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**Formulation, Development and Evaluation of Matrix tablets  
of Lamivudine by using Gum Rosin**

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**Abstract**

Rosin is a natural polymer was used as a hydrophobic matrix forming agent for sustained release and lamivudine used as a hydrophilic agent. The present investigation aimed at formulation, development and evaluation of natural rosin gum based sustained release matrix tablets of lamivudine by direct compression method. Various formulation was prepared with drug and polymer-polymer ratio as- Rosin [1:0.2,1:0.3,1:0.4] namely F1,F2,F3,and Ethyl cellulose [1:0.2,1:0.3,1:0.4] namely F4,F5,F6. The prepared matrix tablets were evaluated for their physicochemical properties such as Physical appearance, hardness, weight variation, friability, drug dissolution. *In vitro* drug release studies was performed by Dissolution test apparatus IP (paddle type) using phosphate buffer pH-6.8 at 100 rpm for 24 hours. Also kinetic release and stability study of tablets were studied. As a result of kinetic studies F2 formulation was optimized and results shows that its follow Higuchi model. In case of stability study of F2 formulation was kept for 60 days, the FTIR spectrum shows the bands are not interact acting with each other as compared with drug polymer mixtures. It was found that the percent drug release decreased with increasing the concentration of natural gums. Rosin has a good potential as a pharmaceutical excipients.

**Key words:** Rosin, Matrix tablet, Lamivudine

**Introduction**

Matrix tablets may be defined as the “oral solid dosage forms in which the drug or active ingredients is homogeneously dispersed throughout the hydrophilic or hydrophobic matrices which serves as release rate retardants”. The present work was related with exploitation of rosin as an excipient in drug delivery systems and focus on their formulation related to matrix dosage form. This type of formulation increase patient compliance due to reduction in frequency of dosing but they also help to reduce severity and frequency of side effects.<sup>3,2,4</sup> Present study aimed at Formulation, development and characterization of sustained release matrix tablet of lamivudine by using rosin polymer for the treatment of HIV virus and eliminate the drug wastage, reduce dose size, reducing dosing frequency and improving the patient compliance. Gum rosin which obtained from oleoresin of pine trees. Rosin, rosin derivatives used for pharmaceutical application as, sfilm-forming, microencapsulation, coating, sustained and controlled release.<sup>1</sup> HIV - human immunodeficiency virus was first clinically observed in 1981 in the United States. In 1986, HIV started in India, in Chennai.<sup>5</sup>

**Material and Methods**

**Materials:** Lamivudine (Aurobindo pharmaceutical pvt. Ltd., hydrabad), Ethyl Cellulose, Magnesium Stearate, Microcrystalline Cellulose, Talc. (all this chemicals are AR grade).

**Method:**

**Direct compression method.**

Pre weighed ingredients passed through Sieve no. 60 mesh separately and collected. Ingredients were mixed in geometrical order and thoroughly mixed in a polythene bag for 15 minutes to get a uniform mixture. Then added drug in this mixture and passed through sieve. Talc and magnesium stearate were added to the powder mixture before punching tablets. Again passed through sieve no. 60 and compressed on a 12 station tablet compression machine using 10mm round flat face punch. Each matrix tablets containing 150 mg of Lamivudine drug.

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**Table 1: Composition of tablets with different formulas**

| S.No         | F1    | F2    | F3    | F4    | F5    | F6    |
|--------------|-------|-------|-------|-------|-------|-------|
| Ratio (p/p)  | 1:0.2 | 1:0.3 | 1:0.4 | 1:0.2 | 1:0.3 | 1:0.4 |
| Drug         | 150mg | 150mg | 150mg | 150mg | 150mg | 150mg |
| Rosin        | 100mg | 100mg | 100mg | 20mg  | 30mg  | 40mg  |
| E.C          | 20mg  | 30mg  | 40mg  | 100mg | 100mg | 100mg |
| MCC          | 24mg  | 14mg  | 4mg   | 24mg  | 14mg  | 4mg   |
| Mg. Stearate | 3mg   | 3mg   | 3mg   | 3mg   | 3mg   | 3mg   |
| Talc         | 3mg   | 3mg   | 3mg   | 3mg   | 3mg   | 3mg   |

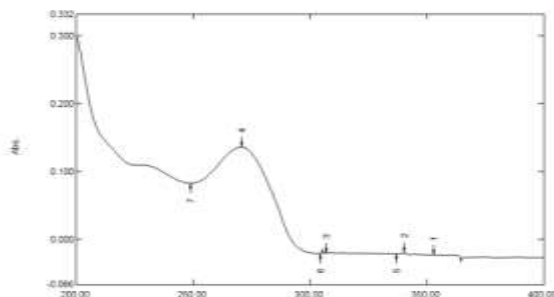
**Results and Discussion**

**Preformulation Studies of Drug and Polymer**

Preformulation studies of drug lamivudine was studied and were mentioned below. Fig 1 and Fig. 3 shown FTIR of drug and Gum rosin.



