Formulation And Evaluation OF Anti-Diabetic Injectable of Gymnema Sylvestre (Gurmar)

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***Abstract*—Gymnema Sylvestre R. Br. (Asclepiadaceae) is a herb distributed throughout the world. The leaves of the plant are widely used for the treatment of diabetes and as a diuretic in Indian proprietary medicines. Gymnemic acid is the main active chemical constituent isolated from the Gymnema Sylvestre plant. The plant is documented to possess beneficial effects as digestive, anti-inflammatory, diuretic, hypoglycemic and antihelmentic. It is believed to be used in dyspepsia, constipation, jaundice, haemorrhoids, cardiopathy, asthma, bronchitis and leucoderma.Gymnema sylvestre formulation having in the form of Tablets, Capsules, Tinctures, Powders and Teas. The Triterpenoids Saponins, Gymnemic Acids, are responsible for therapeutic benefit of the plant. However Poor solubility and low bioavailability affect efficacy of the G. Sylvestre. So, the formulation development may be a better option for improvement in pharmacodynamics and pharmacokinetics profile of the medicinal plant leading to enhanced bioavailability, therapeutic efficiency with dose reduction. the research contributes to formulation aspects of G. Sylvestre**

I INTRODUCTION

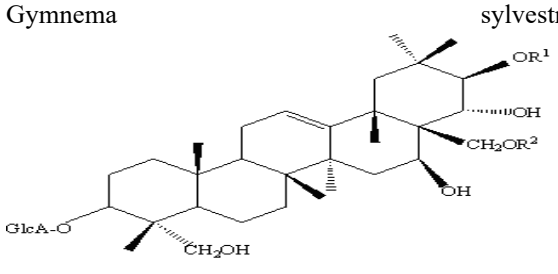
Gymnema Sylvestre R.Br. Is widely used indigenous medicinal plant of India belonging to family Asclepiadaceae. it is commonly known as madhunashini in Sanskrit and also as gurmar,"meaning sugar (madhu/Gur) destroying (nashini /mar)"The plant posseses antisachrogenic property, it temporally suppresses response to sweet taste of sugar. The leaf and root extract as well as traditional formulation of gymnema are used bronchial asthama, cough, skin disease and in wound healing.

It shows anti-diabetic Activity through different mechanisms. The Gymnemic Acid exhibit of pharmacological activity, it delays glucose absorption, it stimulates Insuline secretion it is also used in obesity. The low molecular weight and high molecular weight components of G.Sylvestre extract demonstrated stimulatory effect on β-cell of langerhans by elevating plasma insulin and C-peptide levels. The experimental animal studies of Gymnema have demonstrated reversal of heamoglobin and glycosylation of protein. Gymnemic acid suppress taste sensitivity as it bound to receptor on taste buds and prevent its activation by sugars.

According to the International Diabetic federation, the world diabetic population may raise over 350 million by 2030. it has been reported that popular aqueous solubility and relatively low bioavailability limit pharmacological application of Gymnema.

The leaves of G.Sylvestre have been found to cause hypoglycemia in laboratory animal and shown a use in herbal medicines to treat diabetes mellitus in adult. When leaf extract of plant, administered to a diabetic patient, there is stimulation of the pancreas by virtue of which there is an increase in insulin release. These compounds have also been found to increase fecal excretion of cholesterol. There are some possible mechanism by which the leaves exract of G.Sylvestre possess its hypoglycemic acid effects are: 1)It promotes regeneration of islet cells, 2)It increase secretion of insulin, 3)it cause inhibition of glucose absorption from intestine, 4)It increase utilization of glucose as it increase the activities of enzymes responsible for utilization of glucose by insulin dependent pathways, an increase in phosphorylase activity, decrease in gluconeogenic enzymes and sorbitol dehydrogenase.

In this Research in which the formulation with Gymnema sylvestre.



Gymnemic acid

Properties	Observation
Source	Found In Gymnema Sylvestre
Colour	Light to Dark Green
Odour	Characteristic odour
Taste	Bitter and Astringent Taste
Texture	It Is the Powder

II METHODS:

Preparation of formulation:
The composition of formulation is shown in Table 1. the active ingredient of powder is extracted throughout the petroleum ether, methanol, 1%KOH (Potassium hydroxide). the ingredient was weighed and mixed in a geometric order. The final formulation is obtained with proper filling and sealing. The composition of different formulations is shown in table 1.

Evaluation of formulation:
The phenolic test, steroid test, Glycoside test, sterility test, leaker test, microscopic particle count test, visual inspection we used to evaluate the gymnema sylvestre.

