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# FORMULATION AND EVALUATION OF ORODISPERSIBLE ATENOLOL MALEATE TABLETS: A COMPARATIVE STUDY ON NATURAL SUPER DISINTEGRENTS AND SYNTHETIC SUPER DISINTEGRENTS

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Received on: 08/02/14 Revised on: 18/03/14 Accepted on: 09/04/14

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**DOI: 10.7897/2277-4343.05237**

**ABSTRACT**

Oral Disintegrating Tablets (ODTs) may also be used to deliver drugs to the oral cavity, for local action or, in some cases, absorption across the oral mucosa, thereby avoiding first-pass hepatic metabolism and potentially increasing the rate and extent of uptake, and reducing undesirable metabolites. The objectives of the research work was to formulate oral disintegrating tablets of Atenolol maleate by using different super disintegrates (Natural, Synthetic) in different ratio by direct compression technique and tablets were evaluated for pre compression and post compression parameters such as angle of repose, bulk density, tapped density, compressibility index, drug content and *in-vitro* drug release study, hardness, friability, wetting time and *in vitro* dispersion time. Among the all formulations, the promising formula (CCS3, IH2) have showed fast disintegration and displayed *in vitro* dispersion time of 11 s and 10.5 s. The dissolution rates of the optimized formulations (CCS3, IH2) were found to be good. Among the promising ODT formulation CCS3, IH2 the formula IH2 was found to be superior when compared to formulation CCS3 since formulation IH2 used natural disintegrant (i.e. 6 %w/w Isphagula husk) at a lower concentration than the formulation CCS3 (8 % w/w Cross Carmellose Sodium) hence it was found to be more cost effective. The FTIR studies also showed that there was no interaction between drug and polymer. Formulation CCS3, IH2 were subjected to stability studies as per ICH guidelines at temperatures and humidity of 25 ± 5ºC/60 ± 5 % RH; and 40 ± 5ºC/75 ± 5 % RH. Tablets didn't reveal any appreciable changes with respect to hardness, disintegration time, drug content and dissolution profile.

**Keywords:** Oral Disintegration Tablets (ODTs), Atenolol maleate, Super Disintegrants, Sodium starch Glycolate (SSG), Isphagula husk, Cross Povidone, Micro Crystalline Cellulose (MCC), Cross Carmellose Sodium (CCS).

## INTROUDUCTION

Oral Disintegrating Tablets (ODTs) are used to deliver drugs to the oral cavity, for local action or, in some cases, absorption across the oral mucosa, thereby avoiding first-pass hepatic metabolism and potentially increasing the rate and extent of uptake, and reducing undesirable metabolites. The concept of Fast dissolving Drug Delivery System emerged from the desire to provide patient with more conventional means for taking their medication. It is difficult for many patients to swallow tablets and hard gelatin capsules. Hence they do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy. In some cases such as motion sickness, sudden episodes of allergic attacks or coughing and unavailability of water, swallowing conventional tablets may be difficult. Particularly the difficulty is experienced by pediatric and geriatric patients. Such problems can be resolved by means of Fast Dissolving Tablet. When put on tongue, this tablet disintegrates instantaneously, releasing the drug, which dissolves or disperses in the saliva[1]. The center for drug evaluation and research states an ODT to be: "A solid dosage form containing medicinal substances, which disintegrate rapidly, usually within a matter of seconds, when placed upon the tongue." These tablets are distinguished from conventional, sublingual tablets, lozenges and buccal tablets which require more than a minute to dissolve in the mouth. In the literature these are also called orally disintegrating, Oro disperse, Mouth dissolving, quick dissolving, Fast-melt and rapidly disintegrating tablets and freeze- dried wrafers[2].

### Mechanism of Action Enlapril

Enalapril, after hydrolysis to enalaprilate, inhibits angiotensin-converting enzyme (ACE) in human subjects and animals. ACE is a peptidyl dipeptidase that catalyzes the conversion of angiotensin I to the vasoconstrictor substance, angiotensin II. Angiotensin II also stimulates aldosterone secretion by the adrenal cortex. The beneficial effects of enalapril in hypertension and heart failure appear to result primarily from suppression of the renin-angiotensin-aldosterone system. Inhibition of ACE results in decreased plasma angiotensin II, which leads to decreased vasopressor activity and to decrease aldosterone secretion. Although the latter decrease is small, it results in small increases of serum potassium.

