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## OLIBANUM RESIN BASED AMBROXOL HYDROCHLORIDE TABLETS: FABRICATION AND *IN VITRO* EVALUATION

Y. Indira Muzib\*<sup>1</sup>, Padma Sree. Kurri<sup>1</sup> and Y.R. Ambedkar<sup>2</sup>

Institute of Pharmaceutical Technology, Sri Padmavathi Mahila University, Tirupathi – 517502, Andhra Pradesh, India

Govt. Veterinary Poly. College, Gariveedu, Vizayanagaram, Andhra Pradesh, India

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### Correspondence to Author:

**Y. Indira Muzib**

Professor in Pharmaceutical  
Technology, Institute of  
Pharmaceutica Higuchi kinetics  
 $r^2=0.92981$  Technology, Sri  
Padmavathi Mahila University,  
Tirupathi – 517502, Andhra Pradesh,  
India.


**E-mail:** yindira1415@gmail.com

**ABSTRACT:** Present era meant for utilization of natural resources in the development of dosage forms. In the present investigation natural biodegradable polymer olibanum resin is employed to develop matrix tablets of ambroxol hydrochloride for sustained release. Various Ratios of resins is study its ability to retard the early release of the drug from formulation. The tablets were prepared by wet granulation technique and were subjected for their thickness, weight variation test, drug content, hardness and friability. The *in vitro* dissolution studies were carried out using USP apparatus type II (paddle) at 100 rpm. Drug content of the formulations ranged between  $97.78 \pm 0.08$  to  $100.12$ , where as hardness varies from  $5.9-7.6 \text{ kg/cm}^2$ . From the *in vitro* release studies it was found that F5 formulation was similar to marketed sample hence it was selected as a optimized formulation. Higuchi release kinetics shows  $r^2=0.9298$ , from Korsmeyer- Peppas plot n value  $>0.89$  indicates super case II type of release indicating that the drug release from these formulations is by erosion of polymer. The optimized formulation of Ambroxol hydrochloride matrix tablets (10% w/w) were subjected to short term stability studies at  $45^\circ\text{C}$  with 75% RH for 45 days revealed that no significant differences in physical appearance, drug content, dissolution,  $T_{50}$  and  $T_{90}$  were found

**INTRODUCTION:** Nowadays researchers focused on utility of natural and biodegradable polymers, to minimize usage of synthetic materials in the preparation of pharmaceutical dosage forms. Nature provides us lot of excipients like waxes, and gums etc., Guar gum<sup>1</sup>, Olibanum gum<sup>2</sup>, gum karaya<sup>3</sup>, xanthan gum<sup>4</sup>, chitosan<sup>5</sup>, pectin<sup>6</sup>, resin<sup>7</sup> etc. in the development of controlled and sustained release formulations, colon targeted drug delivery systems<sup>8,9</sup> for a variety of therapeutic agents.

Drug embedded in an insoluble matrix provides a convenient means of controlling the drug release. In this type of system, drug release is followed by penetration of dissolution medium in to the porous matrix to dissolve the drug, followed by diffusion/leaching of the dissolved molecules out of the matrix. Previous studies shows that Olibanum [Frankincense] is an aromatic resin obtained from trees of the genus *Boswellia*, particularly *Boswellia sacra* Syn. *B.carteri*, *B.thurifera* [Burseraceae] used in aromatherapy. *Silver* and *Hojari* are generally considered the highest grades of frankincense.

In ayurvedic medicine Indian frankincense [*Boswellia serrata*] has been used for hundreds of years for treating arthritis, healing wounds, strengthening the female hormone system<sup>10</sup>.

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Ambroxol hydrochloride has secretolytic effects. It stimulates serous cells of bronchi mucous membranes, increases mucous secretion content by changing the structure of bronchial secretion. It improves breathing and suppresses cough to some extent. A short biological half-life of 4hrs<sup>11</sup> calls for a frequent daily dose of 30mg 3-4 times a day<sup>12</sup>. The aim of the present study was to design sustained release dosage form of Ambroxol to prolong clinical efficacy, minimize side effects and to reduce dosing<sup>13</sup>.

Few works has been done on natural polymer like gum olibanum and resin<sup>14, 15, 16</sup> there is no evidence that polymers like olibanum resin was used for formulating sustained release matrix tablets of Ambroxol hydrochloride. Hence trials were made to study the utility of olibanum resin in retarding the drug release for 12 hrs.

