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## Formulation and Evaluation of Bi Layer Tablets of Chlorzoxazone

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### ABSTRACT

The main objective of this research work was to formulate and evaluate the bi layer tablets of chlorzoxazone by using different polymers. Chlorzoxazone is centrally acting skeletal muscle relaxant. The tablets containing immediate releasing layer and sustained release layer. The polymers used are microcrystalline cellulose pH 102, sodium starch glycol ate, croscarmellose, povidone for immediate releasing layer, HPMC K 100 cps, K4cps, E15cps, carbomer 971P, and natural gums like guar gum, Xanthan gum for sustained drug release layer. The matrix tablets were prepared by direct compression and wet granulation methods. All the excipients are tested for compatibility with drug, which revealed that there was no physical and chemical interaction occurred. The Pre formulation parameters such as bulk density, tapped density, compressibility index and Hausner's ratio were analyzed. The In-Vitro drug release studied were Performed in the USP dissolution apparatus- (paddle) using pH 1.2 HCL buffer and pH 6.8 phosphate buffer as dissolution media at 100rpm speed and temperature of  $37^{\circ}\text{C} \pm 5^{\circ}\text{C}$ . The sampling was done at periodic time intervals of 1.5, 3, 4, 6, 8, 10 and 12 hours and was replaced by equal volume of dissolution media after each withdrawal. The cumulative amount of drug release at different intervals is estimated using UV method. Based on the evaluation result the formulations F6 was selected as best formulation among immediate release and is used to compress with sustained release layer. Among all formulation FB8 formulation (HPMC K100m 88%) shown maximum release of 98.84% drug in 12<sup>th</sup> hour.

**Keywords:** Chlorzoxazone, sodium starch glycolate, HPMC K100m, K4M, dissolution studies, sustained release.

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## INTRODUCTION

Oral route is the most commonly employed route of drug administration. Although different route of administration are used for the delivery of drugs, oral route remain the preferred mode. The popularity of the oral route is attributed patient acceptance, ease of administration, accurate dosing, cost effective manufacturing method and generally improved shelf-life of the product. Even for sustained release systems the oral route of administration has been investigated the most, because of flexibility in dosage forms design that the oral route offers.<sup>1</sup>

With many drugs, the basic goal of therapy is to achieve a steady-state blood level or tissue level that is therapeutically effective and non toxic for an extended period of time<sup>2</sup>. To achieve better therapeutic action various types of drug delivery systems are available, out of which sustained release systems are gaining much importance because of their wide advantages over others like ease of administration, convenience and noninvasiveness.

Sustained release dosage forms cover a wide range of prolonged action preparations that provide continuous release of their active ingredients for a specific period of time. By prescribing sustained release systems, it is possible to achieve several desirable therapeutic advantages<sup>2</sup>. As the frequency of dosage is reduced, patient compliance can be improved, and drug administration can be made more convenient. The blood level oscillation characteristic of multiple dosing of conventional dosage forms is reduced, because more even blood level is maintained.

Total amount of drug administered can be reduced by designing sustained release systems. In addition, better control of drug absorption can be attained, since the high blood level peaks that may be observed after administration of a dose of a high availability drug can be reduced by formulation of extended release form. The safety margin of high potency drug can be increased, and the incidence of both local and systemic adverse side effects can be reduced in sensitive patient. Overall, administration of sustained release forms enables increased reliability of therapy<sup>3</sup>.

Chlorzoxazone (5-chloro-2,3-dihydro-1,3-benzoxazol-2- one) is a centrally acting muscle relaxant used to treat muscle spasm and the resulting pain and discomfort<sup>4</sup>. Chlorzoxazone may act by inhibiting calcium and potassium influx which would lead to neuronal inhibition and muscle relaxation. It is having a shorter half life (1.1hour) with the dose administration of 3-4 times a day leads to decreased patient compliance<sup>4,5</sup>. In order to decrease the frequency of drug administration and for improving better patient compliance a sustained-release formulation of Chlorzoxazone is desirable.

