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# "FORMULATION AND EVLUATION OF MOUTH DISSOLVING TABLETS OF OXYCARBANAZEPIN".

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**ABSTRACT:** The concept of Mouth Dissolving Drug Delivery System emerged from the desire to provide patient with conventional mean of taking their medication. Oxcarbazepine is an anticonvulsant drug, mainly used as an add-on or first line treatment in adults and children. Due to sudden onset of attack, it is necessary to formulate antiepileptics into such a delivery system, which provide immediate relief. Hence, the present investigation was undertaken with a view to develop mouth dissolving tablets of oxcarbazepine, which offers a new range of product having desired characteristics and intended benefits. In this study, the mouth dissolving tablets were prepared. A mouth dissolving tablet was prepared by using super disintegrants viz; crospovidone, croscarmellose sodium and sodium starch glycolate All the batches are prepared by direct compression method. Effect of disintegrants concentration on the disintegration behavior was evaluated, and all the tablets were evaluated for hardness, friability, weight variation, water absorption ratio, dissolution, and assay. Among the all preparations F8 emerged as the best formulation and showed maximum dissolution rate.

**KEYWORDS:** Mouth dissolving tablet, Oxcarbazepine, PVP K 30, Cross Povidone , Direct compression, Super disintegrant.

**1.INTRODUCTION:** The tablet is the most widely used dosage form existing today because of its convenience in terms of self-administration, compactness and ease in manufacturing. However, geriatric, pediatric and mentally ill patients experience difficulty in swallowing conventional tablets, which leads to poor patient compliance. To overcome these problems, scientists have developed innovative drug delivery system known as mouth dissolving/disintegrating tablets (ODTs) or fast dissolving tablets. The benefits of ODTs is to improve patients' compliance, rapid onset of action, increased bioavailability and good stability which make these tablets popular as a dosage form of choice in the current market. [1, 2, 3] ODTs are distinguished from conventional, sublingual tablets, buccal tablets and lozenges, which require more than a minute to dissolve in oral cavity. In the literature, ODTs also are called orodisperse, mouth-dissolving, quick-dissolve, fast-melt and freeze-dried wafers. It is estimated that 50 % of the population is affected by dysphasia which results in high incidence of noncompliance and ineffective therapy. To overcome this problem, it is necessary to design a formulation which rapidly disperse / dissolve in the oral cavity without the need of water for swallowing. Such dosage form should disintegrate when placed in the mouth and can be swallowed in the liquid form. [4,5]

These tablets are designed to dissolve or disintegrate rapidly in the saliva generally within <60 seconds (range of 5-50 seconds). Due to the constraints of the current FDDT technologies as highlighted above, there is an unmet need for improved manufacturing processes for fast dissolving tablets that are mechanically strong, allowing ease of handling and packaging and with production costs similar to that of conventional tablets. [6,7]

## 2.MATERIALS AND METHODS:

### 2.1.MATERIALS:

Materials oxcarbazepine was obtained as a gift sample from Psycho Remedies, Ludhiana. Pvpk 30, Croscarmellose sodium, Crospovidone, Sodium starch glycolate, MCC, Talc, Magnesium stearate, Aspartame, Lactose, spray dried Polo mannitol was purchased from S. D. fine Chemicals, Mumbai. All other chemicals and reagents used were of analytical grade.

**2.2. METHODS:** All of the formulations contained oxcarbazepine, Aspartame, Magnesium Stearate, Lactose, Mannitol, PVP K30, Talc and different amounts of various superdisintegrants. Superdisintegrants include Crospovidone, Cross Carmellose Sodium, Sodium Starch Glycolate. PVP K 30 is used as Tablet Binder. Composition of various formulations is listed in Table 1.

