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# DEVELOPMENT AND IN-VITRO EVALUATION OF MOUTH-DISSOLVING OLANZAPINE TABLETS: A COMPARATIVE STUDY WITH A MARKETED FORMULATION

Mohd Sadakat, Dr. Dilip Agrawal, Dr. Mohit Khandelwal
Mahatma Gandhi College of Pharmaceutical Sciences, Jaipur
Corresponding author: Mohd Sadakat, Research Scholar

**Abstract-** Mouth-dissolving tablets offer a practical alternative to conventional tablets for patients who find swallowing difficult. In the present work, olanzapine was selected as the model drug and formulated as a rapidly disintegrating oral tablet. The study focused on the role of commonly used superdisintegrants in achieving rapid tablet breakup and satisfactory drug release.

The objective was to develop and evaluate mouth-dissolving olanzapine tablets prepared with different superdisintegrants, either individually or in combination. Formulations showing the most promising disintegration and dissolution behavior were selected for further stability testing and for comparison with a marketed olanzapine tablet.

The tablets were prepared by direct compression using crospovidone, croscarmellose sodium and sodium starch glycolate. Preformulation studies and powder-flow measurements were carried out before compression. The prepared tablets were then evaluated for their physical characteristics, drug content, wetting time, disintegration and in-vitro dissolution. Dissolution testing was performed using USP Apparatus II in 500 mL of 0.1 N HCl at 37 ± 0.5 °C and 50 rpm, with drug estimation at 259.3 nm. Selected formulations were also stored under accelerated conditions of 40 ± 1 °C/75 ± 5% RH for 45 days.

All formulations showed satisfactory physical characteristics and acceptable drug content. In the A-series, disintegration time ranged from 37 to 220 s, while the B-series disintegrated within 36–67 s. A4 released 100.0% of the drug by 45 min, compared with 99.2% for B1 and 99.5% for B3. The dissolution data for A4, B1 and B3 showed the best fit with the first-order model, with $r^2$ values of 0.997, 0.981 and 0.950, respectively. Their similarity factors (f2)

against the marketed product were 79.1, 76.7 and 77.7.

The study showed that mouth-dissolving olanzapine tablets could be successfully prepared by direct compression. Among the formulations studied, A4, B1 and B3 provided a useful balance of rapid disintegration and high drug release, with crospovidone-containing formulations showing particularly favorable performance. Their dissolution profiles were similar to that of the marketed product in the present in-vitro comparison. These findings are encouraging, although in-vivo studies and bioavailability assessment would be needed before drawing conclusions about in-vivo performance.

Keywords: Olanzapine; mouth-dissolving tablet; orally disintegrating tablet; crospovidone; croscarmellose sodium; sodium starch glycolate; direct compression; dissolution; similarity factor.

## I. INTRODUCTION

Tablets remain one of the most convenient oral dosage forms because they are easy to handle, transport and administer while providing an accurate dose. Despite these advantages, swallowing a conventional tablet can be difficult for some patients, particularly those with dysphagia and for certain pediatric, geriatric and psychiatric populations. Mouth-dissolving tablets were developed to address this practical limitation by breaking apart rapidly in the oral cavity and allowing administration without water. This can make the dosage form more convenient and may improve patient acceptability.

The performance of a mouth-dissolving tablet depends on how quickly the tablet becomes wetted and breaks apart after coming into contact with fluid. Formulation composition, tablet porosity and the choice and concentration of superdisintegrant all contribute to this behavior. Crospovidone, croscarmellose sodium and sodium starch glycolate are commonly used for this purpose, although they promote disintegration through somewhat different mechanisms, including rapid liquid uptake, capillary action and swelling.

Olanzapine is an atypical antipsychotic used in the management of schizophrenia and bipolar disorder. The drug is practically insoluble in water, making dissolution an important consideration during formulation development. In view of these characteristics, the present study was designed to develop a rapidly disintegrating olanzapine tablet by direct compression and to examine how different superdisintegrants influence its disintegration and dissolution. The performance of selected

formulations was subsequently compared with that of a marketed product.

Accordingly, the study was planned to prepare mouth-dissolving olanzapine tablets using different superdisintegrants and their combinations, evaluate their physicochemical and performance characteristics, identify the most promising formulations, assess their short-term stability, and compare their dissolution profiles with a marketed olanzapine tablet.

