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# Formulation and *In-vitro* Evaluation of Escitalopram Oxalate Tablets by Using Super Disintegrants

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ABSTRACT

Oral disintegrating Escitalopram Oxalate tablets have been formulated by direct compressing method. Escitalopram Oxalate is used as antidepressant drug and is beneficial to somebody needing dysphagia. In compatibility report there is no interaction between the drug and also the polymers. The ET1-ET9 used to be developed through direct compressing method using super disintegrants croscarmellose sodium, Hydroxypropyl Cellulose and Polacrillin potassium. All the formulations showed good flow properties. The ET9 displayed to fine results as well as varied evaluation outcomes get pleasure from Hardness, Weight variation, Disintegration time, Drug content and Dissolution profile. Stability studies were carried out with optimized formulation ET9 which was stored for a period of one and two months at $40\pm2^{O}$C temperature and $75\pm5\%$ relative humidity for a period 2 months. There are no changes in the values up to two months, it is a stable formulations.

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## INTRODUCTION

The concept of formulating orally tablets containing escitalopram oxalate offers a suitable and practical approach in serving desired objective of rapid disintegration and dissolution characteristics with increased bioavailability [1]. Tablets will be outlined as solid unit pharmaceutical formulations involving drug substance with or without appropriate excipients and ready by squeezing or moulding methods. ODTs increase the acceptability of bitter drugs by masking their taste [2]. Escitalopram oxalate is selective serotonin reuptake inhibitors are broad-spectrum antidepressants that will be useful for disorder and several other anxiousness disorders [3].

## MATERIALS AND METHODS

Escitalopram Oxalate became purchased free of charge sample from Hetero Labs, Hyderabad; croscarmellose sodium & Hydroxypropyl Cellulose was once purchased from S.D. Fine Chemicals, Mumbai. Saccharin, Polacrillin potassium, Peppermint, Microcrystalline cellulose, mannitol, talc used to be a present sample of Bliss chemicals & pharmaceuticals India Ltd., Mumbai, India and other ingredients victimised in with Analytical grade.

### Methodology

### Compatibility Studies

Sample concentration in KBr must be within the lim-

its of 0.2% to 1%. The thickness of the pellet is way more than a liquid film, so sample with low concentration is required [4]. Too high concentration generally leads to difficulties in obtaining clear pellets.

### Formulation of Escitalopram Oxalate ODTs

Accurately weight quantity of escitalopram oxalate, croscarmellose sodium, saccharin, orange, peppermint, Hydroxypropyl Cellulose and lake sunset yellow were in collaboration passed through screen no 40 (Blend-1). MCC were jointly passed through sieve no 20 (Blend-2) and magnesium stearate was additional and mixed for 10 mins [Table 1] finally compressed into tablets [5].

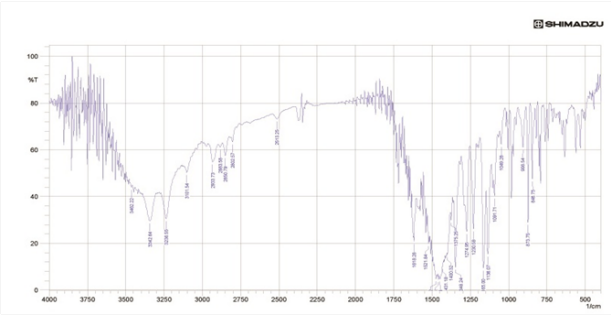


**Figure 1: IR spectrum of Escitalopram Oxalate**

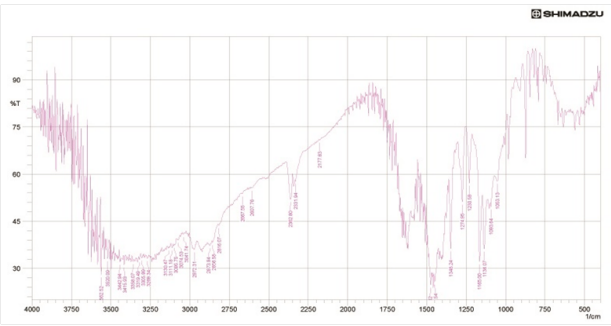


**Figure 2: IR spectrum of Escitalopram Oxalate with other excipients**

### Pre Compression Parameters

The powdered blend was analyzed for flow properties as follows.