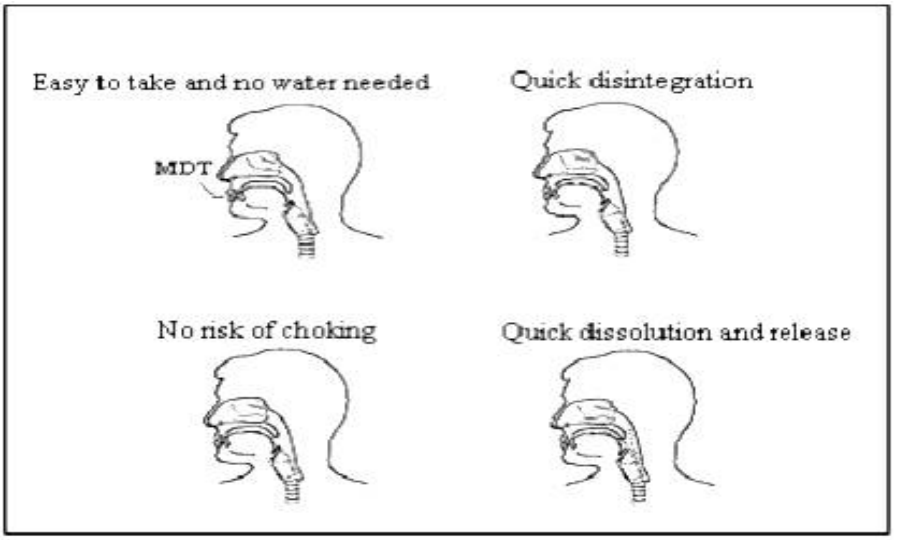


**Figure 1: Advantages of Oral Disintegrating Tablets**

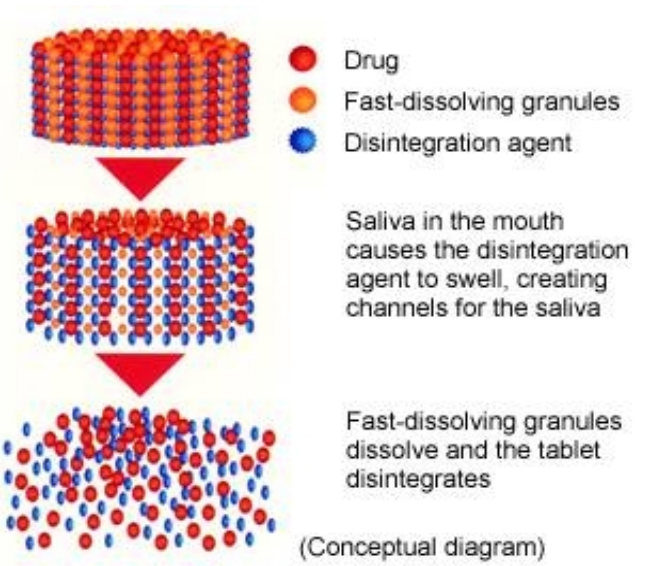


**Figure 2: Disintegration Mechanism of ODT drugs**

## MATERIALS AND METHODS

gelatinized Starch (SD Fine, Mumbai, India), MCC (PH-102), Lactose anhydrous, Cross povidone, Sodium starch Glycolate, Magnesium stearate, Lactose, Cross Carmellose Sodium, Sodium Saccharin , Orange Flavor, Aerosil, Glyceryl behanate.

### Equipments

Analytical balance, pH meter, Friability tester, Hardness tester, Disintegration Tester, Dissolution apparatus (Veego), UV-Visible spectrophotometer (Analytical), Compression machine (sixteen stationary rotary ) (Cadmach), Bulk Density Tester.

### Methodology for Extraction of Natural Polymers

### Extraction of Natural polymer from Ispaghula husk

For the isolation of mucilage, seeds of *Plantago ovata* were used. They were soaked in distilled water for 48 h and then boiled for 1 h for complete release of mucilage into water. The material was filtered by squeezing in a muslin cloth to remove marc. Then equal volume of acetone was added to filtrate to precipitate the mucilage. The mucilage was separated and dried in oven at a temperature less than 60°, powdered (#60 mesh), weighed and stored in desiccators until further use.

### Preparation of Tablets

### Preparation of Mixed blends of drug and excipients

All the ingredients were weighed accordingly specified in the formulation (Table 8) and mixed well except magnesium stearate. Then the blend was passed through sieve no 60 which was used for the evaluation of flow properties.

**Compression of Tablets**
To the mixed blend of powder and excipients finally add magnesium stearate and then mixed for 5 minutes. The mixed blend was compressed with twelve (12) station tablet punching machine using 7 mm flat punches. The working formula was given in Table 1.

**Evaluation of Pre compression parameters**
**Bulk density**
Apparent bulk density was determined by pouring the blend into a graduated cylinder[3]. The bulk volume ($V_b$) and weight of the powder was determined. The results were given in Table 2.

**Tapped density**
The measuring cylinder containing a known mass of powder blend was tapped for a fixed number of times as per USP apparatus-II. The minimum volume occupied by the powder after tapping was measured. The results were given in Table 2.

Tapped density = weight/tapped volume

**Compressibility Index**
Compressibility index is calculated as follows. The results were given in Table 2.

Tapped density- Bulk density/ Tapped density*100

The value below 15 % indicates a powder with good flow characteristics where as above 25 % indicates poor flow ability[4].