## MATERIALS AND METHODS

Chlorzoxazone was received as a gift sample from Wanbury ltd, Chennai (India), Hydroxy Propyl Methyl Cellulose K4M, K100, E15, and other excipients were obtained from Richer pharmaceuticals, Hyderabad.

### **Formulation of the Bilayer Sustained Release Tablets:**

#### **For IR layer (chlorzoxazone) by direct compression method**

Step 1: Weigh the all ingredient in required quantity

Step 2: Transfer all ingredients into a mortar triturate for 10minutes until, to get fine powder and sieve the material. (#60)

Step 3: then transfer the material into blender for proper distribution of drug in blend for 10minutes.

Step 4: then addition of lubricant mix well.

Step 5: Perform the micromeritic properties (Pre compression studies).

#### **For SR layer (CHZ) by wet granulation process:**

All the tablets, each containing mg of CHZ were prepared by wet granulation method. The manufacturing process involves following steps they were

1) Sifting: Drugs, polymers and diluents were sifted through 40 mesh sieve (stage1).

2) Binder preparation: Polymer was dissolved in isopropyl alcohol.

3) Granulation:

Dry mixing: The drug and diluents after stage1 were mixed well to ensure the selected ratio of polymer(s) previously shifted through sieve no 40 for 5 min. Granulation: Granules were prepared by adding step 2 in step 3a and the wet mass pass through sieve no.18.

c) Drying: The produced CHZ granules were dried at  $55^{\circ}\text{C} \pm 5^{\circ}\text{C}$  for 1 hour in a hot-air oven.

4) Sizing: Dried granules were passed through 20 mesh sieve.

5) Lubrication: These granules were blended with lubrication mixture (magnesium stearate and talc) for 5min in polythene bag.

6) Compression: After the lubrication granules were compressed using 16 station rotary tableting machine, equipped with flat-faced, round punches of 10-mm diameter.

Formulation part given in tabular form (table 1&2).

**Table1. Composition of formulations CHZ IR layer**

Ingredients	CONTENT(mg/tablet)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
CHZ	48	48	48	48	48	48	48	48	48
MCC 102	50	50	50	50	50	50	50	50	50
Lactose	61	21	57	49	69	59	69	79	79
SSG	8	12	16	20	10	20	--	10	--
CCS	20	12	16	20	10	10	20	--	10
Povidone	7	7	7	7	7	7	7	7	7
Magnesium Stearate	6	6	6	6	6	6	6	6	6
Total weight (mg)	200	200	200	200	200	200	200	200	200

**Table2: Composition of formulations CHZ SR layer**

Ingredients	FS <sub>1</sub>	FS <sub>2</sub>	FS <sub>3</sub>	FS <sub>4</sub>	FS <sub>5</sub>	FS <sub>6</sub>	FS <sub>7</sub>	FS <sub>8</sub>	FS <sub>9</sub>	FS <sub>10</sub>	FS <sub>11</sub>	FS <sub>12</sub>	FS <sub>13</sub>	FS <sub>14</sub>	FS <sub>15</sub>	FS <sub>16</sub>
CHZ	290	290	290	290	290	290	290	290	290	290	290	290	290	290	290	290
Starch	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55
lactose	79	57	79	57	79	57	79	57	57	57	79	57	79	57	57	57
PEG 6000	44	44	44	44	44	44	44	44	44	44	44	44	44	44	44	44
HPMC k4m	66	88	--	--	--	--	--	--	44	--	--	--	--	--	44	--
Carbomer 971p	--	--	66	88	--	--	--	--	44	--	--	--	--	--	--	--
HPMC E15m	--	--	--	--	--	--	--	--	--	--	--	--	66	88	44	44
Gaur gum	--	--	--	--	--	--	--	--	--	--	66	88	--	--	--	--
Color	Qs	Qs	Qs	Qs	Qs	Qs	Qs									
IPA	Qs	Qs	Qs	Qs	Qs	Qs	Qs									
Xanthan gum	--	--	--	--	66	88	--	--	--	44	--	--	--	--	--	--
HPMC k100m	--	--	--	--	--	--	66	88	--	44	--	--	--	--	--	44
Talc	16	16	16	16	16	16	16	16	16	16	16	16	16	16	16	16
Total weight	550	550	550	550	550	550	550	550	550	550	550	550	550	550	550	550

