



# FORMULATION AND EVALUATION OF FAST DISSOLVING TABLET CONTAINING *LAGENARIA SICERARIA*

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## Abstract :

There are lots of chemical agents available to control and to treat diabetic patients, but total recovery from diabetes has not been reported up to this date. Alternative to these synthetic agents, many herbal plants with hypoglycemic properties are known from across the world. *Gymnema Sylvestre* is an herb native to the tropical forests of southern and central India and Sri Lanka. The medicinal part of the plant is the leaf, which reduces or eliminates the ability to sweetness tastes. *Gymnema sylvestre* leaves are known for several medicinal uses such as antidiabetic, hypolipidemic, stomachic, diuretic, refrigerant, astringent and tonic, the major bioactive constituents of *Gymnema sylvestre* are a group of triterpenoid glycosides known as gymnemic acids with gymnemagenin as common aglycone. which is responsible for its tremendous activity specially its blood glucose lowering capacity. In this studies we have shown that the extract of *Gymnema sylvestre* is useful in controlling blood sugar to treat type II diabetes (NIDDM) when *Gymnema* leaf extract is administered to a diabetic patient it stimulate the pancreas to increase release of insulin. In this preparation the elixir is going to prepare by the simple solution method. It is a clear, sweetened, hydroalcoholic liquid intended for oral use.

**Keywords:** *Gymnema sylvestre*, Plant, Glucose, Fast Dissolving Tablet, Diabetes, Herbal, Insulin, Hydroalcoholic.

## Introduction :-

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms.

Orally disintegrating tablets are also called as oral disperse, mouth dissolving, rapidly disintegrating, fast melt and quick dissolve system. From past decade, there has been an increased demand for more patient-friendly and compliant dosage forms. As a result, the demand for developing new technologies has been increasing day by day.

To overcome this weakness, scientist have developed innovative drug delivery system known as fast dissolving “melt in mouth” or mouth dissolve (MD) tablet. These are novel type of tablet that disintegrate dissolve / disperse in saliva.

There are two different types of dispersible tablet which have to be distinguished, one dosage form disintegrates instantaneously in the mouth, to be swallowed without the need for drinking water, while other tablet formulation can readily be disperse in water, to form dispersion, easy to ingest by the patient.

Aim of present study is formulation & evaluation of fast dissolving tablets containing *Lagenaria siceraria*

## Some Objectives of study -

1. The collection and authentication of drug.
2. To carry out extraction.
3. To study the compatibility of herbal extract with excipients using FTIR.
4. Selection of various diluents and superdisintegrants like MCC, Manitol, crosspovidone, crosscarmellose sodium and sodium starch glycolate, etc.
5. To prepare fast dissolving tablets.
6. To evaluate tablets for hardness, thickness, weight variation, friability, disintegration time, dissolution time etc.

*Lagenaria siceraria* is a medicinal herb having antihypertensive activity. Literature reveals that after oral administration of *Lagenaria siceraria* in normal food. This shows bioavailability (42%) is mainly due to disintegration and dissolution process. The efficacy of the drug may be improved by number of techniques such as complexation, salt formation, solid dispersion and by formulating/preparing into a fast dissolving tablet.

Fast dissolving tablets are formulated with an objective of improving disintegration and dissolution rate of the drug.

- To enhance the efficacy of Herbal medicine *Lagenaria siceraria* formulating as Tablet & increase the bioavailability of the drug.
- To overcome side effects of synthetic drugs there is a need for developing a Herbal novel type of dosage form for oral administration known as mouth dissolving tablets.
- Improve the patient compliance.

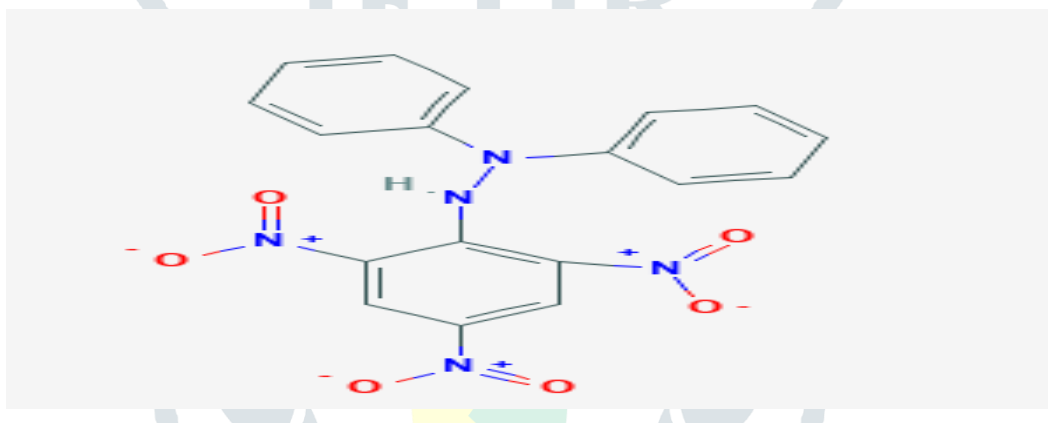
- Faster onset of action.
- Reduced the side effects.

