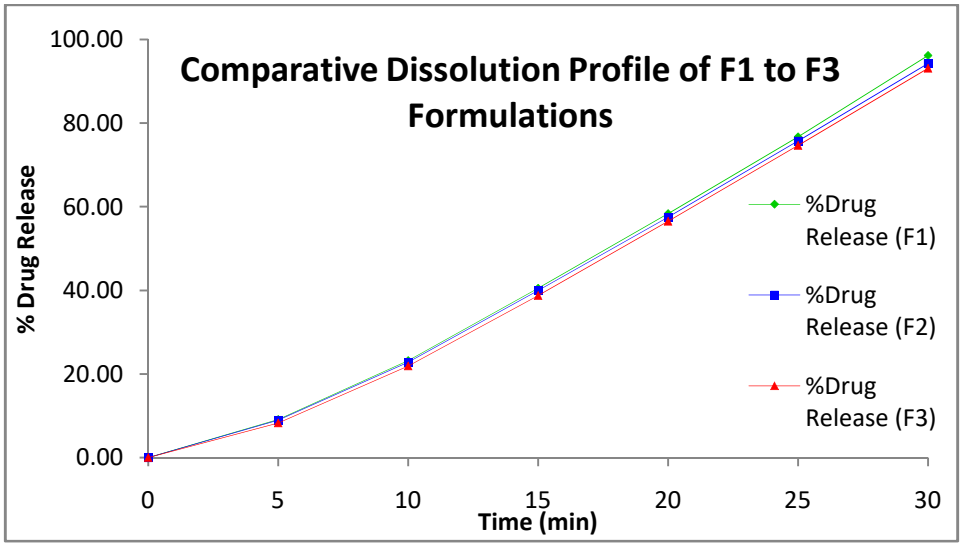


**Figure 2: Dissolution Profile of F1 to F3 Formulations**

*In vitro* drug release study reveals that, at same concentration of synthetic disintegrants like crosscarmellose sodium, sodium starch glycolatealong with natural disintegrant like plantago ovata shows almost similar dissolution profile in 30 minutes. The dissolution study shows that, *in-vitro* drug release profile of Lumateperone Tosylate using synthetic disintegrant and novel disintegrant shows comparative dissolution data.

## IV. CONCLUSION

Immediate release capsule which we have prepared shows the quick onset on action. Comparative results of dissolution study of different formulation concludes that,*Plantago Ovata* as a novel disintegrant can be used as a substitude for synthetic disintegrant.

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