**Compression of the Bilayer Tablet:**

The prepared granules of both the layers were compressed on a Cad Mac Double Rotary Bilayer compression machine on 19/8.5mm caplet shaped punch. The hardness was 6.5- 7.5kg/cm<sup>2</sup> and the tablet thickness was 6.8-7.0mm. Both the prepared granules came from two different hoppers to two different feed frames where they occupied the die cavity. The bottom layer was first compressed with lower pressure, which was then followed by filling of the die cavity by the upper layer granules. The final compression was done only after both the granules occupied the die cavity one on top of the other. Both the layers were identified on the basis of color since the immediate release layer had pink color and the sustain release layer has white color.

**Evaluation of granules:****Bulk Density/ Tap Density of the Drug <sup>6,7</sup>**

Bulk density of the drug API was carried out using bulk density apparatus. Weight of an empty cylinder was taken. Drug was poured in to the cylinder and the volume was measured. The

cylinder was kept in the apparatus and tapped for 100 times. The final volume after 100 taps was measured. Then the following calculations were made:

Loose Bulk Density (LBD) = weight of powder/ volume of packing

Tap Bulk Density (TBD) = weight of powder/tapped volume of packing

Carr's Index = [(TBD. – LBD) x 100] / TBD

Hausner's Ratio = Initial volume / Final volume

#### **Angle of repose:**

The angles of repose of the granules were determined by using funnel method. The accurately weighted granules were taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of the granules. The granules were allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated by using the equation

$$\tan\theta = h/r$$

Where, h and r are the height and radius of the powder cone.

#### **Drug content:**

For determination of drug content three tablets from each formulation were weighed individually and powdered. The quantity of powder was equivalent to 10 mg. The equivalent weight CHZ was transferred into 100 ml volumetric flask diluted to 100ml with sufficient amount of phosphate buffer (pH6.8). Then aliquot of the filtrate was diluted suitably and analyzed spectrophotometrically at 282nm against blank.

#### **Evaluation of matrix tablets:**

##### **Uniformity of weight (Weight variation test):**

20 tablets were weighed individually and collectively. Average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percent deviation was calculated using the following formula (table 6)

$$\% \text{ Deviation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

##### **Hardness test:**

Hardness (diametral crushing strength) is a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength. The tablet should be stable to mechanical stress during handling and transportation. The hardness was tested using Monsanto hardness tester. The average of the five determinations was determined and reported. (Table 6)

##### **Thickness:**

The thickness of the tablets was measured by Digital Vernier Caliper. It is expressed in mm.

**Friability (F):**

The friability of the tablet was determined using Roche Friabilator. It is expressed in %. 10 tablets were initially weighed and transferred into the friabilator. The friabilator was operated at 25 rpm for 4 mins. The tablets were weighed again. Friability of tablet should not exceed 1%. (Table 6)

**In-vitro dissolution studies:**

Dissolution studies were carried out for all the formulations combinations in triplicate, employing USP-II paddle method and 900ml of pH 1.2 buffer (0.1N HCl) for 2hrs and pH 6.8 phosphate buffer as the dissolution medium for remaining 8hours. The medium was allowed to equilibrate to temp of 37°C ±0.5°C. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 10hrs at 100 rpm. At definite time intervals of 5 ml of the aliquot of sample was withdrawn and filtered (0.45µm). The volume replaced with equivalent amount of the fresh dissolution medium. The samples were analyzed spectrophotometrically at 282nm using UV-spectrophotometer. (Table 7&8) (Figure 2&3)

**Stability studies**

The stability studies were conducted for satisfactory formulation as per ICH guidelines. The satisfactory formulation sealed in aluminum packaging and stored at 30±2°C with 65±5% RH for 2months. Samples were analyzed for physical parameters and drug content. (Table 9)

**FT-IR studies:**

To know the functional group analysis of the materials. (Figure 1& Table3)