Phenolic test: In which test is performed for the evaluation of gymnemic acid. That gymnemic acid add 2ml of methanol and 1% alcoholic ferric chloride. Then shows the brown colour their test is positive.

Test	Observation
Gymnemic acid add 2ml methanol and 1%alcoholic ferric chloride	Brown Colour

Steroid test: In which test is performed for the evaluation of gymnemic acid. That gymnemic acid add 2ml of $CHCL_3$(chloroform). after that add 1ml of acetic anhydride. And add 2-3 drops of H_2SO_4(Sulfuric acid). then shows the Brown colour to pass the test.

Test	Observation
Gymnemic acid add 2ml $CHCL_3$ and 1ml acetic anhydride and H_2SO_4	Brown Colour

Glycoside test: In which test is performed for the evaluation of gymnemic acid. That gymnemic acid are add into 2ml of methanol, after add 1ml of alpha naphthol alcoholic solution.they shows the brownish or yellow colour for pass the test.

Test	Observation
Gymnemic Acid Add 2ml methanol, 1ml of Alpha Naphthol Alcoholic solution	Brownish or yellow colour

Leakage test: This test is performed only for Ampoules which have been sealed by fusion to ensure that there should not be any leakage in them. Vials and bottles not subjected to this test because of flexibility of Rubber.
There are two methods for the identification of leaks in parenterals they are -
1) methylene blue dye test.
2) Spark test.

Test	Observation
Ampule place at baseline of Floor then dropwise addition of Methylene blue solution	No Lekage

Methylene Blue Dye Test:the Ampoules are immersed in vacuume chamber consisting of 1% methylene blue solution.A vacuume of about 27-inch Hg is created for about 15 -30 min. These causes the solution to entered the Ampoules with defective sealing. The vaccume is released and Ampoules are observed. If a leakage is present the solution in the Ampoules appear blue colour.

Visual Inspection: This standard operating procedure outlines the step for testing the clarity of Ampoules using an Ampoule clarity test apparatus. which

involves placing Ampoules in a holder,rotating them in front of a black and white background to check for particles,and sorting them as acceptable or defective based on the result.
Dark Background - Light Particles.
Light Background - Dark Particles.

Microscopic Particle count test: This test is performed to calculating the particles. The sample is filtered through a membrane filter under ultra clean condition. Placed under a suitable binocular microscope. Count the number of particles that are equal to or greater than 10µm and the number of particles that are equal to or greater than 25µm.

Test	Observation
A small piece of filter paper. Put a drop of formulation on it then observe under a microscope	Particle size found to 25 µm

III RESULTS AND DISCUSSION:

The physicochemical properties of the injectable formulation were found to be within the acceptable limits. These Result showed a significant decrease in blood sugar levels.the toxicity studies revealed that the formulation was safe and well-tolerated.

Evaluation of gymnemic acid: - This test is performed for the evaluation of gymnemic acid as phenolic test, steroid test, glycoside test, TLC.

Test	Observation	Result
Phenolic test	Brown colour	Pass
Steroid test	Brown colour	pass
Glycoside test	Yellow colour	Pass

Evaluation of parentral: These tests are performed for parentral formulation that is sterility test, leaker test, microscopic particle count test, Visual inspection, etc.

Test	Observation	Result
Leaker test	No Entered	pass
Microscopic particle count test	Particle found to 25µm	pass
Visual inspection	Clear solution	pass

The parentral formulation of anti-Diabetics are most effective that the activated to the pancrease to secretion of Insuline. That are shown the Anti-Diabetics activity at safe and well- tolerated. It showed a significant decrease in blood sugar levels.Gymnemic Acids are responsible for therapeutic benefit of the plant. However Poor solubility and low bioavailability affect efficacy of the G. Sylvestre. There is given to the Intra-venous (IV) at 45^0 and 90^0. These shown the high effect and the effect of Anti-Diabetics.

Composition	Quantity	Uses
Gymnemic Acid	2gm	Active Ingredient
Polysorbate -20 (Propylene glycol)	0.1gm	Surfactant
Benzyl Alcohol	0.1gm	Preservative
Sodium Hydroxide or Hydrochloric Acid	Q.S.	PH Adjuster
Water	Q.S. Upto 20 ml	Solvent

Table No. 1

IV CONCLUSION:

The study demonstrated the successful formulation and evaluation of an antidiabetic Injectable of Gymnema Sylvestre. The result suggest that the Injectable Formulation has Potential as a Treatment for Diabetics.

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