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Formulation And Evaluation Of Herbal Capsules (Lycopene) For Antidiabetic

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ABSTRACT: A firm gelatin capsule containing the antidiabetic medication lycopene was developed for the current trial with the goals of improving patient compliance, increasing therapeutic efficacy, and achieving quick drug release from the dose form. The ability to release drugs quickly, formulation flexibility, and the ability of sealed hard gelatin capsules to effectively block atmospheric oxygen are all benefits of using hard gelatin capsules. The main goal of this effort is to extract lycopene from a hard gelatin capsule and provide an instantaneous release action of the medication. Methanol, carbon tetrachloride, benzene, and boiling methanol were among the extraction techniques used to create the formulations. For the dissolution tests, the formulations were then put into empty hard gelatin capsules. The prepared granules were assessed for Hausner's ratio, Carr's index, bulk density, tapped density, angle of repose, and % yield.

***Keywords*:** Introduction, Extraction, Formulation and Evaluation Bioavailability, Usage.

I. **INTRODUCTION:** The latest advancements in antioxidant science have raised the significance of natural antioxidants for human health. Natural antioxidants have helped many communities all over the world by curing a variety of illnesses and enhancing human health. Cardiovascular diseases are among the many pathological problems that are thought to be largely caused by an unhealthy diet. Proinflammatory conditions, increased reactive oxygen species generation, and abnormal plasma lipid levels are the main causes of cardiovascular disorders. There are numerous natural compounds that lower the risk of disease and protect the heart. Because they offer cardiac protection, antioxidants are among the most crucial chemicals in the prevention of cardiovascular illnesses.Plant and plant-based extracts are used for medicinal purposes such as prevention of diseases because the protection system in plants

prevents various stress damages of active oxygen Plants repair their cells and genetic materials such as radical scavenging compounds (ascorbic acid, carotenoids, and synthesized components) by means of antioxidant enzymes (super oxide dismutase, catalase, and peroxidase). Inhibiting the oxidation of other molecules is the capability of antioxidants. These natural compounds are typically reducing agents such as polyphenols, thiols, carotenoids, and ascorbic acid. Consequently, most effective plants and herbs against oxidative stress have been researched for their importance on human health. The chemical diversity that drives the pharmaceutical industry has been derived from natural products for centuries. Chemical existences resulting from the living creatures such as microorganisms, Plants and marine life are "natural products."

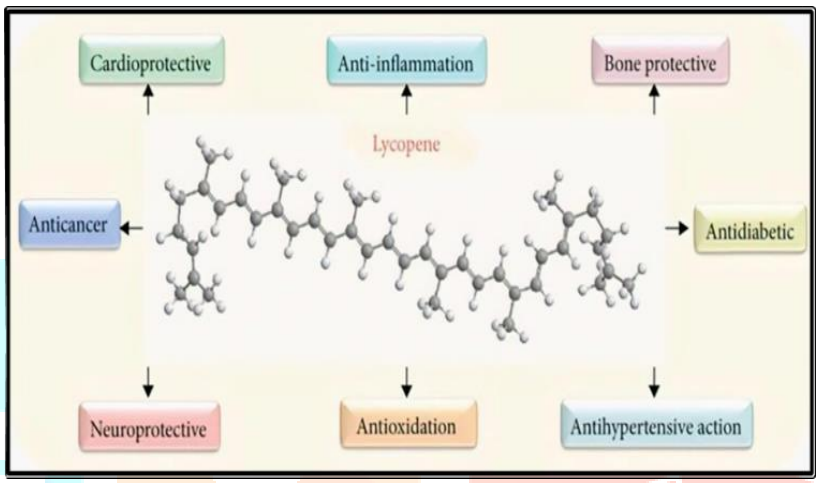

Fig.1. Biological Activities of Lycopene

II.MATERIAL REQUIRED:

The majority of the ingredients needed to extract lycopene from tomatoes are readily available in chemical labs or local shops. A list of the necessary components and materials for the procedure is provided below, along with an explanation of their functions**:**

1. **Fresh Tomatoes:**
   - **Explanation:** The main source of lycopene is fresh, ripe tomatoes. Since the skin of the tomato contains high levels of lycopene, it is best to choose red tomatoes that are fully ripened for the best extraction results.