**Haussner's ratio**
It is an indirect index of ease of powder flow, it is calculated as follows.

Tapped density / Bulk density

Haussner's ratio < 1.25 indicates good flow properties, where as > 1.5 indicates poor flow ability. The results were given in Table 2.

**Angle of Repose**
Angle of repose was determined using funnel method. The blend was poured through funnel that can rise vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose was calculated as follows[5]. The results were given in Table 2.

$$\emptyset = \tan^{-1} h/r$$

**Evaluation of Tablets**
All the prepared tablets were evaluated for the following parameters as per the IP guidelines.

**Weight variation**
Twenty tablets from each formulation were selected randomly and average weight was determined. Individual tablets were then weighed and compared with average weight[6,7]. The results were given in Table 3.

**Hardness test**
The force required to break a tablet in a diametric compression was determined by using Pfizer tablet hardness tester. The results were given in Table 3.

**Friability**
The weight of twenty tablets was noted and placed in the friabilator and then subjected to100 revolutions at 25 rpm. Tablets were dedusted using a soft muslin cloth and reweighed[8,9]. The results were given in Table 3.

Percent friability = [initial weight – final weight / initial weight] × 100

**Wetting time and Water absorption ratio**
A piece of paper folded twice was kept in a petri dish (internal diameter 6 cm) containing 6 ml of purified water. A tablet was put on the paper and time required for complete wetting was measured. The wetted tablet was weighed. Water absorption ratio, R was determined using the following equation[10]. The results were given in Table 3.

R = [Wa – Wb / Wb] × 100
Where Wa, Wb are the weights of tablets before and after wetting.

***In vitro* dispersion time**
Tablet was added to 10 ml of distilled water at 37 ± 0.5˚C, time required for complete dispersion of tablet was measured[11,12]. The results were given in Table 3.

**Drug content uniformity**
The drug content uniformity was determined by taking the powder equivalent to 10 mg, then it was (n = 3) dissolved in pH 6.8 phosphate. Required dilution (10 µg/ml) was prepared and absorbance was taken against the blank at 206 nm. The results were given in Table 3.

***In vitro* disintegration time**
The disintegration was performed using an IP 85 disintegration apparatus with distilled water at 37 ± 0.5˚C. The time taken for disintegration of all formulations was noted in Table 4.

**Dissolution studies**
Dissolution rate of Atenolol maleate from all formulations was performed using LABINDIA DISSO 2000 an eight stage dissolution rate testing apparatus with paddle. The dissolution fluid was 900 ml of pH 6.8 phosphate buffer with a speed of 50 rpm and temperature of 37 ± 0.5˚C were used in each test. 5 ml of sample was withdrawn at different time intervals (2.5, 5, 10, 15 and 20 minutes) and fresh medium was replaced to maintain sink conditions. The samples are analyzed by using UV-Visible spectrophotometer at $\lambda_{max}$ 205 nm. Dissolution studies were performed in triplicate and the results were shown in Table 5. Graph was plotted by taking time on x-axis and % cumulative drug release on y-axis. The graphs were represented in Figure 1-4.

**Stability studies**
The stability studies were conducted for optimized formulations at 25˚C / 60 % RH and 40˚C / 75 % RH[13,14].

**Characterization of Atenolol maleate tablets**

**FTIR studies**

The drug- excipients interaction was studied using FTIR. IR spectra for drug and powdered tablets were recorded in a Fourier transform infrared spectrophotometer using KBr pellet technique[15,16]. This spectra was scanned over the 3600 to 500 $cm^{-1}$ range. The polymers did not show any change on the functional groups of enalpril maleate. The values were mentioned in Table 6. The IR spectras of pure drug and optimized formulations were shown in Figure 5-8.

## RESULTS

**Table 1: Formulation of oral disintegrating tablets of Atenolol maleate**

| Ingredients (mg per tablet) | CCS1 | CCS2 | CCS3 | SSG1 | SSG2 | SSG3 | CP1 | CP2 | CP3 | IH1 | IH2 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Atenolol maleate | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Lactose Anhydrous | 80 | 80 | 80 | 80 | 80 | 80 | 80 | 80 | 80 | 80 | 80 |
| MCC PH-102 | 48.5 | 44 | 41 | 48.5 | 44 | 41 | 48.5 | 44 | 41 | 48.5 | 44 |
| Cross Carmellose Sodium | 4.5 | 9 | 12 | --- | --- | --- | --- | --- | --- | --- | --- |
| Sodium Starch Glycollate | --- | --- | --- | 4.5 | 6 | 12 | --- | --- | --- | --- | --- |
| Crospovidone | --- | --- | --- | --- | ---- | --- | 4.5 | 6 | 12 | --- | --- |
| Ispaghula Husk Powder | --- | --- | --- | --- | --- | --- | --- | --- | --- | 4.5 | 6 |
| Sodium Saccharin | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Orange flavor | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Aerosil | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Magnesium Stearate | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Glyceryl Behanate | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Total Weight | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 |