**Table 3: Functional analysis of pure drug**

S.No	Range(cm-1)	Functional class	Intensity	Assignment
1	3454.66	Amine	Wk	N-H(1-amines),2 bands
2	2987.86	Alkanes	Str	CH <sub>2</sub> ,CH
3	2826.80	Ketone	Med	C-H
4	2720.71	Aldihyde	Med	C-H
5	1593.27	Carboxlic acid and derivatves	Med	N-H(1-amide-2 bond)
6	1382.06	Alkanes	Med	CH <sub>2</sub> deformation
7	1352.16	Alkanes	Med	CH <sub>2</sub> deformation
8	961.56	Alkenes	Bending	CH
9	921.05	Alkenes	Bending	CH
10	844.86	Arenes	Bending	CH <sub>2</sub>
11	799.53	Arenes	Bending	CH <sub>2</sub>
12	773.49	Arenes	Bending	CH <sub>2</sub>
13	709.63	Arenes	Bending	CH <sub>2</sub>
14	691.51	Arenes	Bending	CH <sub>2</sub>
15	678.97	Alkyne	Alkyne	CH deformation
16	655.83	Alkyne	Alkyne	CH deformation

## RESULTS AND DISCUSSIONS:

FTIR spectra of CHZ and physical mixture of CHZ and polymers were taken. Spectra are shown in figure1 for drug. All the characteristic peaks of pure drug were observed in the spectrum of mixture.

### Pre compression parameters:

For IR layer the bulk density, tapped density, Hausner's ratio, Carr's index, angle of repose values are accepted according to ICH guidelines. The limits are within the pharmacopeia limits. (Table 4)

**Table 4. Pre compression data for IR layer**

Formulation code	Bulk density (gm/ml)	Tapped density(gm/ml)	Hausner's ratio	Carr's index (%)	Angle of repose ( $\theta$ )
F1	0.317	0.376	1.18	15.69	26.38
F2	0.291	0.331	1.19	12.11	26.96
F3	0.307	0.347	1.13	12.26	26.85
F4	0.326	0.384	1.17	15.10	29.12
F5	0.286	0.342	1.19	14.00	28.47
F6	0.301	0.350	1.16	16.37	29.14
F7	0.298	0.344	1.15	13.33	25.72
F8	0.307	0.356	1.15	13.76	26.38
F9	0.314	0.361	1.14	13.00	26.54

**Table 5. Pre-compression data of SR layer**

Formulation code	Angle of repose $\theta = \tan^{-1}(h/r)$	Loose Bulk Density(LBD) (g/ml)	Tapped bulk Density (TBD) (g/ml)	Carr's index %	Hausner's ratio
FS <sub>1</sub>	21.04	0.304	0.351	13.41	1.21
FS <sub>2</sub>	21.09	0.317	0.367	13.63	1.18
FS <sub>3</sub>	21.46	0.310	0.36	13.89	1.23
FS <sub>4</sub>	24.88	0.318	0.378	15.87	1.16
FS <sub>5</sub>	24.23	0.294	0.346	15.02	1.14
FS <sub>6</sub>	24.09	0.307	0.36	14.72	1.20
FS <sub>7</sub>	24.78	0.311	0.368	15.21	1.34
FS <sub>8</sub>	25.56	0.265	0.312	15.06	1.21
FS <sub>9</sub>	23.98	0.332	0.391	14.91	1.16
FS <sub>10</sub>	21.14	0.299	0.346	13.54	1.12
FS <sub>11</sub>	22.53	0.27	0.317	14.63	1.19
FS <sub>12</sub>	24.96	0.282	0.336	15.82	1.32
FS <sub>13</sub>	21.38	0.272	0.316	13.89	1.15
FS <sub>14</sub>	21.08	0.289	0.334	13.21	1.20
FS <sub>15</sub>	21.43	0.324	0.376	13.65	1.31
FS <sub>16</sub>	23.56	0.294	0.344	14.27	1.28

### Density:

The bulk density, tapped density values are in the range of 0.291-0.328 and 0.331-0.384

respectively. The Hausner's ratio, Carr's index values are in the range of 1.13-1.19 and 12.11–16.37 respectively.