#### MATERIALS AND METHODS:

Ambroxol hydrochloride was a gift sample from Sree Sai Organics Pvt. Ltd., Kondapalli, Vijayawada. Gum Olibanum was obtained from Girijan co-operative corporation Ltd, Visakhapatnam. All other chemicals used were of analytical grade, and procured from commercial sources.

#### Analytical Method of Ambroxol Hydrochloride:

TABLE 1: COMPOSITION AMBROXOL HYDROCHLORIDE MATRIX TABLET

Batch No	Drug (mg)	Olibanum Resin	Avicel pH 101	Starch	Talc	Mg stearate	Total weight (mg)
F1	75	75	-	7.5	3	1.5	162
F2	75	112.5	-	9.5	4	2	203
F3	75	150	-	11.5	5	2.5	244
F4	75	8.5	72.9	8.5	3.4	1.7	170
F5	75	17	64.4	8.5	3.4	1.7	170
F6	75	25.5	55.9	8.5	3.4	1.7	170

\*Quantity (mg) present per each Matrix tablet

#### Evaluation of granules:

For all the formulations the prepared granules were evaluated for flow properties like angle of repose, loose bulk density, tapped bulk density, compressibility index and Hauser ratio.

Angle of repose  $\theta = \tan^{-1} [h/r]$

Loose bulk density = Weight of powder/Volume of packing.

In this investigation, UV Spectrophotometric estimation based on the measurement of extinction at 248 nm in pH 1.2 and pH 6.8 phosphate buffers were used for the estimation of Ambroxol hydrochloride.<sup>17</sup>

#### Isolation of olibanum resin from gum olibanum:

Powdered olibanum [10gm] was extracted repeatedly with 200ml quantity of solvent ether. The ether extracts were collected in a porcelain dish and concentrated to dry at 40°C to obtain resin fraction. The dried mass was powdered and size was reduced to 200 # mesh.

#### Preparation of matrix tablets<sup>18</sup>

Different tablet formulations were prepared by wet granulation technique **Table 1**. Accurately weighed quantities of pre-sieved drug and matrix material were mixed uniformly and wetted with isopropyl alcohol: water [1:1] as granulating fluid, the cohesive mass thus obtained was screened through a sieve no 16. The granules were dried at 50°C in hot air oven till constant weight was reached. The coarse granules so obtained were once again screened using the same sieve. Talc and magnesium stearate were finally added as glidant and lubricant and were compressed to tablets. Prior to compression, the granules were evaluated for various IPQC tests.

Tapped bulk density= Weight of powder/tapped volume of the packing.

Compressibility Index =  $100 \times \frac{\text{Tapped density}}{\text{Bulk density}}$

Hauser ratio =  $\frac{\text{Tapped density}}{\text{Bulk density}}$

Drug content was determined by extracting powdered granules [75mg] of Ambroxol hydrochloride with water and for the filtered [0.45- $\mu$  membrane] solution absorbance was measured at

248nm. Loss on drying and Moisture content were determined by placing 1gm of granules in an oven which was maintained at 105°C and dried up to constant weight and were calculated from the formula.

Loss on drying =  $\frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$

Moisture content =  $\frac{\text{Initial weight} - \text{Final weight}}{\text{Final weight}} \times 100$

### Physicochemical Compatibility of Drug and Polymer:

The infrared (IR) spectra were recorded using an FTIR spectrophotometer (Bruker FTIR) by the ATR method in the wavelength region between 4000 and 400cm<sup>-1</sup> for pure drug Ambroxol hydrochloride and polymer olibanum resin. The spectra obtained for drug, polymer and formulation were compared.

### Physico-chemical characterization of tablets:

The prepared matrix tablets were evaluated for hardness, weight variation, thickness, friability and drug content. Tablet hardness was determined for 5 tablets using a Monsanto tablet hardness tester. Friability was determined by taking 10 tablets in Roche friabilator. The weight variation was evaluated on 20 tablets using an electronic balance, and the test was performed according to the official method. For determining the drug content, three tablets from each formulation were crushed and powder containing 75mg of Ambroxol hydrochloride was dissolved in 75ml of phosphate buffer pH 6.8. From this 10µg/ml, equivalent solutions were prepared and drug content of Ambroxol hydrochloride was determined by measuring the absorbance of samples at 248nm using UV/Visible spectrophotometer. The swelling behavior of the optimized formulation [F5] was studied. The % increase in weight due to absorbed liquid or water uptake was estimated at each time point. The physicochemical properties of designed tablets are shown in **Table 3**.