Where CCS – Cross carmellose Sodium, SSG - Sodium Starch Glycollate, CP – Crospovidone, IH - Ispaghula Husk Powder

**Table 2: Evaluation of flow properties of the blend**

| Formulations | Angle of repose | Bulk density | Tapped density | Carr's index | Hausner's ratio | Flow ability |
|---|---|---|---|---|---|---|
| CCS1 | 33 | 0.56 | 0.65 | 13.84 | 1.16 | Fair |
| CCS2 | 32 | 0.57 | 0.64 | 13.62 | 1.1 | good |
| CCS3 | 35 | 0.66 | 0.76 | 10.2 | 1.17 | Excellent |
| SSG1 | 28 | 068 | 0.74 | 13.12 | 1.14 | good |
| SSG2 | 32 | 0.54 | 0.62 | 12.14 | 1.12 | good |
| SSG3 | 29 | 0.65 | 0.71 | 8.02 | 1.11 | good |
| CP1 | 36 | 0.67 | 0.75 | 17.8 | 1.16 | Excellent |
| CP2 | 35 | 0.54 | 0.65 | 11.25 | 1.19 | Excellent |
| CP3 | 28 | 0.61 | 0.71 | 10.6 | 1.21 | Excellent |
| IH1 | 38 | 0.59 | 0.63 | 7.8 | 1.09 | good |
| IH2 | 36 | 0.68 | 0.75 | 11.1 | 1.12 | good |

**Table 3: Quality control tests for the oral disintegrating tablets of Atenolol maleate**

| Formulations* | Average Weight* | Hardness *Kg/$cm^2$ | Friability *(%) | Wetting time* | Water absorption ratio* |
|---|---|---|---|---|---|
| CCS1 | 149 ± 0.12 | 3.6 ± 0.11 | 0.481 ± 0.16 | 11.12 ± 0.21 | 39 ± 0.14 |
| CCS2 | 150 ± 0.21 | 3.6 ± 0.24 | 0.56 ± 0.17 | 10.13 ± 0.34 | 28 ± 0.15 |
| **CCS3** | **151.3 ± 1.8** | **3.5 ± 0.49** | **0.57 ± 0.17** | **8.55 ± 0.15** | **34 ± 0.24** |
| SSG1 | 149.5 ± 0.25 | 3.9 ± 0.11 | 0.31 ± 0.16 | 16.87 ± 0.16 | 38 ± 0.16 |
| SSG2 | 148.9 ± 0.54 | 3.8 ± 0.14 | 0.46 ± 0.19 | 14.76 ± 0.19 | 40 ± 0.14 |
| SSG3 | 150 ± 0.01 | 3.9 ± 0.17 | 0.41 ± 0.24 | 15.41 ± 0.13 | 38 ± 0.18 |
| CP1 | 149 ± 0.19 | 3.9 ± 0.21 | 0.54 ± 0.21 | 22.13 ± 0.77 | 42 ± 0.19 |
| CP2 | 148 ± 0.71 | 3.7 ± 0.15 | 0.52 ± 0.27 | 20.14 ± 0.14 | 44 ± 0.28 |
| CP3 | 150 ± 0.76 | 3.7 ± 0.17 | 0.41 ± 0.15 | 18.76 ± 0.21 | 47 ± 0.14 |
| IH1 | 147 ± 0.16 | 3.8 ± 0.2 | 0.31 ± 0.16 | 13.12 ± 0.13 | 51 ± 0.13 |
| **IH2** | **149.4 ± 0.87** | **4.0 ± 0.32** | **0.295 ± 0.22** | **11.56 ± 0.12** | **54 ± 0.17** |

**Table 4: Quality control tests for the oral disintegrating tablets of Atenolol maleate**

| Formulations* | Disintegration time * (sec) | Drug content* (%) | Percentage Drug Dissolved After 10 min* | *In vitro* Dispersion time* (s) |
|---|---|---|---|---|
| CCS1 | 14.25 ± 0.45 | 102.21 ± 0.73 | 89.24 ± 0.42 | 15 ± 0.22 |
| CCS2 | 13.51 ± 0.71 | 98.97 ± 0.12 | 91.21 ± 0.31 | 13 ± 0.65 |
| **CCS3** | **10.64 ± 0.61** | **99.58 ± 0.53** | **97.24 ± 0.86** | **11 ± 0.72** |
| SSG1 | 54.21 ± 0.14 | 97.25 ± 0.62 | 87.24 ± 0.68 | 61 ± 0.25 |
| SSG2 | 56.85 ± 0.32 | 98.21 ± 0.54 | 91.25 ± 0.45 | 59 ± 0.36 |
| SSG3 | 57.21 ± 0.68 | 98.56 ± 0.41 | 91.35 ± 0.76 | 59 ± 0.62 |
| CP1 | 38.25 ± 0.21 | 94.95 ± 0.25 | 84.91 ± 0.13 | 51 ± 0.98 |
| CP2 | 37.65 ± 0.24 | 96.78 ± 0.61 | 88.24 ± 0.95 | 50 ± 0.57 |
| CP3 | 39.78 ± 0.32 | 98.8 ± 0.32 | 95.42 ± 0.42 | 51 ± 0.24 |
| IH1 | 12.24 ± 0.45 | 98.25 ± 0.23 | 97.21 ± 0.68 | 11 ± 0.57 |
| **IH2** | **10.24 ± 0.55** | **99.6 ± 0.4** | **98.21 ± 0.9** | **10 ± 0.32** |