2. **Solvents (Acetone, Ethanol, Hexane, or Petroleum Ether):**
   - **Explanation:** In order to extract lycopene from tomato tissue, solvents are essential. Because they can dissolve lycopene and break down cell membranes, acetone and ethanol are frequently used. Further purification can also be achieved using hexane or petroleum ether because lycopene is non-polar and readily dissolves in non-polar solvents.

3. **Glassware (Beakers, Separatory Funnel, Flasks):**
   - **Explanation:** The various stages of the extraction process must be mixed, extracted, and separated using standard laboratory glassware, such as beakers, separatory funnels, and flasks.

4. **Heating Source (Water Bath or Heating Mantle):**
   - **Explanation:** The tomato pulp or solvent mixture is gradually heated in a heating source, such as a water bath, to aid in the extraction process. This promotes improved solvent penetration and aids in the breakdown of tomato tissue**.**

III. Procedure of Lycopene Extraction from Tomatoe's:

To effectively separate this important antioxidant, lycopene must be extracted from tomatoes using a number of methods. Here is a streamlined method for extracting lycopene in a lab setting using readily available ingredients**.**

Step 1: Preparation of Tomato Pulp:

1**. Choose Fresh Ripe Tomatoes**: Since ripe red tomatoes contain the most lycopene, choose them.
2. **Cleaning:** To get rid of any dirt or pesticides, give the tomatoes a good rinse.
3. **Chopping**: Use a knife or food processor to chop the tomatoes into tiny pieces. This facilitates the extraction process by breaking the skin.
4. **Crushing**: Pulverize the diced tomatoes into a smooth puree using a mortar and pestle. If not accessible, a food processor or blender can be used to get a pulp-like consistency**.**

Step 2: Extraction with Solvent:

Reagents:

1. Methanol 2. Carbon tetrachloride 3. Benzene 4. Boiling methanol

65 milliliters of methanol were added to 50 grams of tomato paste to dehydrate it. To stop hard lumps from forming, this mixture was shook vigorously right away. The viscous suspension was filtered after two hours. The dark red cake was separated by filtering after being agitated for a further fifteen minutes with a 75 ml combination of carbon tetrachloride and methanol of equal volume. After moving to a separating funnel, the carbon tetrachloride phase added one volume of water and well shaken. The carbon tetrachloride phase had evaporated during phase separation, and the residual was diluted with around two milliliters of benzene. When 1 ml of boiling methanol was added in portions using a dropper, crude lycopene crystals formed right away, and the liquid was kept at that temperature to ensure full crystallization. in an ice bath and at ambient temperature, respectively.

Step 3: Purification of Extract:

filtering: To leave the pure lycopene extract in the organic solvent, pass the combination through a filtering apparatus to eliminate the drying agent and any solid contaminants.

Step 4: Lycopene Concentration: Elimination of Solvent:

Let the solvent evaporate until a concentrated extract of lycopene is produced. Depending on the solvent volume and temperature, this should take between thirty and sixty minutes.

Step 5: Evaporation of Solvent:

Use a heating mantle or a water bath to gradually heat the organic solvent (hexane or petroleum ether) in order to concentrate the lycopene extract. Make sure the temperature doesn't go above 40°C to stop lycopene from degrading.

Step 6: Storage of Lycopene:

1. Storage: To avoid deterioration from light and oxygen, the finished lycopene extract should be kept in low temperatures (ideally in the refrigerator) in dark, airtight containers.