#### Angle of repose:

The Angle of repose values are in the range of 25.72–29.14 for immediate release layer blend. For SR layer bulk density, tapped density, Hausner's ratio, Carr's index, angle of repose values are accepted according to ICH guidelines. (Table 6)

**Table 6. Post compression studies of Bilayer tablets**

Formulation	Weight variation	Hardness (Kg/cm <sup>2</sup> )	Friability (%)	Thickness (mm)	Content uniformity
FB <sub>1</sub>	751±0.61	6.4±0.30	0.72±0.12	6.8±0.02	99.28±0.21
FB <sub>2</sub>	752±0.54	6.3±0.20	0.68±0.08	6.9±0.08	97.16±0.17
FB <sub>3</sub>	748±0.91	6.7±0.25	0.69±0.09	6.8±0.06	101.18±0.14
FB <sub>4</sub>	749±0.58	6.6±0.10	0.66±0.15	6.8±0.04	97.68±0.23
FB <sub>5</sub>	751±0.46	6.7±0.40	0.68±0.14	6.8±0.01	99.41±0.10
FB <sub>6</sub>	748±0.23	6.9±0.25	0.65±0.06	6.7±0.02	98.19±0.17
FB <sub>7</sub>	750±0.53	7.2±0.30	0.67±0.08	6.8±0.04	102.6±0.12
FB <sub>8</sub>	752±0.42	7.1±0.10	0.68±0.16	6.9±0.06	99.31±0.21
FB <sub>9</sub>	752±0.38	7.3±0.14	0.59±0.14	6.8±0.04	98.12±0.35
FB <sub>10</sub>	749±2.32	6.8±0.32	0.59±0.21	6.8±0.01	98.63±0.26
FB <sub>11</sub>	750±2.67	6.8±0.39	0.57±0.54	6.9±0.04	98.15±0.12
FB <sub>12</sub>	748±0.23	6.4±0.42	0.6±0.34	6.8±0.06	99.42±0.22
FB <sub>13</sub>	751±1.56	6.5±0.29	0.54±0.22	6.8±0.01	99.14±0.14
FB <sub>14</sub>	750±2.23	7.5±0.12	0.53±0.71	6.8±0.08	99.25±0.16
FB <sub>15</sub>	750±0.56	6.4±0.14	0.54±0.42	6.7±0.09	99.30±0.13
FB <sub>16</sub>	750±1.12	6.9±0.51	0.57±0.88	6.8±0.02	99.17±0.12

#### Density:

The bulk density, tapped density values are in the range of 0.27- 0.332 and 0.312-0.378 respectively. The Hausner's ratio, Carr's index values are in the range of 1.15-1.34 and 13.21-15.87 respectively.

#### Angle of repose:

The Angle of repose values are in the range of 21.14–25.56 for sustained release layer blend.

#### Evaluation of Tablets:

##### Weight variation test:

All the tablets pass the weight variation test as the average % weight variation was within the pharmacopoeia limit of 7.5 %. Weight variation limits are from 748±0.23 to 752±0.38. (table6)

The tablet hardness values ranged from 6.0 to 7.5 kg/cm<sup>2</sup> for all formulations and were almost same. This indicates good tablet strength. The hardness values limits are from 6.3±0.20 to 7.5±0.12.

**Friability test:**

The friability values were found to be within the limit (1.0%) for all the formulations. This indicated good handling property of the prepared tablets. The friability values limits are from  $0.54 \pm 0.22$  to  $0.72 \pm 0.12$ .

**Thickness:**

The tablet thicknesses of all the tablets are ranged from  $6.7 \pm 0.02$  to  $6.9 \pm 0.08$ .