Tablets were prepared by Direct compression- Formulations F1-F9, were prepared by blending each superdisintegrant in three different proportions. The superdisntegrant blends were thoroughly mixed with preset fixed amounts of oxcarbazepine, Aspartame, and magnesium stearate, MCC, Talc, Lactose, in a polybag by a geometric dilution method. The powder mixture, thus prepared, was passed through sieve #40 and then compressed into tablets with a multiple punch tablet machine (Lab press). [8,9]

**Table 1**: Formulations of oxcarbazepine MDT Tablets (in mg) by Direct compression.

| FORMULATION | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|
| Oxcarbazepine | 100 | 100 | 100 | 100 | 100 |
| PVP K30 | 10 | 10 | 10 | 10 | 10 |
| Cross Povidone | 10 | 20 | 30 | - | - |
| Cros Carmellose Sodium | - | - | - | 10 | 20 |
| Sodium Starch Glycolate | - | - | - | - | - |
| Polo | 10 | 10 | 10 | 10 | 10 |
| Aspartame | 3 | 3 | 3 | 3 | 3 |
| Lactose | 64 | 54 | 44 | 64 | 54 |
| Mannitol | 30 | 30 | 30 | 30 | 30 |
| Microcrystalline cellulose | 21 | 21 | 21 | 21 | 21 |
| Talc | 105 | 1.5 | 1.5 | 1.5 | 1.5 |
| Mg Stearate | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Total Weight | 250 | 250 | 250 | 250 | 250 |

Total weight – 250mg/tablet

## 3. EVALUATION PARAMETERS:

**3.1. Tablet weight variation:** Twenty tablets were randomly selected and accurately weighed. Results are expressed as mean values ± SD [10]

**3.2. Tablet Thickness:** 4 The thickness of the tablets was determined using a Micrometer screw gauge. Five tablets from each type of formulation were used and average values were calculated. It is expressed in mm. [11,12]

**3.3. Hardness:** The resistance of tablets to shipping, breakage, under conditions of storage, transportation and handling before usage depends on its hardness. For each formulation, the hardness of 6 tablets was determined using the Monsanto hardness tester. The tablet was held along its oblong axis in between the two jaws of the tester. At this point, reading should be zero kg/cm2. Then constant force was applied by rotating the knob until the tablet fractured. The value at this point was noted. [13,14]

**3.4. Friability Test:** The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%). Twenty tablets were initially weighed and transferred into Friabilator. The Friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again. The % friability was then calculated by the following formula. [15,16]

$$\%F = \frac{\text{Initial Weight- Final Weight}}{\text{Initial Weight}} \times 100$$

Percentage Friability = W – W0 × 100 / W

Where, W0 = initially weight W = weight after friability

Percentages Friability of tablets less than 1 % are considered acceptable.

**3.5. Weight variation test:** To find out weight variation, 20 tablets of each type of formulation were weighed individually using an electronic balance, average weight was calculated and individual tablet weight was then compared with average value to find the deviation in weight. [17,18]

**3.6. Wetting time:** A piece of tissue paper folded twice containing amaranth powder on the upper surface was placed in a small Petri dish (ID =6.5 cm) containing 6 ml of 5.4 pH buffer, a tablet was put on the paper and the time required for formation of pink color was measured as wetting time. The study was performed in triplicate. [19,20]

**Table 2:** Specifications for tablets as Per India Pharmacopoeia.

| Sr.No. | Average Weight of Tablet | % Deviation |
|---|---|---|
| 1 | 80 mg or less | 10 |
| 2 | More than 80 mg but less than 250 mg | 7.5 |
| 3 | 250 or more | 5 |

**3.7. Water absorption:** A piece of tissue paper folded twice was placed in a small Petri dish containing 6ml of water. A tablet was put on the tissue paper and allowed to wet completely. The wetted tablet was then weighed.13 Water absorption ratio R was determined using following equation. [21,22]

$$R = \frac{(Wb - Wa)}{Wa} \times 100$$

Where, Wa = Weight of the tablet after wetting

Wb= Weight of the tablet before wetting

**3.6. Uniformity of drug content:** Accurately weighed amount of drug-excipient blend was dissolved in small amount of methanol and the volume was made up to 100ml with distilled water in 100ml volumetric flask, which was previously cleaned and dried. This solution was filtered and measured for absorption at 255nm in a Jasco V 530 UV-visible spectrophotometer. [23,24]

% Purity = 10 C (Au / As)

Where, C – Concentration, Au and As – Absorbance of unknown and standard respectively.