Angle of repose: $\theta = \tan^{-1}$ (h/r)

Bulk density = Weight of powder/ Bulk volume

Tapped density = Weight of powder/ Tapped volume

Carr's Index (I) = (Tapped Density - Bulk Density)/ (Tapped Density) x100

Hausner's ratio = Tapped density/ Bulk density [Table 2] [6].

### Post Compression Parameters

### Thickness

Thickness was determined for 20 pre weighed tablets of each batch using a digital vernier scale and the average thickness was determined in mm [7]. The tablet thickness should be controlled within a $\pm$ 5% variation of a standard.

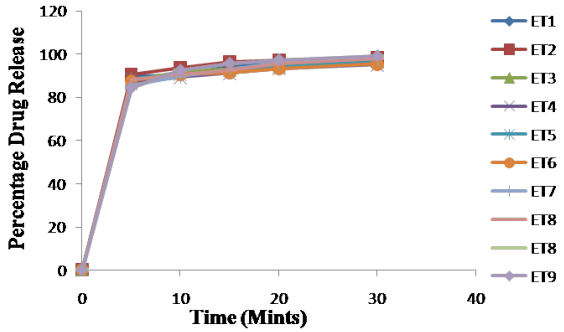


**Figure 3: *In-vitro* Dissolution Study of Escitalopram Oxalate ODTs**

### Weight Variation

20 tablets were selected randomly from a batch and were individually weighed and then the average weight was calculated. The tablets meet the USP specifications if not more than 2 tablets are outside the percentage limit [8].

### Hardness

The crushing load which is the force required to break the tablet in the radial direction was measured using a Monsanto hardness tester. The hardness of 10 tablets was noted and the average hardness was calculated [9].

### Friability

Friability test was performed to predict the tablet ability to endure any abrasions in packaging, handling & in transport. Roche friabilator, a commonly used instrument was routine watch over friability of the tablets. 20 tablets have been reweighed from each and every batch and situated in friabillator and set to rotate at an rpm of 25 for 4 min [10].

$$Friability = \frac{(Intial\ weight\ of\ tab - Final\ weight\ of\ tab)}{Initial\ weight\ of\ tab} \times 100$$

### Disintegration Time

The disintegration test is carried out in an apparatus containing a basket rack assembly with six glass tubes of 7.75 cm in length and 2.15 mm in diameter, the bottom of which consists of a #10 mesh sieve. The basket is raised and lowered 28-32 times per minute in a medium of 900 ml which is maintained at 37$^{o}$C $\pm$1$^{o}$C Six tablets were placed in each of the tubes and the time required for complete passage of tablet fragments through the mesh (# 10) was considered as the disintegration time of the tablet [11].

### Wetting Time

Six circular tissue papers of 10 cm diameter were

**Table 1: Formulation of Escitalopram Oxalate Tablets**

| Excipients | ET1 | ET2 | ET3 | ET4 | ET5 | ET6 | ET7 | ET8 | ET9 |
|---|---|---|---|---|---|---|---|---|---|
| Escitalopram Oxalate | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 |
| Croscarmellose sodium | 14 | 14 | 18 | 18 | 20 | 20 | 20 | 20 | 20 |
| Hydroxypropyl cellulose | 6 | 6 | 12 | 12 | 12 | 10 | 12 | 12 | 12 |
| Polacrillin potassium | 10 | 20 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| Saccharin | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Orange | 11 | 13 | 13 | 13 | 14 | 13 | 14 | 14 | 14 |
| Peppermint | 0 | 8 | 6 | 6 | 8 | 6 | 8 | 8 | 8 |
| Lake sunset yellow | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Prosolv ODT | 0 | 0 | 0 | 0 | 115 | 75 | 40 | 0 | 0 |
| MCC | 153 | 93 | 95 | 75 | 0 | 0 | 0 | 0 | 0 |
| Mannitol | 10 | 50 | 55 | 65 | 10 | 55 | 85 | 215 | 215 |
| Talc | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |

Note: Quantities in mg

**Table 2: Derived Properties of Escitalopram Oxalate ODTs**

| Parameters | ET1 | ET2 | ET3 | ET4 | ET5 | ET6 | ET7 | ET8 | ET9 |
|---|---|---|---|---|---|---|---|---|---|
| Angle of Repose ($\theta$) | 47.23 | 36.35 | 33.26 | 31.08 | 40.15 | 37.04 | 30.52 | 28.35 | 27.89 |
| Bulk Density (g.mL) | 0.235 | 0.613 | 0.645 | 0.565 | 0.376 | 0.584 | 0.382 | 0.478 | 0.452 |
| Tapped Density (g.mL) | 0.412 | 0.738 | 0.722 | 0.665 | 0.538 | 0.705 | 0.434 | 0.518 | 0.502 |
| Compressibility Index (%) | 32.18 | 17.15 | 13.10 | 13.75 | 25.15 | 18.17 | 12.33 | 8.98 | 9.15 |
| Hausner's Ratio (HR) | 1.45 | 1.20 | 1.14 | 1.15 | 1.32 | 1.22 | 1.16 | 1.10 | 1.10 |

**Table 3: Post Compression Parameters of Escitalopram Oxalate ODTs**

| Form. Code | Average weight (mg) | Thickness (mm) | Hardness (kg/cm$^2$) | Friability (%) | Disintegration Time (sec) | Wetting time (sec) | Drug Content (%) |
|---|---|---|---|---|---|---|---|
| ET1 | 248±0.1 | 3.52±0.1 | 2.6±0.3 | 0.28±0.2 | 100 | 190 | 98±0.2 |
| ET2 | 247±0.3 | 3.56±0.7 | 2.4±0.5 | 0.18±0.4 | 56 | 108 | 95±0.6 |
| ET3 | 248±0.4 | 3.69±0.4 | 2.3±0.6 | 0.20±0.6 | 48 | 86 | 99±0.5 |
| ET4 | 247±0.6 | 3.78±0.6 | 2.3±0.2 | 0.15±0.2 | 42 | 40 | 96±0.2 |
| ET5 | 246±1.2 | 3.49±0.3 | 2.2±0.3 | 0.55±0.7 | 45 | 110 | 98±0.3 |
| ET6 | 245±1.4 | 3.61±0.3 | 2.9±0.6 | 0.40±0.3 | 28 | 98 | 95±0.7 |
| ET7 | 240±1.5 | 3.65±0.5 | 2.7±0.5 | 0.17±0.2 | 20 | 43 | 98±0.5 |
| ET8 | 242±1.8 | 3.70±0.3 | 3.5±0.8 | 0.10±0.3 | 16 | 27 | 97±0.3 |
| ET9 | 249±0.6 | 3.72±0.2 | 3.6±0.8 | 0.10±0.5 | 18 | 26 | 99±0.2 |

**Table 4: *In-vitro* Dissolution Study of Escitalopram Oxalate ODTs**

| Time (min) | ET1 | ET2 | ET3 | ET4 | ET5 | ET6 | ET7 | ET8 | ET9 |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 89.84 | 90.58 | 87.74 | 86.39 | 88.48 | 87.57 | 85.45 | 88.34 | 84.40 |
| 10 | 90.36 | 93.84 | 91.93 | 89.15 | 90.36 | 90.49 | 89.58 | 90.48 | 92.56 |
| 15 | 94.45 | 96.57 | 93.27 | 91.03 | 92.46 | 91.21 | 92.67 | 92.40 | 95.74 |
| 20 | 96.98 | 97.24 | 95.05 | 93.27 | 94.05 | 93.29 | 95.69 | 95.75 | 97.34 |
| 30 | 97.65 | 98.37 | 96.45 | 95.06 | 96.75 | 95.43 | 97.78 | 97.89 | 99.12 |