## II. MATERIALS AND METHODS

### 2.1 Materials and equipment

Olanzapine was used as the active pharmaceutical ingredient. The formulation excipients were crospovidone, croscarmellose sodium, sodium starch glycolate, microcrystalline cellulose (Avicel PH 102), mannitol, aspartame, talc and sodium stearyl fumarate. The main instruments used during the study included a Shimadzu 1800 UV-visible spectrophotometer, FTIR spectrophotometer, tablet compression machine, USP dissolution apparatus, disintegration tester, friability tester, Monsanto hardness tester, bulk-density apparatus and Vernier caliper.

### 2.2 Preformulation studies

The drug was first characterized by melting point determination and FTIR spectroscopy. The FTIR spectrum was recorded using a KBr disc over the range of 4000–400 cm−1. The powder blends were evaluated for bulk density, tapped density, angle of repose, Carr's compressibility index and Hausner's ratio. Drug–excipient compatibility was assessed by comparing the FTIR spectra of the drug with those of selected formulations.

### 2.3 Preparation of mouth-dissolving tablets

The tablets were prepared by direct compression, using microcrystalline cellulose and directly compressible mannitol as the main filler system. Crospovidone, croscarmellose sodium and sodium starch glycolate were studied at different concentrations, and selected combinations were evaluated in a 1:1 ratio. Aspartame was incorporated at 4% w/w to improve palatability, while sodium stearyl fumarate was used as the lubricant. Care was taken during blending to minimize excessive hydrophobicity, which could otherwise interfere with wetting and disintegration.

Two formulation approaches were investigated. In the first, individual superdisintegrants were incorporated into the formulations designated A1–A10. In the second, selected

superdisintegrants were combined to obtain formulations B1–B3. Each combination formulation contained 5 mg of olanzapine and had an average tablet weight of 100 mg. The composition of the B-series formulations is presented below.

| **Ingredient (mg/tablet)** | **B1** | **B2** | **B3** |
|---|---|---|---|
| Olanzapine | 5 | 5 | 5 |
| Croscarmellose sodium | 2.5 | 2.5 | — |
| Crospovidone | 2.5 | — | 2.5 |
| Sodium starch glycolate | — | 2.5 | 2.5 |
| Avicel PH 102 | 15 | 15 | 15 |
| Aspartame | 4 | 4 | 4 |
| Sodium stearyl fumarate | 1 | 1 | 1 |
| Talc | 2 | 2 | 2 |
| Mannitol | 68 | 68 | 68 |
| Average tablet weight (mg) | 100 | 100 | 100 |

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### 2.4 Evaluation of tablets

The prepared tablets were evaluated for weight variation, thickness, hardness, friability, drug content, wetting time and in-vitro disintegration. For weight variation, 20 tablets were examined. Hardness was measured using five tablets, thickness was determined for ten tablets, and friability was evaluated using 10 tablets at 25 rpm for 100 revolutions.

Wetting time was measured using the moistened tissue-paper method. Disintegration was evaluated using a modified procedure suitable for rapidly disintegrating tablets, with complete dispersion of the tablet fragments taken as the endpoint.

### 2.5 Dissolution study

Dissolution testing was carried out using USP Apparatus II (paddle) at 37 ± 0.5 °C and 50 rpm in 500 mL of 0.1 N HCl. At predetermined time points, 5 mL samples were withdrawn and passed through a 0.45-µm cellulose acetate membrane filter. The withdrawn volume was replaced with an equal volume of fresh dissolution medium. Drug concentration was determined spectrophotometrically at 259.3 nm. The release data were analyzed using zero-order and first-order kinetic models.

### 2.6 Stability study

The formulations A4, B1 and B3 were selected for accelerated stability testing. After packing in aluminium foil, the tablets were stored at 40 ± 1 °C/75 ± 5% RH for 45 days. Hardness, drug content, disintegration time and cumulative drug release at 45 min were assessed at 15-day intervals.

**The dissolution behavior of the selected formulations was compared with that of Oleanz 5 mg tablets manufactured by Sun Pharma. The similarity factor (f2) was calculated using the dissolution profiles. In accordance with the approach used in the thesis, an f2 value above 50 was taken to indicate similar dissolution behavior.**

The selected formulations were compared with Oleanz 5 mg tablets (Sun Pharma) using dissolution profiles. The similarity factor f2 was calculated as reported in the thesis; values above 50 were interpreted as indicating similar dissolution behavior.

## III. RESULTS

### 3.1 Preformulation findings

The procured olanzapine sample showed a melting point of 198 °C, which was close to the reference value of approximately 195 °C reported in the thesis drug profile. FTIR spectra

were obtained for the drug and selected formulations. The observed spectra were reported to support compatibility between olanzapine and the excipients used in the selected formulations.