### Drug Profile :-

**Table 1 :-** Drug Profile

Name	<b>1,1-Diphenyl-2-picrylhydrazine</b>
Molecular Weight:	395.3 g/mol
Synonyms	2,2-Diphenyl-1-picrylhydrazine
Molecular formula	C <sub>18</sub> H <sub>13</sub> N <sub>5</sub> O <sub>6</sub>
Appearance	Semisolid in nature, Brown in colour
Solubility	Practically Insoluble In Water, Freely Soluble In Ethanol & phenol
Category	cardiotonic

**Figure 1:** Structure of 1,1-Diphenyl-2-picrylhydrazine



### Materials and Method :-

**Table 2 :-** List of Excipients

Sr. No.	Material	Source
1.	Lagenaria siceraria	Lab isolation
2.	Crosscarmellose sodium	HiMedia Laboratories Ltd, Mumbai
3.	Crosspovidone	HiMedia Laboratories Ltd, Mumbai
4.	Sodium starch glycolate	HiMedia Laboratories Ltd, Mumbai
5.	Microcrystalline cellulose	Merck Specialties' limited., Mumbai
6.	Magnesium stearate	Oxford Laboratory, Mumbai.
7.	Talc	NR Chem, Mumbai.
8.	Lactose	Merck Specialties' limited., Mumbai

Table 3 :- List of Equipments

Sr.No.	Name of instrument	Model
1.	Digital balance	Shimadzu Corporation Japan.
2.	UV spectrophotometer	UV-VIS Shimadzu- 1800 Japan.
3.	pH meter	Electro lab.
4.	Fourier Transformer Infrared Spectroscopy	Perkin Elmer IR Series Model no.- 21 Spectrometer.
5.	Tablet compression machine	Rimek Minipress-II MT, Karnavati Ltd.
6.	Hardness Tester	Monsanto Hardness Tester.
7.	Thickness Tester	Vernier Calipar
8.	USP Tablet Dissolution app. Type-II.	USP Type 2, Paddle app. mod.no.40.
9.	Sieves.	Sethi Pvt Ltd.
10.	Friability Test apparatus	Roche friabilator.
11.	Sonicator	The ultrasonics PCi Analytics sonicator

## A. Preformulation study:

### 1. Isolation of *Lagenaria siceraria* active extract:

Bottle guard were purchased from local market, crushed and blended for further process. Then *Lagenaria siceraria* pulp was kept in contact with petroleum ether in a conical flask for 12 h. The flask was kept on the electrical shaker for the continuous shaking. The material was then filtered out and dried at room temperature for complete removal of petroleum ether. The blended powder was then soaked in distilled water. The swollen wet mass was then spread on a glass tray and dried at 60°C. The dried material was then passed through mesh #30. The material was winnowed and again passed through mesh #60.

### 2. Identification of active constituents:

Detection of various phytoconstituents were carried out for tannin, saponin, flavonoids, cardiac glycoside, and carbohydrates.

### 3. Standard calibration of LS extract:

Concentration of 1mg/ml standard working solution of drug was prepared in methanol. 1ml of this solution is then added to PBS 6.4 to make 10µg/ml of stock solution. By taking 2, 4, 6, 8, 10, and 12 ml of stock solution, dilutions were made with a PBS 6.4 to make concentrations of 0.2, 0.4, 0.6, 0.8, 1, and 1.2µg/ml. The absorbance of these solutions was measured at 320 nm, using UV- Visible spectrophotometer. Absorbance Vs concentration graph were plotted to obtain standard calibration curve.

#### 4. FTIR studies:

Drug excipient compatibility studies were studied by comparing graphs of FTIR in a range of 400 – 4000/nm. Graph were taken for drug alone and drug with excipients in 1:1 ratio.

#### B. Formulation of tablets:

Quantities of ingredients were taken by accurate weighing on digital balance, mixed all contents in mortar and tablets were prepared by direct compression method.