**3.7. Disintegration time:** Initially the disintegration time for oral dispersible tablets was measured using the conventional test for tablets as described in the Pharmacopoeia. Tablets were placed in the disintegration tubes and time required for complete disintegration, that is without leaving any residues on the screen was recorded as disintegration time. A modified method was also used to check the disintegration time. In about 6-8 ml of 5.4 pH buffer was taken in measuring cylinder. Tablet was placed in the cylinder and complete dispersion of tablet in the cylinder was recorded as the disintegration time. [25,26]

**3.8. Dissolution study:** Sample volume of 10 ml was withdrawn at regular time intervals from a zone midway between the surface of dissolution medium and the top of rotating paddle not less than 1 cm apart from the vessel wall. The volume withdrawn was replaced by fresh volume of dissolution medium to maintain constant volume of medium. The filtered samples were analyzed spectrophotometrically at 255 nm using 5.4 pH buffer as a blank. Drug content in dissolution sample was determined by calibration curve. [27,28]

## 4. RESULT AND DISUSSION:

**Table 3: Evaluation Parameters.**

| Formulation code | Evaluation Parameter | | | | |
|---|---|---|---|---|---|
| | Thickness ± S.D. (mm) (n=5) | Hardness ± S.D. (kg/cm$^2$) (n=5) | Friability (%) | Average weight variation(n=10) | Drug content (%) |
| F1 | 4.51±0.04 | 3.81±0.06 | 0.41± | 247.3±1.6 | 98.75±0.60 |
| F2 | 4.46±0.02 | 3.91±0.02 | 0.43± | 249.2±1.9 | 99.4±0.98 |
| F3 | 4.74±0.03 | 3.69±0.03 | 0.45± | 249.5±1.8 | 99.2±0.67 |
| F4 | 4.66±0.06 | 3.79±0.03 | 0.47± | 245.4±0.9 | 98.85±0.47 |
| F5 | 4.46±0.09 | 3.82±0.02 | 0.49± | 246.6±1.5 | 99.1±0.65 |

**Table 4: Results of wetting time, water absorption ratio and disintegration time of mouth dissolving tablet formulation of Oxcarbazepine.**

| Formulation code | Wetting time (Sec) mean ±SD | Water absorption ratio mean ± SD | Disintegration time (Sec) mean±SD |
|---|---|---|---|
| F1 | 30±1.2 | 80.12±0.12 | 36±1.2 |
| F2 | 25±1.0 | 90.45±0.74 | 28±1.0 |
| F3 | 28±2.1 | 84.45±0.32 | 34±2.1 |
| F4 | 28±7.1 | 82.42±0.41 | 34±7.1 |
| F5 | 27±2.0 | 81.10±0.47 | 33±2.0 |

**Table 5: In vitro drug release of Oxcarbazepine from formulations.**

| Time(min) | Percent drug release at time(min) | | | | |
|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 |
| 05 | 47.20±0.9 | 49.2±0.6 | 50.31±0.3 | 46.21±0.9 | 44.21±0.6 4 |
| 10 | 65.10±0.3 | 64.21±0.2 | 69.20±0.9 | 64.41±0.4 | 61.23±0.5 6 |
| 15 | 80.01±0.34 | 79.01±0.1 | 84.23±0.3 | 78.14±0.3 | 79.32±0.4 |
| 20 | 84.87±0.32 | 83.02±0.69 | 88.35±0.2 | 83.54±0.1 | 84.24±0.2 8 |
| 25 | 90.58±0.7 | 92.58±0.6 | 97.21±0.7 | 92.30±0.5 | 93.25±0.2 |
| 30 | 96.58±0.7 | 97.71±0.1 | 99.73±0.9 | 95.21±0.2 9 | 96.58±.0.5 |

## 5.CONCLUSION:

In the present study total five formulations were prepared using direct compression technique, each containing 100 mg of Oxcarbazepine. All formulations (F1-F5) were prepared by using 5% ,10%, 15% of crospovidone, 2%,4%,6% of SLS, to the total weight of pharmaceutical ingredients. The total weight of tablet was taken as 250 mg. Magnesium stearate was added as 1% and Mannitol was added as q.s. A mouth dissolving tablet was prepared by using super disintegrants crospovidone, croscarmellose sodium and sodium starch glycolate that could dissolve within 30 minutes. The post-compression parameters of all formulations were determined and the values were found to be satisfactory. From the drug content and in-vitro dissolution studies of the formulations, it was concluded that the formulation F3 i.e. the formulation containing crospovidone 30 mg is the best formulation.

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