Fig.2: Crushing Tomato

Fig.3. Extraction With Solvent

Fig.4. Filtration Of Extract

Fig.5. Solvent Removal

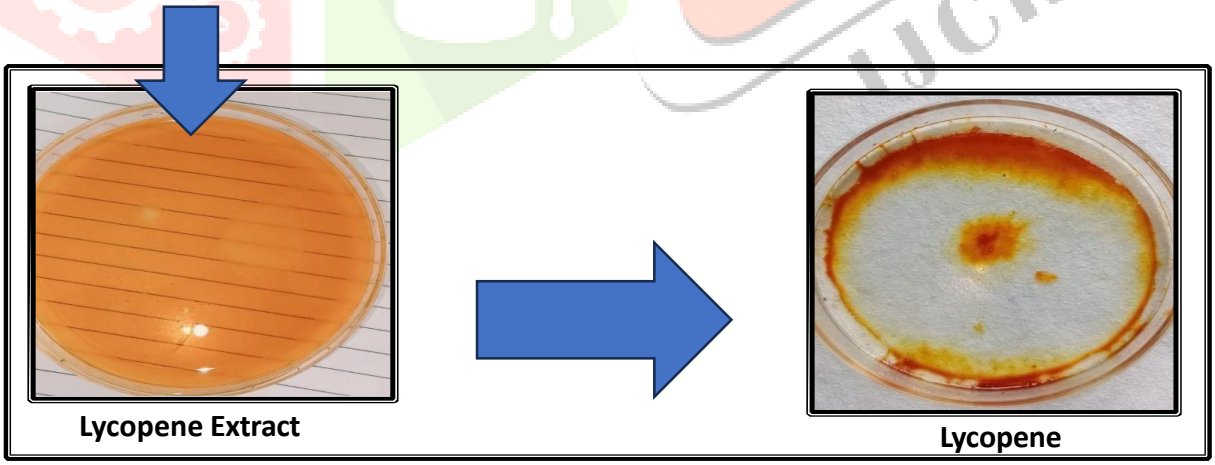

Fig.6. Evaporation Of Solvent

Fig.8. Lycopene Capsules

Fig.7. Lycopene Powder

IV.Formulation of capsule:

A hand-operated capsule filling machine was used to put the prepared granules into hard gelatin capsules (size 0), with each capsule holding 1000 mg of granules. The components of the capsules are listed in the table. Lycopene capsules without sodium starch glycolate (SSG) were labeled F1, and capsules with 2%, 3%, and 5% SSG were labeled F2, F3, and F4, respectively.

Sr. No.	Ingredients	Quantity of capsule			
		F1	F2	F3	F4
1	Lycopene Extract	500	500	500	500
2	Lactose Monohydrate	340	320	310	290
3	Starch powder (10%)	100	100	100	100
4	Magnesium sterate	30	30	30	30
5	Sodium starch glycolate	-	20	30	50

VPROCEDURE:

1] Prior to formulation:

ascertain the size of the capsule (typically 0 or 00). Determine how much lycopene and excipients are needed for each capsule.

2] Mixing and Weighing:

Weigh the lycopene that is needed. Weigh the proper amounts of lubricant, glidant, and diluent. To ensure consistency, run all powders through filter #60. In a mortar, thoroughly combine lycopene and diluent.

3] Preparing the capsules :

involves cleaning and separating the hard gelatin capsules into bodies and caps. Place the capsule bodies into the capsule punching machine's lower section. Using a spatula and spreader, pour the lycopene mixture into the capsule bodies. Evenly level the powder.

4] Sealing the capsules:

cover the filled bodies with the capsule caps. To lock the capsules, press with the top of the capsule punching machine. Gather the capsules that are filled.

Fig.9. Lycopene Capsules

VI. Evaluation Parameters:

1. Dissolution test:

2. The degree and pace at which a solution forms from a dosage form—such as a pill, capsule, ointment, etc.—is measured by dissolution testing. A drug's bioavailability and therapeutic efficacy depend on how well it dissolves. The terms "drug release" and "dissolution" are interchangeable.