**Table 4:** Formulation table

Ingredients(mg/Tab)	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
L.S. Extract	25	25	25	25	25	25	25	25	25
Crosscarmellose sodium	2	4	6	-	-	-	-	-	-
Crosspovidone	-	-	-	2	4	6	-	-	-
Sodium starch Glycolate	-	-	-	-	-	-	2	4	6
Micro Crystalline cellulose	91	89	87	91	89	87	91	89	87
Magnesium stearate	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1
Total wt (in mg)	120	120	120	120	120	120	120	120	120

#### C. Evaluation :

##### a) Hardness

The hardness of the tablets is an indication of its strength measuring the force required to break the tablet across tests it. The force is measured in kg and hardness of about 3-5kg/cm<sup>2</sup> is considered to be satisfactory for uncoated tablets. Hardness of ten tablets from each formulation was determined by using mansanto hardness tester.

##### b) Thickness

Thickness of the tablets is determined by using vernier calliper.

**c) Diameter**

The diameter of the tablets is determined by using vernier calliper.

**d) Drug content**

Five tablets from each batch are weighed and powdered, 10mg equivalent of the powder is taken and diluted with 10ml of PBS 6.4 and the volume is made up to 100 ml. From this 10ml of the solution is taken and the volume is made up to 100ml with PBS 6.4. The absorbance of the solution is measured using UV-Spectrophotometer at 320 nm.

**e) Weight variation test**

Twenty tablets are taken and their weight is determined individually and collectively on a digital weighing balance the average weight of one tablet is determined from the collective weight

**Table 5:** USP specification for the uniformity of weight

Sr.no.	Average weight (mg)	Maximum % difference Allowed
1	130 or less	10 %
2	130-324 mg	7.5 %
3	More than 324 mg	5 %

**f) Friability**

Friability is the loss of weight of tablet in the container due to removal of particles from surface. Friability test is carried out to access the ability of the tablet to withstand abrasion in packaging, handling and transport. Roche friabilator is employed for finding the friability of tablets. 20 tablets from each formulation are employed for finding the friability of tablets. The tablets are weighed and placed in roche friabilator. That is rotated at 25 rpm for 4 min. The tablets are dusted and weighed again. The percentage of weight loss is calculated again using the formula.

$$\text{Percentage friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \times 100$$

**g) Disintegration test**

The disintegration test is performed using an USP disintegration apparatus with distilled water at  $27 \pm 0.5^\circ\text{C}$ . the time reported to obtain complete disintegration of 6 tablets are recorded and average is reported.

**h) Dissolution Studies**

The release rate of the formulated LS extract tablets are characterized using USP type 2 (Paddle) at 50 rpm, 900ml of distilled water is used as dissolution medium. 10ml of samples are withdrawn from the dissolution medium and replace with 10ml of fresh media. The samples are withdrawn at 5,10,15,30 and 45 mins, and

analysed using UV-Spectrophotometer. Results of the dissolution rate are recorded

**i) Stability study**

Stability studies were conducted as per ICH guidelines at  $45 \pm 2^\circ\text{C}$  temperature and  $75 \pm 5\%$  RH.

**Result :-**

**FORMULATION DEVELOPMENT STUDIES:**

**1. Identification of active constituents:**

Detection of various phytoconstituents was carried out for tannin, saponin, flavonoids, cardiac glycoside, and carbohydrates.

**Table 6:** Identification of active constituents

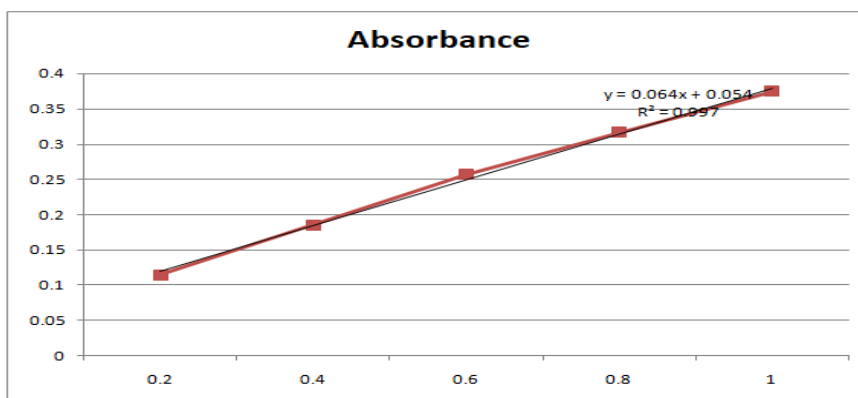
Test	Observation
Saponins	+++
Tannin	-
Flavonoids	-
Cardiac Glycosides	+++
Carbohydrate	+++

