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# Preparation and Evaluation of Bi-layered Tablets of Carbamazepine

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**ABSTRACT**
The present work has been done to formulate bi-layered tablet of Carbamazepine sodium containing immediate release layer and sustained release layer. The FTIR study revealed that there was no interaction between drug and polymer and combination can be safely prepared. Both layers were prepared by wet granulation technique as poor flow property exhibited by pure drug. The immediate release layer was formulated by using sodium starch glycolate, croscarmellose sodium as superdisintegrants and evaluated for physical parameters, disintegration time and in vitro drug release. The optimized immediate release layer (IF6) with highest in vitro release of 98.11 was selected for bi-layered tablet formulation. HPMC K4M and HPMC K100M polymer used to retard the drug release from sustained release layer in different proportion and combination and evaluated for physical parameter along with in vitro drug release studies.. The optimized sustained release layer (SF8) which extends the Carbamazepine sodium release more than 18 hrs was selected. In vitro drug release studies were performed using USP type II apparatus (paddle method) in 900 ml of phosphate buffer pH 6.8 at 100 rpm. Finally Bi-layered tablets were prepared by double compression of selected sustained release layer and immediate release layer of Carbamazepine sodium. The tablets were evaluated for hardness, thickness, weight variation, friability, drug content uniformity and in vitro drug release. All the physical parameters were in acceptable limit of pharmacopeial specification. The stability studies, shown the bi-layer tablet was stable at $40^0$C/ 75% RH for a period of 3 months.

## INTRODUCTION

Oral route is most favoured administration route due to lower cost therapy and also can be administered easily i.e., Desirable for patient. Oral dosage form that are said conventional provide specific concentration of drug in systemic circulation without any control on delivery of drug and leads to fluctuations in plasma drug level.

Oral drug delivery system has many advantages like increase efficacy drug activity duration, patient compliance, dose frequency decrement, route administration, reduce adverse effect and specific delivery to the site.Oral course has been quite possibly the most mainstream courses of medication conveyance because of its simplicity of organization, patient consistence, least sterility limitations and adaptable plan of measurement structures. For a long time, therapy of an intense sickness or ongoing ailment has for the most part achieved by conveyance of medications to patients utilizing regular medication conveyance framework. Indeed, even today these regular medication conveyance frameworks are the essential drug items ordinarily found in the solution. Regular oral medication items are planned to deliver the dynamic standard that follows oral organization to acquire complete & fast fundamental medication assimilation

The tablet is the most widely used dosage form because of its convenience in terms of self-administration, compactness and ease in manufacturing. Tablets are solid dosage forms containing medicinal substances with or without suitable diluents. According to Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents. They are varying in size and weight, depending on number of medicinal substances and the intended mode of administration. It is most popular dosage form and 70% of the total medicines are dispensed in the form of tablet

**Advantages of the Oral Route**

- Modest
- By and large safe course of medication
- Advantageous for the patient
- The patient can self-manage
- No sterile precautionary measures required.

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- Threat of intense medication response is negligible
- Neither uncommon information nor extraordinary supplies (needles, needles) are needed for its use

**Disadvantages of the Oral Route**

- The retention of drugs may alter.
- Requires initial digestion
- Ineffective for people who are vomiting
- The medication might be obliterated by stomach related to proteins

**Formulation Table**

| Sl. No. | Ingredients | F1 | F2 | F3 | F4 | F5 | F6 |
|---|---|---|---|---|---|---|---|
| **1** | Carbamazepine | 125 | 125 | 125 | 125 | 125 | 125 |
| **2** | Lactose | 82 | 79.5 | 82 | 79.5 | 82 | 79.5 |
| **3** | Croscarmellose sodium | 10 | 12.5 | - | - | 5 | 6.25 |
| **4** | Sodium starch glycolate | - | - | 10 | 12.5 | 5 | 6.25 |
| **5** | Microcrystalline cellulose | 25 | 25 | 25 | 25 | 25 | 25 |
| **6** | Ponceau 4R | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 |
| **7** | Magnesium stearate | 3 | 3 | 3 | 3 | 3 | 3 |
| **8** | Talc | 5 | 5 | 5 | 5 | 5 | 5 |
| **9** | Total | 250 | 250 | 250 | 250 | 250 | 250 |

**Post-compression parameters**

| Formulation | Weight variation Mean ± SD | Hardness Mean ± SD | Friability Mean ± SD | Thickness Mean ± SD | Drug content (%) Mean ± SD |
|---|---|---|---|---|---|
| **BTF** | 550.75±0.46 | 7.05±0.15 | 0.38±0.01 | 6.28±0.14 | 99.23±0.53 |

**In-vitro dissolution study**

| Time in min | % CUMULATIVE DRUG RELEASE | | | | | |
|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 |
| 0 | 0.000±0.000 | 0.000±0.000 | 0.000±0.000 | 0.000±0.000 | 0.000±0.000 | 0.000±0.000 |
| 1 | 17.056±0.612 | 21.226±0.872 | 20.847±0.450 | 26.532±1.306 | 30.323±1.125 | 36.008±1.174 |
| 3 | 31.805±1.075 | 31.908±1.280 | 33.738±2.620 | 54.965±2.391 | 56.561±0.778 | 60.653±2.255 |
| 5 | 53.454±2.280 | 56.489±2.100 | 56.488±1.288 | 68.244±0.593 | 64.455±2.346 | 68.247±1.723 |
| 10 | 64.837±2.481 | 68.251±3.001 | 68.250±1.176 | 81.525±0.896 | 77.735±1.791 | 83.424±2.060 |
| 15 | 71.106±1.634 | 78.121±1.913 | 74.141±1.523 | 89.829±1.107 | 81.543±0.873 | 92.918±1.314 |
| 20 | 80.408±1.038 | 83.445±1.088 | 82.685±0.582 | 94.829±0.788 | 87.246±1.865 | 98.624±0.722 |
| 25 | 86.676±1.427 | 92.366±1.472 | 90.280±1.281 | 97.497±0.931 | 92.376±1.325 | 98.827±1.427 |
| 30 | 91.047±2.031 | 94.842±1.632 | 93.135±0.852 | 98.075±1.265 | 96.743±1.731 | 99.404±1.162 |

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**Kinetic release**

| FORMULATION CODE | KINETIC MODELS | | | | |
|---|---|---|---|---|---|
| | Zero Order $_R2$ | First Order $_R2$ | Higuchi $_R2$ | Korsmeyern | $R^2$ |
| **F1** | 0.8362 | 0.9816 | 0.9689 | 0.8915 | 0.6657 |
| **F2** | 0.8228 | 0.9844 | 0.9677 | 0.8694 | 0.6263 |
| **F3** | 0.8231 | 0.9819 | 0.9643 | 0.8711 | 0.6336 |
| **F4** | 0.7068 | 0.9850 | 0.9059 | 0.8424 | 0.5642 |
| **F5** | 0.7101 | 0.9606 | 0.9055 | 0.804 | 0.5134 |
| **F6** | 0.6835 | 0.9792 | 0.8945 | 0.8034 | 0.5129 |

**Stability Studies:**

The bi-layered tablets were subjected to short term stability study, storing the formulation at $40^0$C / 75% RH for 3 months. The data for stability studies revealed that no considerable differences in physical parameters, drug content and in vitro drug release rate were observed.

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