**Fig :1 FTIR Spectrum Of Lamivudine.**

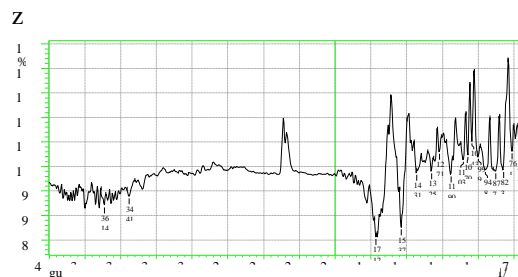


**Fig :2 UV Spectrum Of Pure Drug Lamivudine.**

Solubility= solubility of lamivudine in water (0.559) mg/ml, in ph 6.8 (0.403) mg/ml, in methanol (0.368)mg/ml, 0.1N HCL (0.552)mg/ml.Melting Point= Hot melt capillary method. Ranges between 168 -178°C.

**Polymer = Gum Rosin**

The preformulation studies of naturally obtained Gum Rosin was evaluated by FTIR, M.P, Angle of repose, Bulk density, Tapped density, Hausners ratio, Solubility as shown in below :



**Fig :3 FTIR Of Gum Rosin.**

Different Parameters.

- M.P.- 72°C-80°C.
- Angle of repose - 29-34°.
- Bulk density - 0.3-0.4 gm/cc.
- Tapped density - 1.3-1.6 gm/cc.
- Hausners ratio - 3.2-4.2.
- Solubility- Acetone and Dichloromethane.

**Compatibility study of drug and polymers**

In this study drug and polymer ratio (1:1) was carried out by FTIR spectrum of pure drug and both polymer(Rosin + Ethyl Cellulose) kept 25°C/ 45%RH for 15 days and 30 days and no changes was observed.

**Evaluation Parameters Of Matrix Tablets**

Evaluation parameter of matrix tablets of lamivudine by using gum rosin by Direct compression method for the treatment of HIV was evaluated as shown in table no. 2.

Visual Appearance - Off white in colour, Round and convex.

**Table 2: Optimized Tablets Of Different Parameters.**

| Formulation code | Hardness [kg/cm <sup>2</sup> ] | Thickness [mm] | % Weight variation | Friability [%] |
|------------------|--------------------------------|----------------|--------------------|----------------|
| F1               | 5.8                            | 5.2            | 2.402              | 0.64           |
| F2               | 5.8                            | 5.3            | 2.919              | 0.09           |
| F3               | 5.4                            | 6              | 3.176              | 0.48           |
| F4               | 5.2                            | 5.3            | 2.872              | 0.71           |
| F5               | 5.0                            | 5.2            | 2.695              | 0.58           |
| F6               | 4.7                            | 6              | 3.513              | 0.26           |

**In-Vitro Dissolution Studies**

In-vitro drug release studies were carried out for three tablets of each batches in dissolution medium. The drug release of matrix tablets at different time intervals was measured [shimadzu UV-1800] at 270 nm.

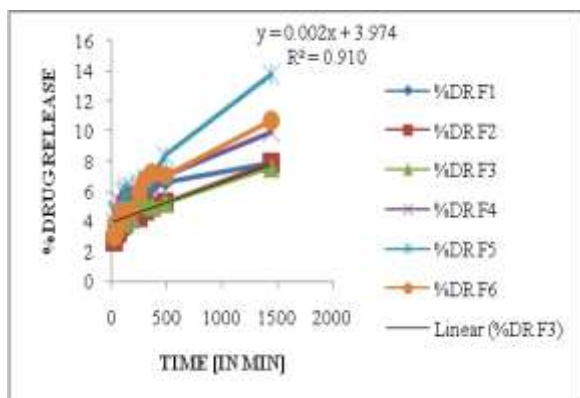


Fig :4 Combined Drug Release Of Formulated Matrix Tablets

Release Kinetic Modeling

Release kinetics was studied for three optimized formulation batches viz., F2, F3 & F6. The results were presented in table 3.

Table 3: Model Fitting Of Release Profile Of Formulated Matrix Tablets.

| Formulation | Zero order     | First order    | Higuchi        | Hixson crowell |
|-------------|----------------|----------------|----------------|----------------|
|             | R <sup>2</sup> | R <sup>2</sup> | R <sup>2</sup> | R <sup>2</sup> |
| F2          | 0.965          | 0.727          | 0.997          | 0.971          |
| F3          | 0.949          | 0.706          | 0.988          | 0.976          |
| F6          | 0.975          | 0.741          | 0.988          | 0.976          |

Among of them F2 [ROSIN 1:0.3] formulation are follow the release patten of higuchi model (%CDR V/S root time in minute). And giving a best release as compared to other formulation.

Stability Study

The optimized formulation F2 [rosin 1:0.3] was further study of stability of drug in tablets kept on at 25°C for 60 days after analysed by FTIR. Peaks of the Lamivudine indicates that no interaction occurred between drug+ excipients

Conclusion

Matrix tablets of lamivudine was successfully prepared by direct compression method. Its provide once daily sustained release, reduce dosing frequency and patient compliance. Optimized formulation F1, F2, F3, F4, F5,

F6 containing lamivudine and determination of hardness, thickness, weight variation, friability, *in-vitro* dissolution. Among of them three formulation F2, F3 and F6 are best formulation and further studied by using kinetic release models. Again among of them F2 formulation are giving best release and further studied. Stability study of matrix tablets of F2 formulation. Matrix tablets of lamivudine by using gum rosin shows good release characteristics due to rosin is a hydrophobic polymer form a matrices come into the contact of fluid and giving drug release for upto 24 hours. Present study was showed the Formulation, development and characterization of sustained release matrix tablet of lamivudine by using rosin polymer for treatment of HIV virus which in turn will eliminate drug wastage, reduce dose size, reducing dosing frequency, improving the patient compliance.

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