### *In vitro* drug release & kinetic studies<sup>19, 20, 21</sup>

The *in vitro* dissolution studies were carried out using USP apparatus type II [paddle] in simulated gastric fluid [pH 1.2±0.1] for the first 2hrs and in phosphate buffer pH 6.8 from 3 to 12hrs. Rotation

speed of 100rpm at temperature of 37± 0.2°C and dissolution medium of 900ml was maintained throughout the experiment. At predetermined time intervals, 5ml of samples were withdrawn and fresh dissolution medium was replaced after each withdrawal. The samples withdrawn were filtered through 0.45µ membrane filter, and absorbance was measured spectrophotometrically at 248nm using a UV-visible spectrophotometer and cumulative percent drug release was calculated. All dissolution studies were carried out in triplicate.

The same was carried out on commercial Ambroxol SR capsules for comparative evaluation. The rate and mechanism of release of Ambroxol hydrochloride from the prepared matrix tablets were analyzed by fitting the release data in to Zero-order, First order, Higuchi's equation and Korsmeyer model. The value of n is <0.45 for fickian release, > 0.45 and < 0.89 for non-fickian release, 0.89 for the case II release and > 0.89 for super case II type release.

### CALCULATION OF SIMILARITY FACTOR [F<sub>2</sub>]<sup>22</sup>

Similarity factor was calculated for the optimized formulation [F5] with the marketed sample using the formula  $f_2 = 50 + \log \left\{ \left[ 1 + \frac{1}{n} \sum_{t=1}^n \left( \frac{R_t - T_t}{T_t} \right)^2 \right]^{0.5} \right\} \times 100$  where n is the number of dissolution sampling times, R<sub>t</sub> and T<sub>t</sub> are the individual or mean percent dissolved at each time point for the reference and test dissolution profiles respectively.

### Stability Studies:

Stability studies were conducted on Ambroxol hydrochloride matrix tablets containing 10% W/W olibanum resin to assess their stability with respect to their physical appearance, drug content and drug release characteristics after storing them at 45°C with 75% RH for 45 days.

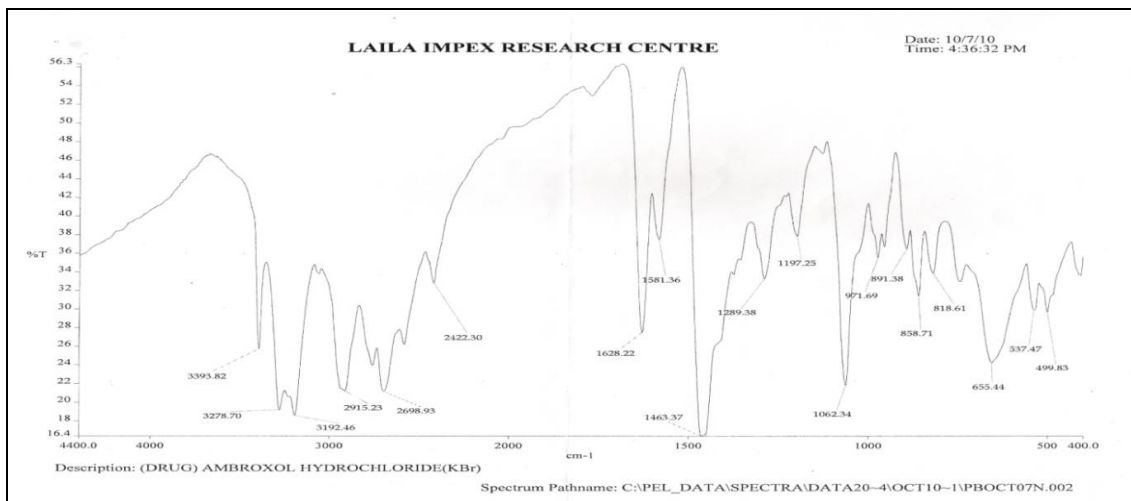
## RESULTS AND DISCUSSION:

### FTIR studies:

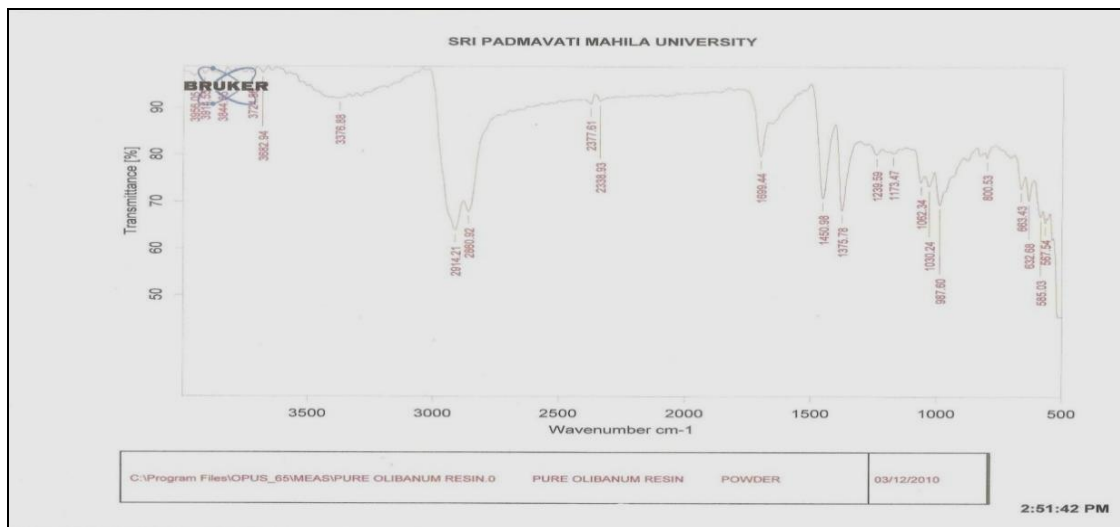
IR spectra of the pure drug and the optimized formulation F5 was compared and no interaction was observed between the drug and polymer used for the study as there is no shift of positions of the bands in both the spectra shown in **Fig.1, 2, 3**. The IR spectrum shows that both drug and polymer were not interacted each other and appear as

separate entities which is clearly shown in the spectra. Both hydroxyl and secondary amino group stretching vibration were merged to each other and therefore appear on single strong broad band at  $3393.82\text{ cm}^{-1}$  for Ambroxol pure drug. In case of

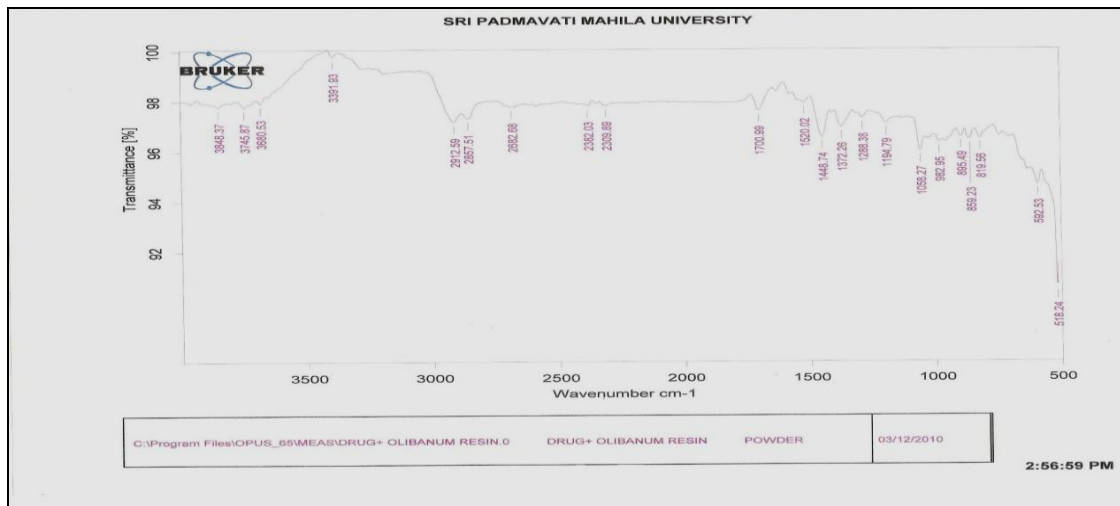
Ambroxol and secondary amine of Ambroxol vibrations were merged to each other and appear as a single broad hydrogen bonded band for F5 the peak was at  $3391.93\text{ cm}^{-1}$ .