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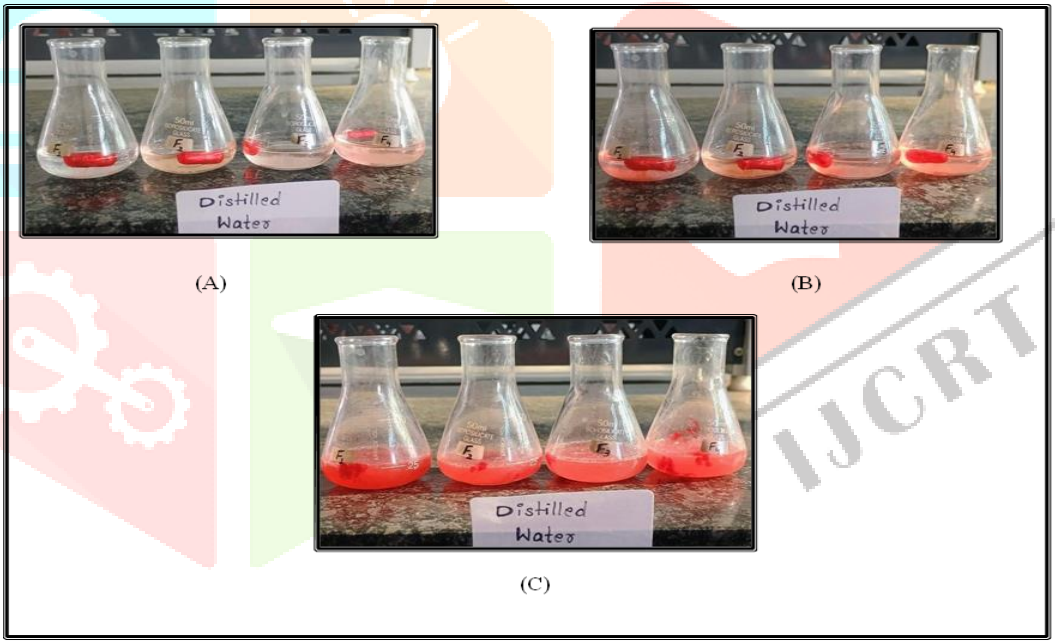


Fig.10. Dissolution Test

3. Angle of Repose:

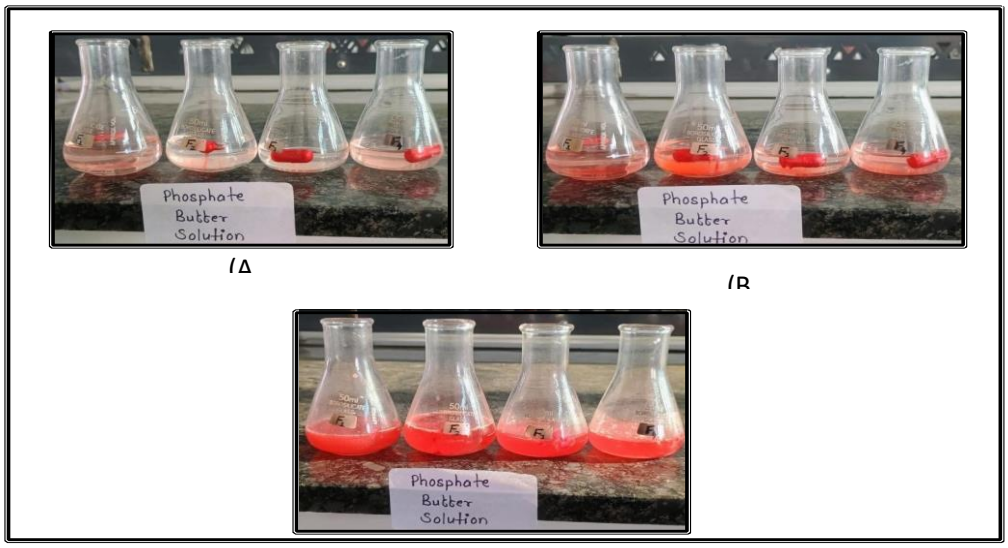
The funnel method was used to calculate the angle of repose (α). A vertically adjustable funnel was used to pour the mixture until the desired maximum cone height (h) was reached. The angle of repose was computed and the heap's radius (r) was measured:

$$\alpha = \tan^{-1}(h/r)$$

4. Disintegetion test:

Using phosphate buffer solution 6.8 pH (simulated saliva fluid) and assembly at 37"C±0.5 °C as disintegration media, the disintegration test was conducted under specific conditions for four randomly chosen capsules (F1, F2, F3, and F4) to break down into particles.