**Drug content:**

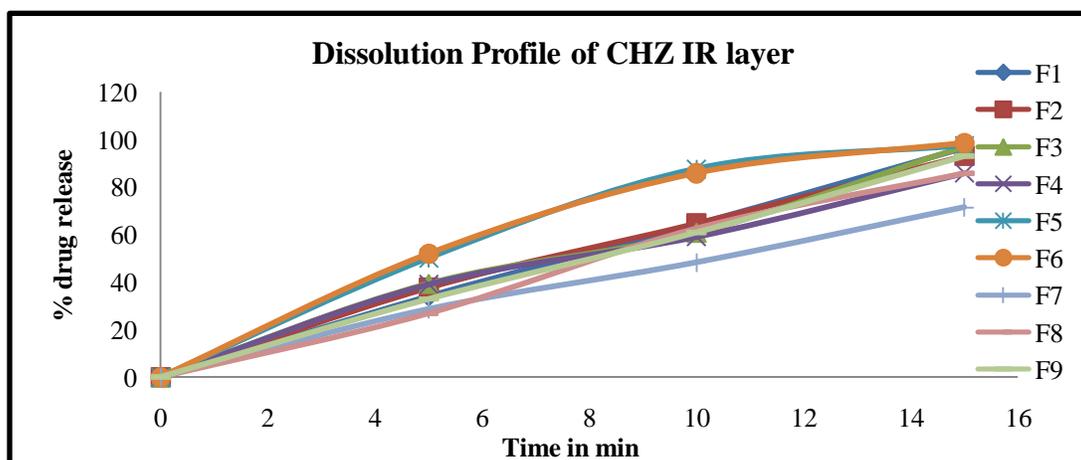
The drug content uniformity values are ranged from  $97.16 \pm 0.17$  to  $102.6 \pm 0.12$ .

**In -vitro drug release study:****Paddle method:**

Dissolution data of Matrix tablets formulations of Bi layer Tablets by Paddle method (USP II) are reported in Table 7 & Figure 2. (IR layer) The dissolution profile of CHZ IR layer was given in graphical representation, the formulation F6 was maximum drug release, hence we conclude that the F6 was best formula and F6 IR layer was compress with CHZ SR layers. (Table8 & Figure 3) (SR layer)

**Table7. Cumulative % drug released (%CDR) formulations of CHZ IR layer**

Time in min	5min	10min	15min
F1	33.97	64.37	96.55
F2	37.54	64.37	92.98
F3	39.33	60.79	98.44
F4	39.33	59	85.82
F5	50.06	87.61	98.34
F6	51.85	85.82	98.84
F7	28.6	48.27	71.52
F8	26.82	62.58	85.82
F9	32.18	60.79	92.9