**FIGURE .1 FTIR SPECTRA OF AMBROXOL HYDROCHLORIDE**



**FIGURE .2 FTIR SPECTRA OF OLIBANUM RESIN**



**FIG.3: FT IR SPECTRA OF F5MATRIX TABLETS**

**Physical properties of granules:**

The prepared granules were evaluated for angle of repose, loose bulk density (LBD), tapped bulk density (TBD), compressibility index (CI) and Hausner ratio given in **Table 2**. The angle of repose of all the formulations granules was found to be in

the range of 25-30° for which the flow was found to be excellent and except F1 shows the flow was good. Based on the CI, HR for the formulations F3, F4, F5 and F6 the flow was good and for F1, F2 the flow property was fair.

**TABLE 2: PHYSICAL PROPERTIES OF GRANULES FORMULATED WITH OLIBANUM RESIN\***

Batch No	Angle of Repose	LBD (g/ml)	TBD (g/ml)	CI (%)	HR	DC (%)	MC (%)	LOD (%)
F1	30.16±0.07	0.33±0.02	0.41±0.02	19.51±0.03	1.24±0.02	99.61±0.02	4.9±0.2	4.5±0.3
F2	27.67±0.05	0.33±0.03	0.39±0.04	15.38±0.01	1.18±0.03	97.78±0.03	4.4±0.7	3.9±0.5
F3	25.85±0.04	0.33±0.08	0.37±0.04	10.81±0.05	1.12±0.05	98.61±0.01	3.8±0.5	3.3±0.1
F4	27.11±0.06	0.38±0.05	0.43±0.07	11.62±0.01	1.13±0.03	100.24±0.06	4.8±0.4	4.3±0.4
F5	25.98±0.04	0.41±0.03	0.47±0.02	12.76±0.05	1.14±0.04	99.87±0.03	4.5±0.4	4.0±0.3
F6	26.35±0.02	0.45±0.08	0.51±0.05	11.76±0.04	1.13±0.06	97.42±0.08	4.1±0.3	3.7±0.2

\* All the values are expressed as mean± SD, n=5

**Physical properties of tablets:**

The compressed tablets were evaluated for physical properties like weight variation, hardness, friability

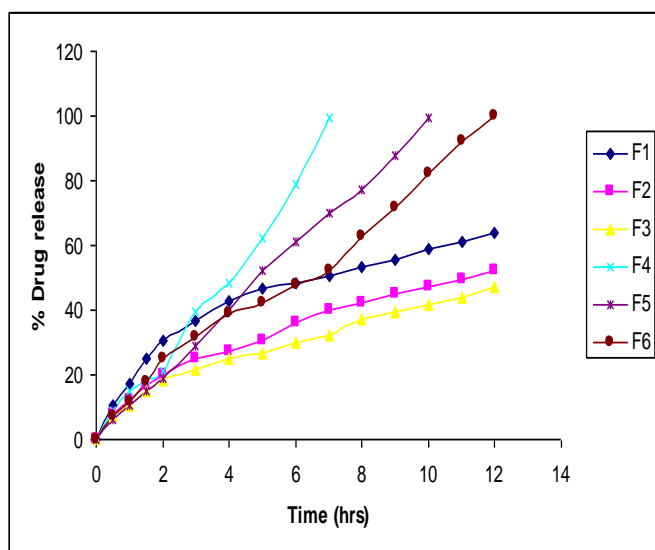
and content of active ingredient. The results obtained were within the prescribed limits. The results are tabulated in the **Table 3**.