Fig.11. Disintegration Test



5. Bulk Density:

By putting the mix of presieved medication excipients into a graduated cylinder and measuring the volume (Vb) and weight (M) "as it is," the apparent bulk density (ρb) was ascertained**.**

$$\rho b = M/Vb$$

6. Tapped Density:

For a predetermined number of taps, the measuring cylinder with a known mass of mix was tapped. The blend's weight (M) and minimum volume (Vt) in the cylinder were measured. The following formula was used to compute the tapped density (ρt).

$$\rho t = M/ Vt$$

7. Hausner's Ratio:

Hausner's ratio is an index of ease of powder flow; it is calculated by following formula:

$$\text{Hausner's ratio} = \rho t \backslash \rho b$$

Where,

ρt = Tapped density

ρb = Untapped bulk density

8. Carr's Index:

Compressive strength is the most straightforward technique to assess a powder's free flow property. Compressive strength is a percentage that can be computed as follows and indicates how easily a material can be made to flow:

$$C = (\rho t - \rho b) / \rho t * 100$$

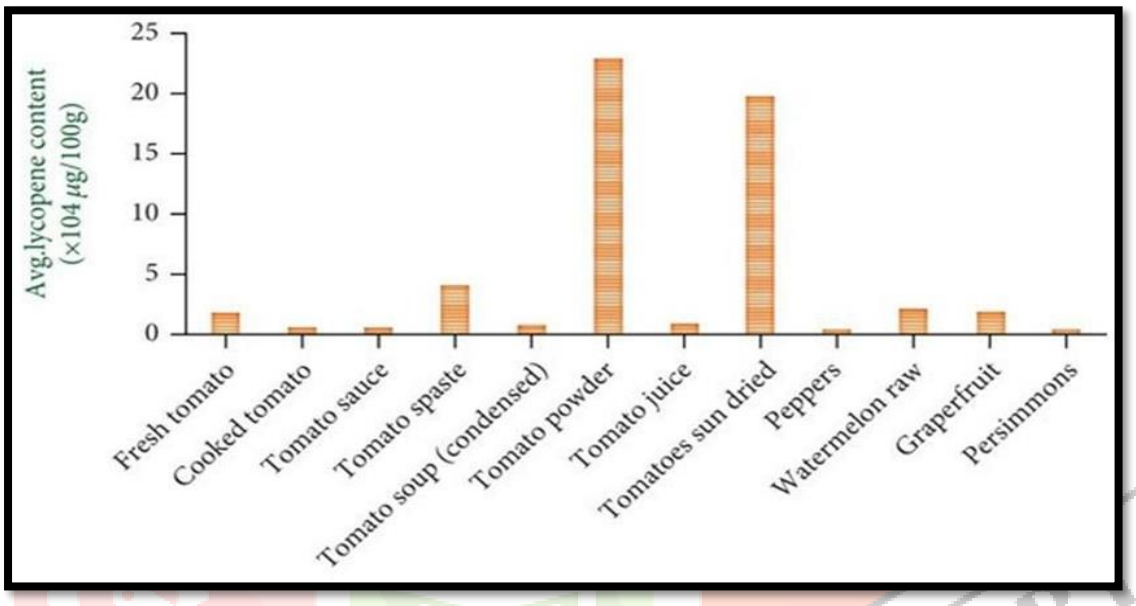
Where,

ρt = Tapped density

ρb = Untapped bulk density

VII. Bioavailability of Lycopene Capsules:

Being a fat-soluble substance, lycopene is better absorbed when taken with dietary lipids. Processing and cooking are also important: Cooking and Processing: By dissolving cell walls and transforming lycopene into more absorbable forms, heat processing—such as boiling tomatoes—increases lycopene bioavailability. Lycopene, for instance, is up to four times more accessible in tomato paste than it is in fresh tomatoes. Dietary Fats: Eating foods high in lycopene along with fats like avocado or olive oil improves absorption. According to research, eating tomato salsa with avocado can improve the absorption of lycopene by 4.4 times when compared to eating salsa without avocado. The percentage of a nutrient that is absorbed and used by the body is known as its bioavailability. The form of consumption, the dietary matrix, and the presence of fat are some of the factors that affect lycopene's bioavailability



VIII. Usage of Lycopene:

Encourage Heart Health: Although results are mixed, lycopene may lower the risk of cardiovascular illnesses by lowering blood pressure and cholesterol. Health Tips Promote

Better Skin Health: Lycopene's antioxidant qualities may shield the skin from UV rays and oxidative stress, as well as enhance skin health in general.

Promote Prostate Health: According to certain research, lycopene may lower the risk of prostate cancer. Excellent health.

Offer Antioxidant Advantages: Lycopene aids in shielding cells from harm brought on by free radicals. Verywell Medical