### 3.2 Powder flow and pre-compression properties

The powder blends showed reasonably consistent flow characteristics. For A1–A10, the angle of repose was approximately 31.87–35.62°, Carr's index was 13.47–21.15% and Hausner's ratio was 1.15–1.26. For B1–B3, the corresponding ranges were 34.21–34.46°, 17.18–19.84% and 1.20–1.24%, respectively. Overall, these findings supported the suitability of the blends for processing by direct compression.

### 3.3 Post-compression evaluation

| **Formulation** | **Thickness (mm)** | **Hardness (kg/cm²)** | **Friability (%)** | **Weight (mg)** | **Wetting time (s)** |
|---|---|---|---|---|---|
| A1 | 2.60 | 3.3 | 0.57 | 100 | 41 |
| A2 | 2.61 | 3.1 | 0.55 | 101 | 35 |
| A3 | 2.61 | 3.3 | 0.57 | 99 | 28 |
| A4 | 2.61 | 3.3 | 0.58 | 99 | 16 |
| A5 | 2.61 | 3.5 | 0.56 | 99 | 26 |
| A6 | 2.59 | 3.3 | 0.56 | 100 | 21 |
| A7 | 2.60 | 3.1 | 0.56 | 99 | 15 |

| | | | | | |
|---|---|---|---|---|---|
| A8 | 2.61 | 3.5 | 0.57 | 100 | 37 |
| A9 | 2.59 | 3.5 | 0.56 | 100 | 37 |
| A10 | 2.62 | 3.3 | 0.56 | 100 | 40 |
| B1 | 2.63 | 3.1 | 0.56 | 100 | 19 |
| B2 | 2.60 | 3.6 | 0.57 | 100 | 24 |
| B3 | 2.58 | 3.5 | 0.57 | 101 | 18 |

The post-compression data showed relatively narrow ranges for thickness, hardness and friability. Wetting time was lowest for A7 (15 s) and A4 (16 s) among the A-series, while B3 showed the shortest wetting time among the combination batches (18 s).

**3.4 Disintegration and drug content**

| **Formulation** | **Disintegration time (s)** | **Drug content (%)** |
|---|---|---|
| A1 | 220 | 98.65 |
| A2 | 135 | 97.14 |
| A3 | 79 | 98.46 |
| A4 | 37 | 99.51 |
| A5 | 121 | 98.27 |

| | | |
|---|---|---|
| A6 | 86 | 97.66 |
| A7 | 53 | 98.65 |
| A8 | 161 | 98.70 |
| A9 | 91 | 99.10 |
| A10 | 60 | 99.53 |
| B1 | 39 | 98.21 |
| B2 | 67 | 96.35 |
| B3 | 36 | 99.79 |

Disintegration time ranged from 37 to 220 s in A1–A10 and from 36 to 67 s in B1–B3. A4, B1 and B3 were selected for further evaluation because of their favorable combination of rapid disintegration and dissolution performance.

**3.5 Dissolution behavior**

| **Time (min)** | **A1** | **A2** | **A3** | **A4** | **A5** | **A6** | **A7** | **A8** | **A9** | **A10** |
|---|---|---|---|---|---|---|---|---|---|---|
| 5 | 15.18 | 19.20 | 22.09 | 42.70 | 15.54 | 19.50 | 21.18 | 15.93 | 17.58 | 22.50 |
| 10 | 17.03 | 22.50 | 39.70 | 71.70 | 17.76 | 23.40 | 44.20 | 18.20 | 19.87 | 42.10 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 15 | 32.74 | 37.80 | 47.50 | 81.50 | 32.84 | 42.60 | 56.70 | 25.52 | 35.56 | 58.20 |
| 20 | 35.00 | 42.20 | 61.10 | 87.80 | 34.09 | 53.20 | 74.30 | 35.04 | 47.82 | 71.70 |
| 30 | 46.25 | 50.80 | 74.60 | 95.50 | 46.05 | 58.20 | 81.20 | 45.66 | 48.65 | 77.10 |
| 45 | 55.07 | 64.20 | 81.30 | 100.00 | 55.35 | 67.70 | 87.58 | 52.32 | 58.89 | 86.20 |

| **Time (min)** | **B1** | **B2** | **B3** |
|---|---|---|---|
| 5 | 41.8 | 23.1 | 38.9 |
| 10 | 74.54 | 41.8 | 69.8 |
| 15 | 78.8 | 54.5 | 75.6 |
| 20 | 84.3 | 69.2 | 83.2 |
| 30 | 93.8 | 74.8 | 91.4 |
| 45 | 99.2 | 85.8 | 99.5 |

At 45 min, A4 achieved 100.0% release, while B1 and B3 achieved 99.2% and 99.5%, respectively. The thesis reports that formulations containing crospovidone showed better dissolution than formulations containing the other individual superdisintegrants and that increasing superdisintegrant concentration generally improved release.