**2. Standard calibration curve of drug in UV spectrophotometer at pH 7.4**

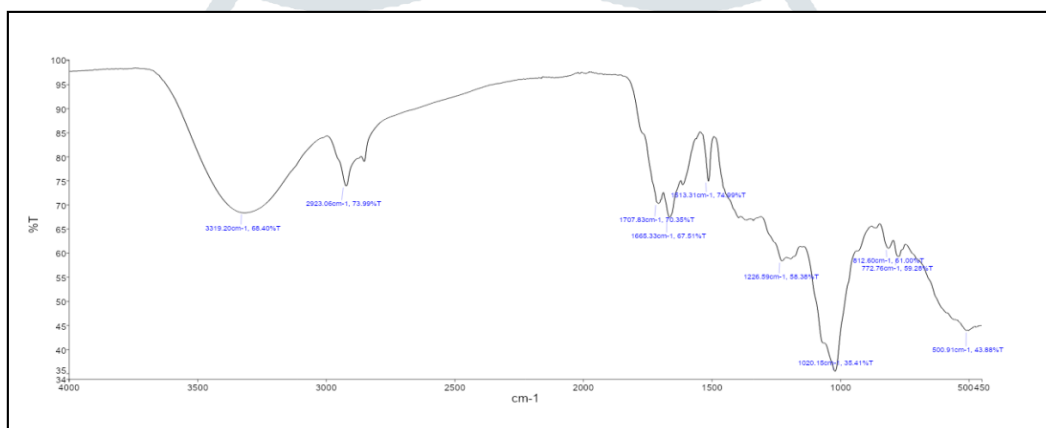
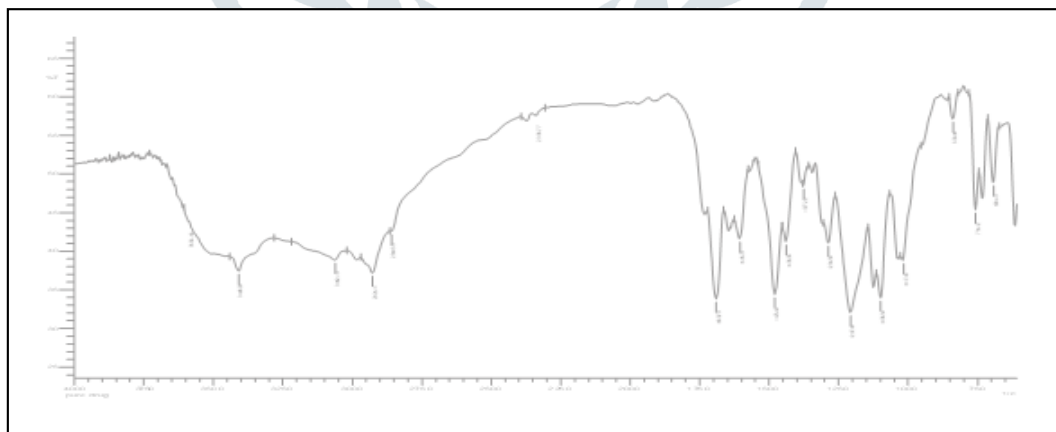
The UV absorbance's of drug standard solutions in the range of 0.2-1.0  $\mu\text{g/ml}$  of drug in buffer pH 6.4 showed linearity at  $\lambda$  max 320 nm. The linearity was plotted for absorbance (A) against concentration (C) with  $R^2$  value 0.997 and with the slope equation  $y=0.064x + 0.054$ . The absorbance values and standard curve were in below figure.

**Table 6:-** Absorbance values of drug at 320 nm

Sr. No.	Concentration ( $\mu\text{g/ml}$ )	Absorbance at 320 nm
1.	0.2	0.115
2.	0.4	0.185
3.	0.6	0.257
4.	0.8	0.316
5.	1.0	0.374

**Figure 2: Calibration curve of drug**

### 3. FTIR Studies of Drug and Excipients

**Figure 3: FTIR Studies of Drug****Figure 4: FTIR Studies of Drug & Excipients**

There was no difference in FTIR spectra. It was observed that the drug remained intact in the presence of superdisintegrants.

#### POST FORMULATION STUDIES:

The tablets obtained after compression were evaluated on various parameters to determine their quality and to ensure that the resultant product meets all necessary criteria's required for the fast dissolving tablets.