**Table 5: Dissolution profile of the oral disintegrating tablets of Atenolol maleate**

| Formulations | Cumulative % drug dissolved (minutes) | | | | | |
|---|---|---|---|---|---|---|
| | **0** | **2.5** | **5** | **10** | **15** | **20** |
| CCS1 | 0 | 37.6 ± 0.26 | 60.24 ± 0.35 | 79.25 ± 0.92 | 91.25 ± 0.24 | 98.47 ± 0.31 |
| CCS2 | 0 | 41.25 ± 0.12 | 62.25 ± 0.95 | 81.54 ± 0.7 | 89.350.89 | 97.28 ± 0.71 |
| **CCS3** | **0** | **50.24 ± 0.21** | **71.26 ± 0.31** | **85.45 ± 0.12** | **91.78 ± 0.21** | **99.12 ± 0.11** |
| SSG1 | 0 | 44.2 ± 3.16 | 59.21 ± 0.24 | 78.4 ± 0.12 | 89.9 ± 0.1 | 95.24 ± 0.21 |
| SSG2 | 0 | 43.21 ± 0.14 | 60.21 ± 0.1 | 75.26 ± 0.21 | 88.7 ± 0.31 | 96.25 ± 0.14 |
| SSG3 | 0 | 43.8 ± 2.3 | 69.35 ± 0.35 | 78.98 ± 0.26 | 91.36 ± 0.32 | 94.27 ± 0.12 |
| CP1 | 0 | 39.8 ± 1.26 | 67.2 ± 0.54 | 79.28 ± 0.11 | 90.4 ± 0.12 | 93.14 ± 0.78 |
| CP2 | 0 | 41.6 ± 0.51 | 68.5 ± 0.32 | 75.9 ± 0.64 | 88.6 ± 0.85 | 95.7 ± 0.74 |
| CP3 | 0 | 43.7 ± 2.5 | 60.35 ± 0.12 | 75.44 ± 0.46 | 88.69 ± 1.3 | 97.25 ± 0.2 |
| IH1 | 0 | 45.26 ± 0.2 | 69.24 ± 0.21 | 81.24 ± 0.3 | 89.19 ± 0.2 | 97.02 ± 0.13 |
| **IH2** | **0** | **49.12 ± 0.74** | **70.26 ± 0.1** | **85.29 ± 0.3** | **91.42 ± 0.6** | **99.7 ± 0.1** |

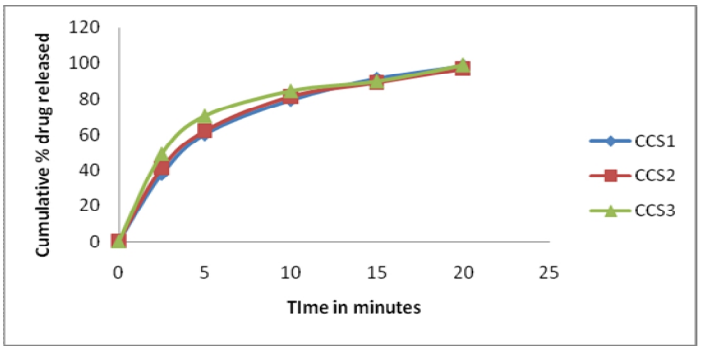


**Figure 3: Comparative dissolution profile of Atenolol maleate tablets containing different concentrations of cross carmellose sodium as super disintegrant**

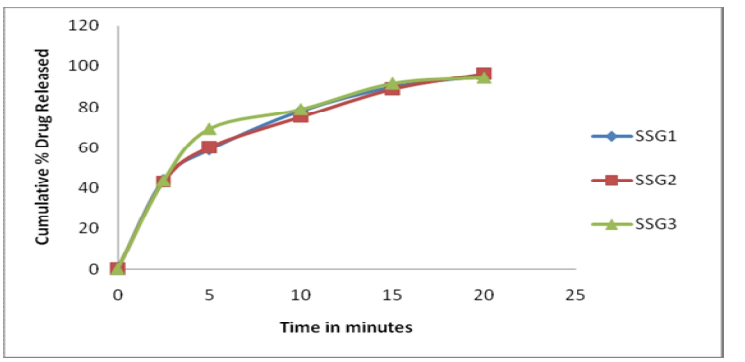


**Figure 4: Comparative dissolution profile of Atenolol maleate tablets containing different concentrations of sodium starch glycollate as super disintegrant**