Cancer Prevention: According to some research, lycopene's antioxidant and anti-inflammatory properties may lower the chance of developing several cancers, including those of the stomach, lung, and prostate.

Eye Health: Lycopene is an antioxidant that may help shield the eyes from oxidative stress and vision problems associated with aging.

Male Fertility: According to certain research, lycopene may enhance the general reproductive health and sperm quality of men.

IX. Possible Side Effects:

When taken in moderation from foods like tomatoes, lycopene is usually regarded as safe. However, there are some adverse effects when taking supplements in the form of capsules, particularly if used in excess.

Digestive Disorders
Allergy Responses
Interaction with prescription drugs
Overindulgence

X. RESULT:

Sr.No.	Name of test	Sample result			
		F1	F2	F3	F4
1	Dissolution test (time)	11:25:04 min.	18:02:10 min.	25:49:05 min.	33:10:39 min.
2	Angle of repose (h/r)	0.24	0.28	0.41	0.43
3	Disintegration test (time)	07:39:20 min.	12:07:00 min.	17:41:15 min.	22:20:04 min.
4	Bulk density (gm/cm$^{3)}$	0.71±0.02	0.73±0.03	0.70±0.01	0.69±0.02
5	Tapped density (gm/cm$^{3)}$	0.76±0.02	0.79±0.01	0.81±0.03	0.82±0.01
6	Hausner's ratio	1.07±0.06	1.01±0.02	1.15±0.01	1.18±0.01
7	Carr's index (%)	6.57±0.07	7059±0.05	13.58±0.01	15.85±0.03

Fig.12.- Final Product

XXI. Conclusion:

The viability of utilizing natural sources for the creation of antioxidant-rich nutraceuticals is demonstrated by the effective manufacture of lycopene capsules from tomato extract. The extraction procedure produced a stable lycopene concentrate, and the prepared capsules satisfied pharmacopeial requirements for drug concentration, homogeneity, and disintegration time. According to evaluation results, the capsules have consistent release profiles that are appropriate for oral administration, along with good physical and chemical stability. These results lend credence to the possibility that lycopene capsules made from tomatoes could be useful supplements for boosting antioxidant activity and supporting overall

health. The therapeutic effects should be confirmed by more research, including bioavailability and clinical efficacy. When compared to formulations containing lycopene powder, all of the developed oral formulations including lycopene extract shown superior antidiabetic effectiveness. According to the current study, it may be more desired, advantageous, and therapeutically effective to formulate plant extracts into a suitable and acceptable herbal dosage form rather than combining the raw plant materials or isolated phytoconstituents.

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