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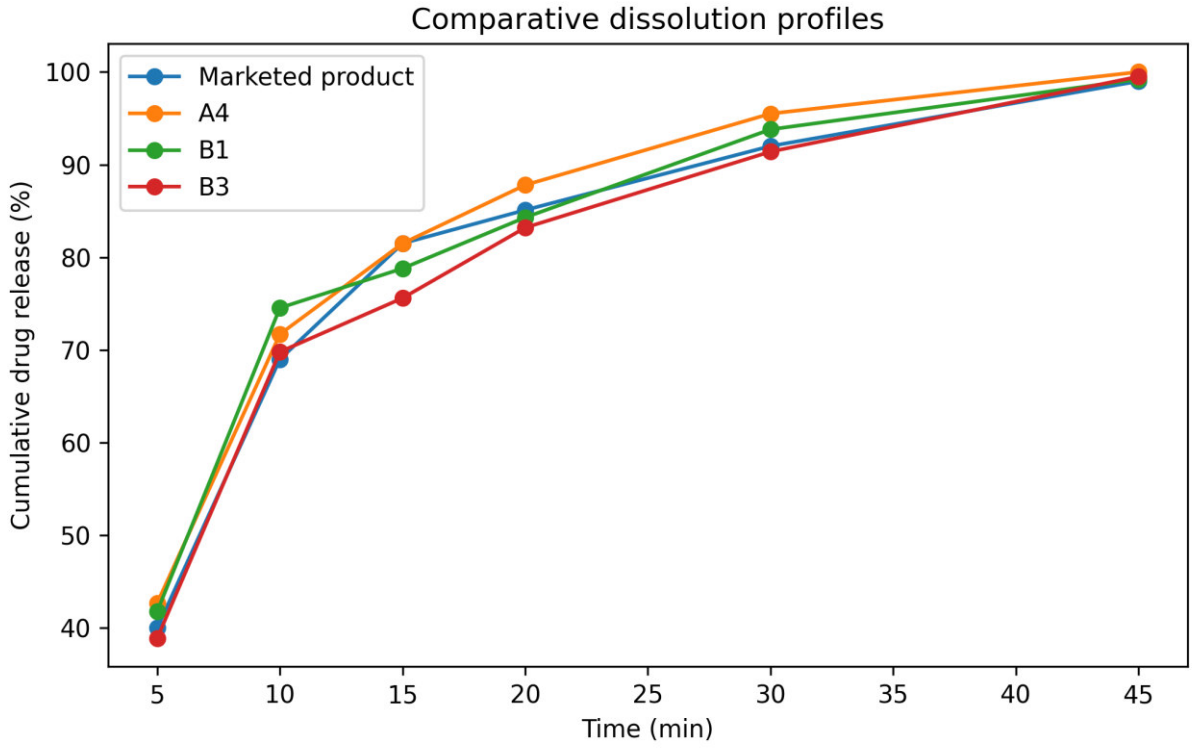



Figure 1. Comparative dissolution profiles of selected formulations and the marketed product.

The post-compression results were relatively consistent across the formulations, with only small differences in thickness, hardness and friability. Among the A-series, A7 and A4 showed the shortest wetting times at 15 and 16 s, respectively. B3 showed the shortest wetting time among the combination formulations, at 18 s.

| **Formulation** | **Zero-order $r^2$** | **First-order $r^2$** | **Best-fit model** |
|---|---|---|---|
| A4 | 0.670 | 0.997 | First order |

| | | | |
|---|---|---|---|
| B1 | 0.667 | 0.981 | First order |
| B3 | 0.708 | 0.950 | First order |

The first-order model provided the highest coefficient of determination for all three selected formulations, with $r^2$ values of 0.997 for A4, 0.981 for B1 and 0.950 for B3.