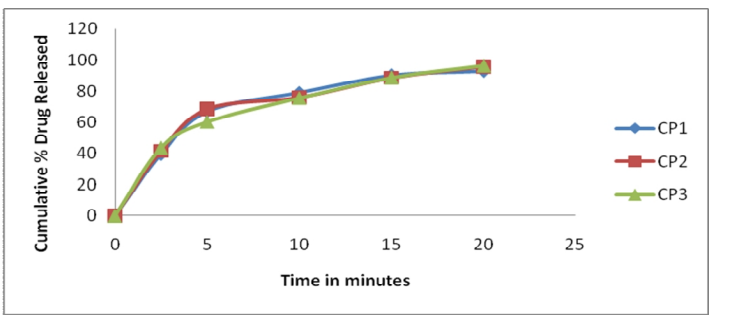


**Figure 5: Comparative dissolution profile of Atenolol maleate tablets containing different concentrations of cross povidone as super disintegrant**

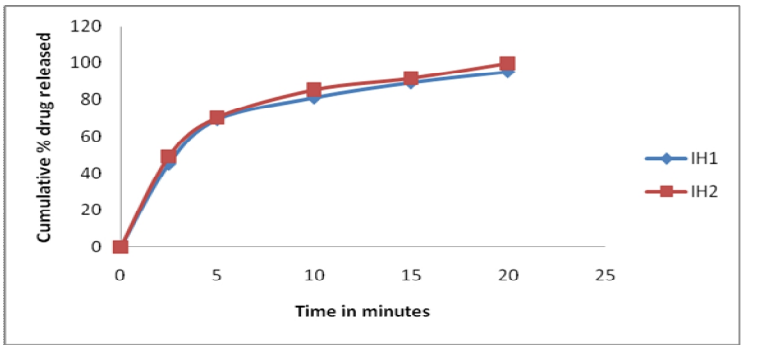


**Figure 6: Comparison of dissolution profiles of Atenolol maleate tablets containing different concentrations of Ispaghula husk powder as a natural super disintegrant**