**Table 5: Stability study of ET9 Escitalopram Oxalate ODTs**

| Parameters | Initial | $40^oC \pm 2^oC$ / 75% ± 5% RH | |
|---|---|---|---|
| | | $1^{st}$ Month | $2^{nd}$ Month |
| Thickness (mm) | 3.72 ± 0.2 | 3.72 ± 0.2 | 3.72 ± 0.1 |
| Hardness (kp) | 3.6 ± 0.8 | 3.6 ± 0.5 | 3.6 ± 0.4 |
| % Friability | 0.10 ± 0.5 | 0.10 ± 0.2 | 0.11 ± 0.2 |
| Disintegration Time (sec) | 18 | 18 | 19 |
| *In-vitro* Dissolution | 99.12 | 99.11 | 99.10 |

placed in a Petri dish and 10 ml of water containing amaranth dye was added to it to identify complete wetting of tablet surface. A tablet was carefully placed on the surface of tissue paper in petri dish at ambient temperature [12]. The time taken by water to reach the upper surface of the tablet and to completely wet the tablet was noted as wetting time.

### Drug Content

Weighting amount containing 100mg of Escitalopram Oxalate used to be conveyed within 100ml volumetrically flask. To that 50ml consisting of methyl alcohol was additional plus sonicated to dissolve the drug plus blended completely [7]. The absorbance measured by UV spectroscopy against the blank at wavelength of 238 nm.

### *In-vitro* Dissolution Studies

The dissolution test was carried out in USP Apparatus Type II (paddle) with 900 ml of 0.1 N Hydrochloric acid as the dissolution medium which is maintained at temperature 37±2° C. Paddle was allowed to rotate at 50 rpm and medium temperature of $37^oC \pm 0.5^oC$. Samples (5 ml) were withdrawn at suitable intervals, filtered and absorbance measured at 238 nm using UV-Visible Spectrophotometer [13] [Figure 3] [Table 4].

### Stability Studies

The product obtain accelerated stableness reports at 40°C±2°C/75% ±5% RH for two months [14].

## RESULTS AND DISCUSSION

### Compatibility Study

From drug excipient compatibility trend analysis, we referred to absence of interactions in between pure drug and excipients as shown in Figures 1 and 2.

### Weight Variation & Thickness

The average weight of the tablets 247 ± 0.3 mg to 249 ± 0.6 mg and the thickness is determined by 3.52 ± 0.1 mm to 3.72 ± 0.2 mm [Table 3].

### Hardness & Friability

The hardness was determined 2.2 ± 0.3 to 3.6 ± 0.8 kg/cm$^2$ during compression and friability for all the formulation [Table 3] varies from 0.10±0.3 to 0.55±0.7 %.

### Drug Content & Wetting Time

The all the formulations was found to be 95 ± 0.6% to 99 ± 0.5 %. Wetting time was acknowledge [Table 3] to be 26 to 190 sec.

### Disintegration Time

The all formulations was found to be 16 sec to 100 sec [Table 3].

### Stability Studies

The ET9 was subjected to accelerated stability record [Table 5] as first and second months 40±2°C/75±5% RH the drugs encounter impending good.

## CONCLUSION

Formulation ET9 showed satisfactory results with various evaluation parameters like Hardness, Weight variation, Disintegration time, wetting time, Dissolution studies and Assay. After make accelerated stableness reports the particular tablets encounter to be stable. ET9 formulation was carried out with crospovidone, Hydroxypropyl cellulose, Polacrillin potassium as super disintegrates results in good wetting time 26 seconds and disintegration time 18seconds. All the pre compression and therefore the post compression parameters displayed to good results.

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### Conflict of Interest

The authors attest that they have no conflict of interest in this study.

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