**Table 7:** Tablet evaluation results

Formulation code	Hardness (kg/cm <sup>2</sup> )	Friability (%)	Weight variation (mg)	Thickness (mm)	Disintegration time (Sec)	Content uniformity/ drug content (%)
F1	4.5±0.35	0.73±0.3	120.10±0.6	3.1±0.15	45±7.21	94.02±0.90
F2	5.2±0.20	0.70±0.6	122.16±0.3	3.2±0.20	38±4.10	95.21±0.11
F3	5.6±0.18	0.81±0.6	117.20±0.6	2.9±0.20	32±2.21	95.20±0.16
F4	4.5±0.26	0.74±0.6	119.14±0.5	3.0±0.10	47±6.50	94.15±0.18
F5	5.3±0.25	0.76±0.3	121.13±0.2	3.5±0.30	41±4.52	93.05±0.20
F6	4.3±0.40	0.85±0.4	119.12±0.1	3.1±0.21	29±1.20	96.16±0.15
F7	4.4±0.19	0.77±0.4	122.12±0.3	2.8±0.25	48±8.30	92.10±0.18
F8	5.9±0.26	0.73±0.5	120.11±0.2	3.2±0.15	44±3.20	96.05±0.10
F9	4.2±0.20	0.78±0.5	118.40±0.3	3.2±0.40	38±2.21	94.12±0.12

Results obtained shows that minimum disintegration time required is 29 sec for F6 batch having drug content of 96.16 %. Hence F6 is considered to be optimized batch.

#### 4. % Drug release

**Table 8:** % Drug release

Time (min)	% Drug release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	32.48	32.70	41.04	32.48	32.70	36.21	17.12	30.51	35.56
4	42.58	46.75	57.29	42.58	43.24	54.43	30.29	41.04	51.36
6	53.77	60.58	68.48	52.90	55.31	65.41	40.38	53.99	62.99
8	62.99	76.60	79.68	62.34	68.48	81.43	58.17	64.53	75.73
10	71.56	87.36	95.26	70.02	80.56	92.41	68.48	75.73	90.43

#### 5. Stability studies:

Formulation F6 was selected for stability study because it gives faster drug release (92.41 %) from the tablet and has less disintegration time (29sec) as compared to other formulations. The formulations were evaluated for disintegration time, hardness, friability, and In-Vitro drug release.

**Table 9:** Stability studies

Parameter	Initial	After 21 day
Shape	Round	No Change
Colour	Faint brown	No Change
Hardness (kg/cm <sup>2</sup> )	4.3	No Change
Friability (%w/w)	0.85	No Change
Weight variation	119.12	No Change
Disintegration time	29 sec	30 sec
% Drug Release	92.41%	89.27%

**Conclusion :-**

Development of *Gymnema sylvestre* leaf extract elixir is a suitable drug delivery method to increase bioavailability. → Different formulations of *Gymnema sylvestre* leaf extract elixirs evaluation parameters results were observed, F7 & F8 formulation was found to be the best formulation as antidiabetic activity in alloxan induced diabetes in rat. → *Gymnema sylvestre* leaf extract formulation of FTIR studies concluded that there was no interaction between drug and excipients. → Glycerin has been used as viscosity building agent. Sodium saccharin used as sweetening agent. → Methyl paraben, Propyl paraben has been used as preservative while orange syrup flavour used as flavouring agent. → The FTIR studies revealed that, the formulated product is a mixture of drug and the polymers used but not the reaction product with the excipients used. → It appeared in this study that when *Gymnema sylvestre* leaf extract is administered in appropriate dosage form to a diabetic patient it stimulates the pancreas to increase release of insulin.

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to increase release of insulin. Multiple mechanisms mediated by many active principles in gymnema sylvestre extract may be responsible to stimulate the pancreas to increase release of insulin. The major bioactive constituents of gymnema sylvestre are a group of triterpenoid glycosides known as gymnemic acids with gymnemagenin as common aglycone. Purified gymnemic acids have been reported as antihyperglycemic, normoglycemic and antihyperlipidemic in studies. Gymnema leaves contain active compounds like Gymnemic acid, Gymnemagenin, Gymnestogenin, Gurmarin, etc. The atomic arrangement of gymnemic acid molecules is similar to that of glucose molecules. These molecules fill the receptor locations on the taste buds thereby preventing its activation by sugar molecules present in the food. This prevents craving for sugar. Similarly, Gymnemic acid molecules fill the receptor location in the absorptive external layers of the intestine thereby preventing the sugar molecules absorption, which results in low blood sugar

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