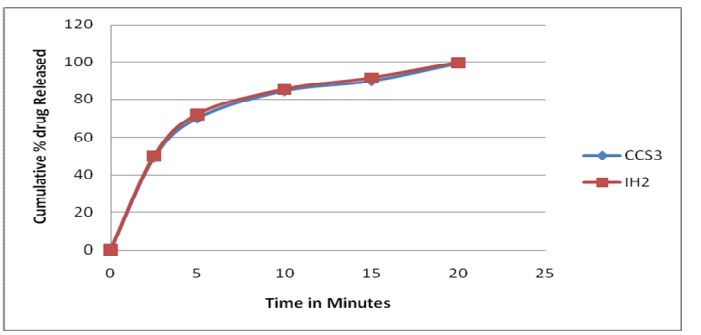


**Figure 7: Comparison of dissolution profiles of optimized formulations CCS3 and IH2**

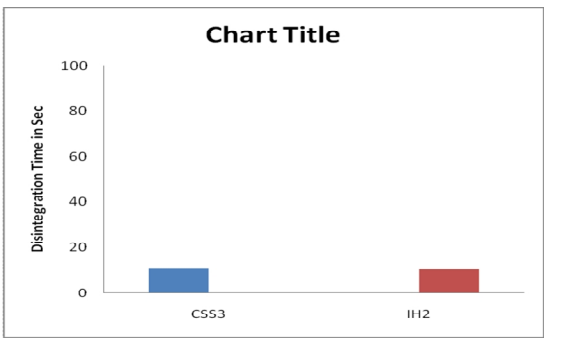


**Figure 8: Comparision of disintegration time of optimized formulations**

## FTIR Studies

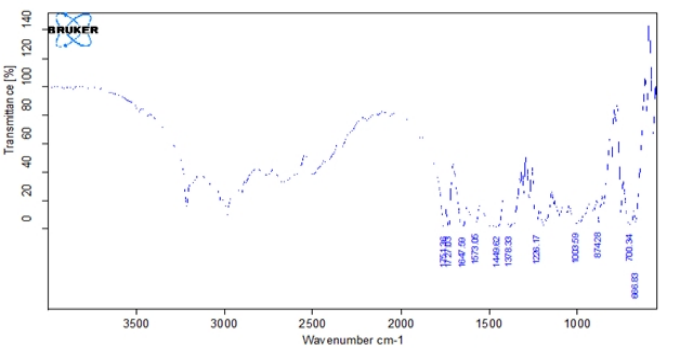


**Figure 9: FTIR of Atenolol maleate (pure drug)**

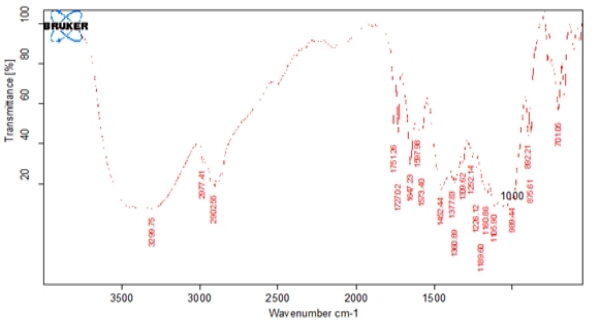


**Figure 10: FTIR of formulation CSS3**

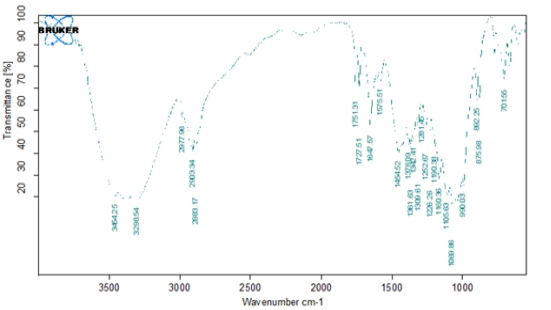


**Figure 11: FTIR of formulation IH2**

**Table 6: FTIR values of Optimized Formulations**

| Material | Peak | Functional group |
|---|---|---|
| Pure API | 3274.34<br>1751.36<br>1727.03<br>1647.59 | NH group<br>C=O in esters<br>C=O in acids<br>C=O in amides |
| Formulation CCS3 (Drug : CCS) | 3299.75<br>1751.26<br>1727.02<br>1647.23 | NH group<br>C=O in esters<br>C=O in acids<br>C=O in amides |
| Formulation S2 (Drug : Isphagula husk) | 3298.54<br>1751.31<br>1727.51<br>1647.57 | NH group<br>C=O in esters<br>C=O in acids<br>C=O in amides |

## Stability Analysis

**Table 7: Stability Analysis of Optimized Formulations**

| Formulation | No of days | 25˚C and 60 % RH | | 40˚C and 75 % RH | |
|---|---|---|---|---|---|
| | | Wetting time (s) | Disintegration time (s) | Wetting time (s) | Disintegration time (s) |
| **CCS3** | 0 | 8.47 ± 0.124 | 10.68 ± 0.226 | 8.47 ± 0.225 | 10.68 ± 0.146 |
| | 15 | 8.45 ± 0.148 | 10.65 ± 0.446 | 8.45 ± 0.256 | 10.61 ± 0.228 |
| | 30 | 8.48 ± 0.346 | 10.66 ± 0.424 | 8.46 ± 0.154 | 10.59 ± 0.446 |
| | 45 | 8.43 ± 0.146 | 10.64 ± 0.568 | 8.44 ± 0.654 | 10.62 ± 0.356 |
| | 60 | 8.44 ± 0.214 | 10.62 ± 0.146 | 8.43 ± 0.168 | 10.64 ± 0.186 |

| Formulation | No of days | 25˚C / 60 % RH | | 40˚C / 75 % RH | |
|---|---|---|---|---|---|
| | | Wetting time(s) | Disintegration time (s) | Wetting time (s) | Disintegration time (s) |
| IH2 | 0 | 11.56 ± 0.146 | 10.02 ± 0.148 | 11.56 ± 0.983 | 10.02 ± 0.146 |
| | 15 | 11.54 ± 0.566 | 9.98 ± 0.167 | 11.53 ± 0.156 | 10.0 ± 0.264 |
| | 30 | 11.50 ± 0.354 | 9.99 ± 0.964 | 11.51 ± 0.256 | 9.97 ± 0.446 |
| | 45 | 11.51 ± 0.446 | 9.98 ± 0.843 | 11.54 ± 0.140 | 9.99 ± 0.356 |
| | 60 | 11.49 ± 0.176 | 9.97 ± 0.116 | 11.50 ± 0.146 | 9.98 ± 0.264 |

## Drug content

**Table 8: Drug content**

| Formulation | No of days | 25˚C / 60 % RH | | 40˚C / 75 % RH | |
|---|---|---|---|---|---|
| | | Drug content | Dissolution | Drug content | Dissolution |
| CCS3 | 0 | 99.08 ± 0.86 | | 99.08 ± 0.86 | |
| | 15 | 98.12 ± 0.56 | | 98.75 ± 0.23 | |
| | 30 | 98.74 ± 0,24 | | 98.06 ± 0.36 | |
| | 45 | 98.38 ± 0.328 | | 97.86 ± 0.28 | |
| | 60 | 98.25 ± 0.156 | | 97.54 ± 0.442 | |
| IH2 | 0 | 98.6 ± 0.24 | | 98.6 ± 0.86 | |
| | 15 | 98.24 ± 0.168 | | 98.36 ± 0.52 | |
| | 30 | 98.36 ± 0.264 | | 98.12 ± 0.16 | |
| | 45 | 98.14 ± 0.188 | | 97.56 ± 0.34 | |
| | 60 | 98.08 ± 0.22 | | 97.24 ± 0.28 | |