**Figure2. Dissolution profiles of formulations F<sub>1</sub>-F<sub>9</sub>**

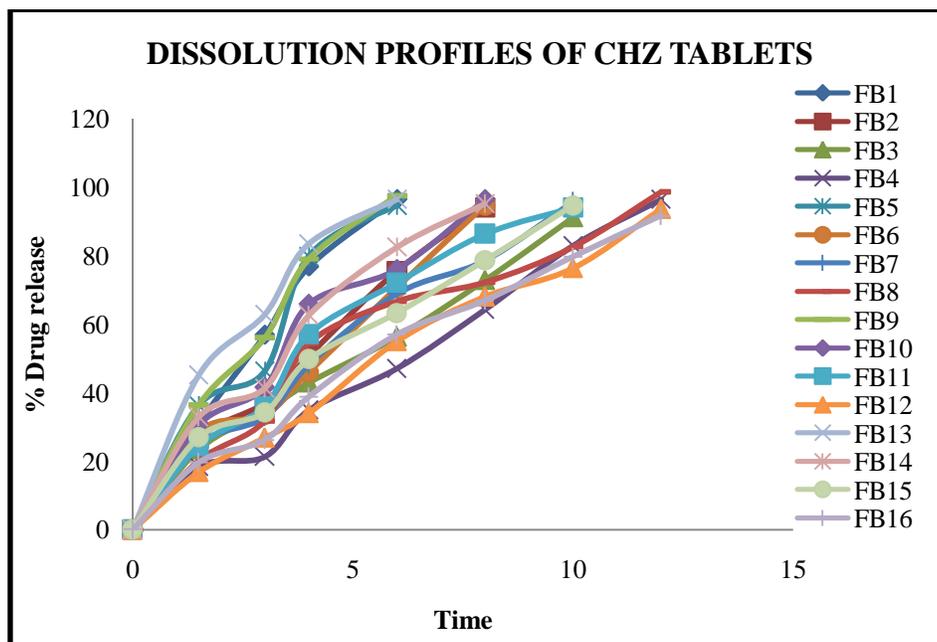


Figure 3. Dissolution profiles of formulations FB<sub>1</sub>-FB<sub>16</sub>

Table 8. Cumulative % drug released (%CDR) formulations of CHZ bi layer tablets

Time in hrs	1.5 hr	3rd hr	4th hr	6hr	8hr	10th hr	12hr
FB1	30.96	56.87	76.8	96.47	--	--	--
FB2	26.54	37.04	50.74	75.46	94.12	--	--
FB3	23.4	34.44	42.96	56.31	72.89	91.24	--
FB4	18.4	21.3	34.89	47.1	64.31	82.97	96.47
FB5	36.29	46.3	79.86	94.66	--	--	--
FB6	28.64	33.5	45.98	70.64	94.68	--	--
FB7	24.92	32.84	48.23	68.91	78.61	95.87	--
FB8	20.14	31.8	54.44	66.67	72.22	82.54	98.63
FB9	36.45	56.06	79.08	97.58	--	--	--
FB10	30.58	41.56	65.89	76.06	96.48	--	--
FB11	24.39	36.08	57.08	72.12	86.34	94.01	--
FB12	16.8	26.87	34.02	55.05	68.07	76.4	93.68
FB13	45.13	62.87	83.54	96.47	--	--	--
FB14	32.89	41.31	62.58	82.45	95.13	--	--
FB15	26.94	34.25	49.78	63.31	78.64	94.69	--
FB16	19.64	26.16	38.79	56.97	66.89	79.68	91.68

In this dissolution profile the formulation FB<sub>8</sub> was show maximum drug release within 12hours and it shows sustain of the drug release in Bilayer form. Formulation FB<sub>8</sub> contains (SR layer) HPMC k100m (18%) show better in-vitro drug release profile and the other polymers are well in drug release but they not reached in up to 12hrs.

### Stability Studies

There was no significant change in physical and chemical properties of the tablets of formulation FB<sub>8</sub> after 3 months. Parameters quantified at various time intervals were shown. (Table9) There

was no significant change in physical and chemical properties of the tablets of formulation F6 after 3 Months, parameters like % drug release and assay values at various conditions (at 40<sup>0</sup>C/ 75% RH) as per ICH guidelines quantified at various time intervals were shown in Table and dissolution profile in Table 9.

**Table 9. Results of stability studies of optimized formulation FB<sub>8</sub>**

S.NO	Parameters	Initial	1 month	2 month	3 month	Limits as per specification
1	400C/75% RH % Release	98.63	98.22	98.01	97.62	Not less than 85 %
2	400C/75% RH Assay Value	98.31	98.28	98.22	98.17	Not less than 90 % Not more than 110 %

## CONCLUSION:

Both immediate release and sustained release formulation are prepared and contain in a single dosage form. The study describes the formulation of both immediate and sustained release drug for increased therapeutic efficacy and patient convenience. The bi layer tablets were prepared by direct compression for immediate layer and wet granulation techniques for SR layer IPA as a solvent which has been tried many times for the good release behavior by taking various polymers. Suitable formulation has been optimized. In the present study an effort has been made to evaluate the drug content in the formulations against the claim kinetic study. During pre formulation it has been observed that there is no drug- drug and drug excipients interaction, so the excipients which have been selected for the formulation are compatible with the drugs. This system provides zero order or near zero order release for IR layer and SR layer provides Higuchi model. This concept also demonstrates a wide technology for various applications such as instant release/slow release from one dosage form, because It allows the precise modulation of drug release process even for drug characteristics by extreme physicochemical properties. The bi layer tablets of chlorzoxazone containing immediate release layer and sustained release layers were prepared by using different polymers. Among all the formulations FB<sub>8</sub> with the polymer HPMC K100m in the concentration of 18% had shown a prolonged sustained action up to 12 hours with the drug result of 98.84%. By this technology we reduced the dosing frequency thereby increase the patient compliance when compared to conventional dosage form.

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