**TABLE 3: PHYSICAL PROPERTIES OF TABLETS FORMULATED WITH OLIBANUM RESIN\***

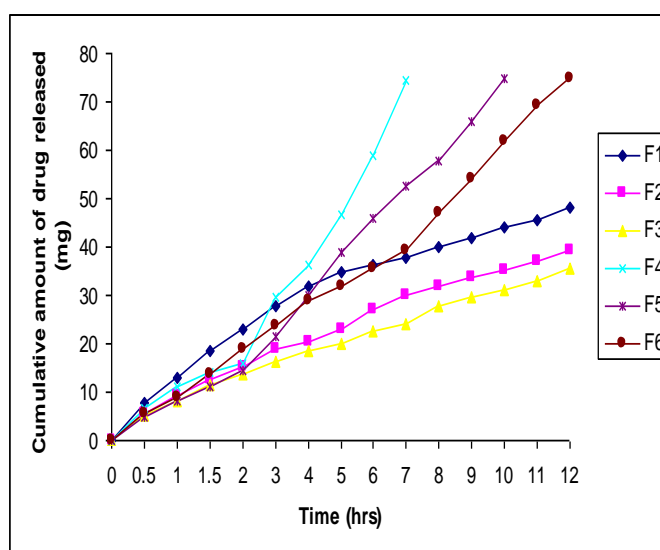
Batch No	Wt in mg	Hardness (Kg/cm <sup>2</sup> )	Thickness (mm)	Friability (%)	DC (%)
F1	160.5±0.09	5.9±0.7	2.81±0.05	0.67±0.02	98.04±0.03
F2	203.8±0.03	6.1±0.3	3.49±0.03	0.36±0.07	99.12±0.02
F3	242.6±0.08	6.5±0.5	3.91±0.08	0.59±0.09	97.78±0.08
F4	171.3±0.03	6.8±0.2	2.88±0.02	0.22±0.04	98.90±0.04
F5	168.5±0.07	7.1±0.8	2.92±0.03	0.48±0.04	99.83±0.06
F6	169.3±0.02	7.6±0.4	2.94±0.07	0.31±0.05	100.12±0.02

\*All the values are expressed as mean ±SD, n=5

**In vitro release studies:**



**FIG. 4: DISSOLUTION PROFILES OF AMBROXOL HYDROCHLORIDE MATRIX TABLETS FORMULATED WITH OLIBANUM RESIN**



**FIG. 5: ZERO ORDER PLOT OF AMBROXOL HYDROCHLORIDE MATRIX TABLETS FORMULATED WITH OLIBANUM RESIN**



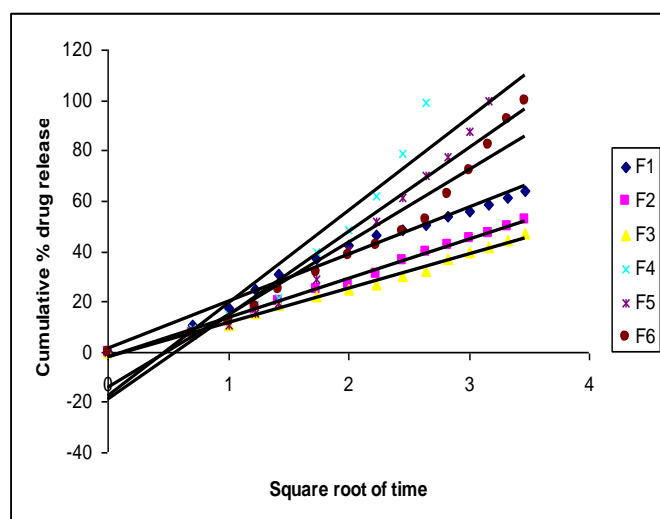


FIG. 6: HIGUCHI PLOT OF AMBROXOL HYDROCHLORIDE MATRIX TABLETS FORMULATED WITH OLIBANUM RESIN

With olibanum resin firstly 1:1, 1:1.5, 1:2 ratio's [F1, F2, F3] were formulated but even at the 12<sup>th</sup> hour the release was too low. So, a 5%, 10% and 15% resin containing formulations were prepared and conducted drug release studies. 5%, 10% resin containing formulations (F4, F5) failed to sustain the drug release till 12<sup>th</sup> hour but F5 gave a close release profile with that of MS so F5 was selected as optimized formulation. F6 with 15% resin

showed 99.86% drug release at 12<sup>th</sup> hour. The release data of matrix tablets were fitted into various mathematical models to evaluate the kinetics and mechanism of drug release from the tablets (Fig. 4, 5, 6). The model that best fits the release data is selected based on the correlation coefficient ( $r^2$ ) value in various models. The model that gives high " $r^2$ " value is considered as the best fit of the release data. The " $r^2$ " values for zero order, first order, Higuchi model and Korsmeyers-Peppas plot are given in the Table 4.

These results indicate that the drug release from the formulations F4, F5, F6 followed Zero order kinetics whereas, the formulations F1, F2, F3 followed Higuchi kinetics. Release of the drug from a matrix tablet containing hydrophilic polymers generally involves factors of diffusion. To evaluate drug release mechanism from the tablets, plots of percent released versus square root of time as per Higuchi's equation were constructed. The formulations F1, F2, F3 show better linearity for Higuchi release kinetics with ( $r^2 > 0.99$ ). It indicates that the drug release is by diffusion mechanism.