## DISCUSSION

The present work led to the development of orodispersible tablets of Atenolol maleate by using different concentration of natural and synthetic super disintegrents. The prepared oral disintegrating tablets of Atenolol maleate were found to be good in appearance without cracking, lamination and chipping. The promising formula (CCS3, IH2) have showed fast disintegration and displayed *in vitro* dispersion time of 11 s and 10.5 s. The dissolution rates of the optimized formulations (CCS3, IH2) were found to be good. Among the promising ODT formulation CCS3, IH2 the formula IH2 was found to be superior when compared to formulation CCS3 since formulation IH2 used natural disintegrant (6 %w/w Isphagula husk) at a lower concentration than the formulation CCS3 (8 % w/w Cross Carmellose Sodium) and hence it is found to be more cost effective. The FTIR studies were also showed the there was no interaction between drug and polymer. The stability study was done for 3 months all parameters such as wetting time, disintegration time, drug content and *in-vitro* dissolution studied at the end of every month, the results shows that no significant changes in that parameters.

**ACKNOWLDGEMENT**

The author is very thankful to Elite pharmaceuticals, Guntur, Andra Pradesh, India for providing polymers and other excipients and also thankful to Principal Nama Sreekanth, Priyadarshini institute of pharmaceutical education and Research for providing lab premises for conducting the research work and also thankful to co-authors for giving a lot of support during literature survey and research work

**REFERENCES**

1. Lachman L, Liberman H and Kanig J. The theory and Practice of Industrial Pharmacy; Third edition. p. 293-345, 346-373.
2. Swarbrick J and Boylan J. Encyclopedia of Pharmaceutical Technology; Volume 14. p. 345-348, 385-400, 401-418.
3. Taylor and Francis. International Journal of Toxicology: Toxicity of excipients - A food and drug administration perspective 2003; 22(5): 377-380.
4. Chowhan Z. Pharmaceutical Technology: Excipients and their functionality in drug product development 1993; 2(9): 211-221.
5. Lachman L, Liberman L and Schwartz J. Pharmaceutical Dosage Forms: tablets 2004; 2(1): 134-142.
6. Banker G and Rhodes C. Drug and Pharmaceutical Sciences: Modern Pharmaceutics; Third edition; Volume 2. p. 333-394.
7. Swarbrick J and Boylan J. Encyclopedia of Pharmaceutical Technology; 7. p. 121-160.
8. Seager H. Drug delivery products and the zydis fast dissolving dosage forms, J. Pharm. Pharmacology 1998; 50(4): 375-382. http://dx.doi.org/10.1111/j.2042-7158.1998.tb06876.x
9. Indurwade NH, Rajyaguru T and Nakhat PD. Fast Dissolving drug delivery systems: A Brief overview, Indian Drugs 2002; 39(8): 405-09.
10. Devrajan PV, Gore SP. Fast Dissolving Tablets: The Future Compaction**,** Express Pharma Pulse 2000; 7(1): 16-19.
11. Habib W, Khankari R, Hontz J. Fast-dissolving Drug Delivery Systems, Critical Reviews and Therapeutic Drug Carrier Systems 2000; 17(1): 61-72. http://dx.doi.org/10.1615/CritRevTherDrugCarrierSyst.v17.i1.20
12. Kuchekar BS, Badhan AC, Mahajan HS. Fast Dissolving drug delivery systems: A brief overview Pharma Times 2003; 2(1): 7-9. Reddy L, Ghose B and Rajneesh. Fast Dissolving drug delivery systems: A brief overview, Indian J. Pharm. Sci 2002; 64(4): 331-336.
13. Parakh SR and Gothoskar AV. Fast Dissolving drug delivery systems: A brief overview, Pharma Tech 2003; 2(1): 92-100.
14. Lalla J.K. and Sharma A H; Fast Dissolving drug delivery systems: A Brief overview. Indian Drugs 1994; 31(11): 503-508.
15. Nail SL and Gatlin LA. Freeze drying: Principles and Practice, in Pharmaceutical Dosage Forms-Parenteral Medications 1993; 2(1): 158-163.

**Cite this article as:**

Brahmaiah Bonthagarala, Prasanth Pasumarthi, Katta Vamsi Kiran, Sathram Nataraja, Sudarshan Donthiboina. Formulation and evaluation of orodispersible atenolol maleate tablets: A comparative study on natural super disintegrents and synthetic super disintegrents. Int. J. Res. Ayurveda Pharm. 2014;5(2):185-192 http://dx.doi.org/10.7897/2277-4343.05237

Source of support: Nil, Conflict of interest: None Declared