**3.7 Stability**

| **Formulation** | **Time** | **Hardness (kg/cm²)** | **Drug content (%)** | **Disintegration (s)** | **Release at 45 min (%)** |
|---|---|---|---|---|---|
| A4 | 15 days | 3.30 | 99.50 | 39 | 99.2 |
| A4 | 30 days | 3.33 | 98.56 | 41 | 99.7 |
| A4 | 45 days | 3.12 | 96.78 | 46 | 98.5 |
| B1 | 15 days | 3.12 | 98.12 | 40 | 99.5 |
| B1 | 30 days | 3.24 | 97.64 | 40 | 99.7 |
| B1 | 45 days | 3.18 | 96.38 | 45 | 98.8 |
| B3 | 15 days | 3.41 | 98.81 | 36 | 99.1 |
| B3 | 30 days | 3.38 | 97.13 | 39 | 98.5 |
| B3 | 45 days | 3.50 | 96.31 | 45 | 98.9 |

The selected formulations showed only modest changes in hardness, drug content, disintegration time and 45-min drug release during the 45-day accelerated stability study. The thesis therefore considered the selected formulations stable over the study period.

**3.8 Comparison with marketed product**

| **Time (min)** | **Marketed Oleanz 5 mg** | **A4** | **B1** | **B3** |
|---|---|---|---|---|
| 5 | 40.0 | 42.70 | 41.8 | 38.9 |
| 10 | 69.0 | 71.70 | 74.54 | 69.8 |
| 15 | 81.5 | 81.50 | 78.8 | 75.6 |
| 20 | 85.1 | 87.80 | 84.3 | 83.2 |
| 30 | 92.0 | 95.50 | 93.8 | 91.4 |
| 45 | 99.0 | 100.00 | 99.2 | 99.5 |
| f1 | — | 2.7 | 2.8 | 2.3 |
| f2 | — | 79.1 | 76.7 | 77.7 |

All three selected formulations had f2 values greater than 50 (76.7–79.1), indicating similar dissolution profiles to the marketed product according to the similarity-factor approach used in the thesis.

## IV. DISCUSSION

Disintegration time varied considerably across the individual-superdisintegrant formulations, ranging from 37 to 220 s. The combination formulations showed faster disintegration overall, with times ranging from 36 to 67 s. On the basis of the combined disintegration and dissolution results, A4, B1 and B3 were selected for further study.

Among the individual-superdisintegrant batches, A4 was particularly effective, with a disintegration time of 37 s and complete dissolution at 45 min. The combination batches B1 and B3 also showed rapid disintegration (39 and 36 s, respectively) and high drug release at 45 min (99.2 and 99.5%). These findings support the thesis observation that combining crospovidone with croscarmellose sodium or sodium starch glycolate can produce favorable performance.

The selected formulations showed first-order model fit according to the thesis calculations. Importantly, the dissolution profiles of A4, B1 and B3 were similar to the marketed product

based on f2 values. This supports comparable in-vitro release behavior, but it should not be interpreted as proof of pharmaceutical equivalence or bioequivalence because the present study did not include comparative in-vivo pharmacokinetic evaluation.

The 45-day accelerated stability results were encouraging, with drug content remaining above 96% in all reported observations and only modest changes in disintegration and dissolution. Longer-term stability under ICH-relevant conditions, including a validated stability protocol and statistical evaluation, would strengthen the evidence for product stability.

**A clear difference in dissolution performance was observed among the formulations. At 45 min, A4 reached 100.0% drug release, while B1 and B3 reached 99.2% and 99.5%, respectively. The results also indicated that formulations containing crospovidone generally released the drug more rapidly than formulations containing the other individual superdisintegrants. Within the study conditions, increasing the concentration of superdisintegrant was also associated with improved drug release.**

Mouth-dissolving olanzapine tablets were successfully developed by direct compression using crospovidone, croscarmellose sodium and sodium starch glycolate as superdisintegrants. The prepared tablets exhibited acceptable physical characteristics, rapid disintegration and high drug release. A4, B1 and B3 were identified as promising formulations, with 45-min drug release of 100.0%, 99.2% and 99.5%, respectively. Their dissolution profiles were similar to the marketed Oleanz 5 mg product, with f2 values of 79.1, 76.7 and 77.7. Short-term accelerated stability testing indicated no major deterioration over 45 days. Further work should include comprehensive long-term stability, in-vivo performance, pharmacokinetic/bioavailability studies and, where appropriate, comparative clinical evaluation.

## V. DECLARATIONS

Ethics approval: Not applicable to the reported in-vitro formulation and evaluation work.

For all three selected formulations, the first-order model gave the higher coefficient of determination. The $r^2$ values were 0.997 for A4, 0.981 for B1 and 0.950 for B3, indicating that the observed release data were better described by the first-order model than by the zero-order model under the conditions of this study.

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Data availability: The experimental data are contained in the underlying thesis and can be made available by the corresponding author subject to institutional/journal requirements.

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