TABLE 4: RELEASE KINETICS OF AMBROXOL HYDROCHLORIDE MATRIX TABLET FORMULATED WITH OLIBANUM RESIN

Batch No	Release Model								T <sub>50</sub> (hrs)	T <sub>90</sub> (hrs)
	Zero order		First order	Higuchi		Koresmeyer-	Peppas			
	r <sup>2</sup>	k	r <sup>2</sup>	r <sup>2</sup>	k	n	r <sup>2</sup>	k		
F1	0.7967	6.4873	0.9295	0.9914	19.1424	0.5286	0.9844	18.4017	6.9	16.8
F2	0.9143	5.0529	0.9708	0.9957	14.6778	0.5888	0.9971	12.3660	11.1	20.6
F3	0.9172	4.4402	0.9669	0.9944	12.8861	0.5734	0.9961	11.1574	12.6	22.8
F4	0.9938	13.1994	0.7628	0.9044	27.8107	0.9138	0.9880	14.4074	4.1	6.3
F5	0.9993	9.9164	0.7870	0.9298	25.2422	0.9484	0.9982	10.8391	4.8	9.2
F6	0.9903	8.2601	0.7277	0.9441	23.2657	0.7909	0.9953	12.7537	6.3	10.7

The dissolution data was fitted to Korsmeyer equation which is used to describe the drug release behaviour from polymeric systems. The formulations F1, F2, F3 showed diffusion coefficient value (n) greater than 0.45 but less than 0.89 shown in the Table 4. So, it indicates Non-Fickian [anomalous] transport mechanism indicating that the drug release is by a combination of both diffusion and erosion of polymer. And the formulations F4, F5, F6 showed n value >0.89 indicates super case II type of release indicating that the drug release from these formulations is by erosion of polymer.

Similarity factor was calculated for the formulations, it was found that F5 formulation is to the release profile of marketed sample showed in the Table 5, hence it was optimized and subjected for further studies.

#### Swelling index:

The swelling index of the optimized formulation F5 was found to be 59.12%. Plastic viscosity was found to be 0.21centipoise. It was observed that there is an inverse relation for swelling index and plastic viscosity with release rate constant.

**Stability Studies:**

The optimized Ambroxol hydrochloride matrix tablets F5 were packed in amber colored screw capped bottles and subjected to short term stability

studies at 45°C with 75% RH for 45days as per ICH guidelines showed negligible change over time for the parameters like appearance, the drug release profiles, drug content, T<sub>50</sub> and T<sub>90</sub> (**Table 5**).

**TABLE 5: SIMILARITY FACTOR OF AMBROXOL HYDROCHLORIDE MATRIX TABLETS FORMULATED WITH OLIBANUM RESIN (F5) AND MS (f<sub>2</sub>=68.96)**

S.no	Time	Average % Drug release		f <sub>2</sub>	MDT(T) / MDT(R)	AUC(T) / AUC(R)
		Reference	Test			
1	0	0.000	0.000	0.000	0.000	0.000
2	0.5	6.25	6.25	100.00	1.000	1.000
3	1	13.59	10.67	85.38	0.879	0.888
4	1.5	18.72	15.06	79.69	0.955	0.837
5	2	22.69	19.16	77.57	1.017	0.833
6	3	33.35	28.70	74.64	1.022	0.844
7	4	39.79	40.07	76.12	1.158	0.883
8	5	56.02	52.08	75.05	1.020	0.911
9	6	58.78	61.18	75.44	1.128	0.933
10	7	76.42	69.97	72.23	0.972	0.943
11	8	79.39	77.28	72.82	1.036	0.943
12	9	85.35	87.87	73.19	1.089	0.955
13	10	90.35	99.51	68.96	1.150	0.974

**CONCLUSION:** The present study was to make an evaluation of sustained release matrix tablets of Ambroxol hydrochloride formulated with olibanum resin as a release retardant and to conduct the drug release kinetics to assess the drug release mechanism. From the studies it was concluded that olibanum resin successfully control the early release of drug and extends the release till 12 hours. Release of drug was followed diffusion and erosion mechanism. The %W/W of polymer plays a major role in overall release of the drug and the formulated matrix tablets with 10% olibanum resin offered comparative release profile with that of marketed sample.

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