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Research Article

DEVELOPMENT AND STANDARDIZATION OF *ELLUMTHIPPALLYADI LEHYA* CANDY

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ABSTRACT

Ellumthippallyadi Lehya is one among the classical *lehya* formulation mentioned in sahasrayogam. *Lehya* formulations are often sticky, dense, and may have a strong odor, which can be unappealing, especially for sensitive individuals. Dosage accuracy can also vary with difference in consistency. Candies, though primarily consumed for taste and pleasure are increasingly being explored for their potential as carriers for therapeutic agents. Development of new dosage forms and ensuring their quality and safety through pharmaceutical standardization is essential for their acceptance especially in health focused formulations. *Ellumthippallyadi Lehya Yoga* was converted to a candy as a modified dosage form with a uniform weight of 3g. Machinery support was used for the production of candies. The drugs were taken in the ratio as mentioned in the reference. The constituents in one candy were adjusted considering the amount of *Loha bhasma* as 50 mg in each candy. The candies were made using palm sugar candy as base and liquid glucose was added for desired consistency. *Elluthippallyadi Lehya* Candy was subjected to standard pharmaceutical evaluations, including organoleptic properties, weight variation, and Disintegration time, pH, and heavy metal analysis using standard methods. The *Ellumthippallyadi Lehya* candy demonstrated compliance with standard pharmaceutical parameters and its other safety parameters ensured its potential as a convenient dosage form.

INTRODUCTION

Ayurveda is a system of medicine with rich heritage and numerous principles. The unique way of maintaining equilibrium of health and the cure of diseases makes it different from other health care systems. Development of new dosage forms without disturbing the basic principles of *Ayurveda* is a need of the era[1]. Value-added formulations can enhance the bioavailability of a drug, meaning the drug is more efficiently absorbed into the bloodstream, improving bioavailability can lead to better therapeutic effects and reduced dosages[2]. *Ellumthippallyadi lehya* (ETL) is a semisolid preparation mentioned in *sahasrayogam*[3].

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An attempt is made to modify *Ellumthippallyadi lehya* in to a better palatable and convenient dosage form as a candy[4] and also to minimize the difficulties in administration. The major ingredients are *Tila, Pippali, Kolaphala, Sunthi, and Loha bhasma*. These often contains high levels of minerals and other nutrients and may have action in regulating metabolism at cellular level. Along with these ingredients it contains palm sugar candy and liquid glucose in its composition. Palm sugar candy is considered as a best alternative sweetener in Indian market due to its low Glycemic index (GI) value and high micro nutritional level[5].

The use of herbo-mineral formulations combines the strengths of both plant-based herbs and minerals, often acting synergistically to enhance bioavailability and improve therapeutic outcomes. Traditional preparations incorporated with contemporary technologies can help extend their shelf life and biovailability[6].This study aims to formulate and evaluate newly developed *Ellumthippallyadi Lehya* candy for its wider acceptability.

MATERIALS AND METHODS

Raw drug collection

All the raw drugs were purchased from different stores inside Kerala. Authenticated after analysing the various physico-chemical properties in accordance with Ayurveda Pharmacopia of India (API).

Preparation of Candy

Required Ingredients: Fine powders of herbal drugs like *Tila, Pippali, Sunthi, Kola phala, Nagara* and the mineral drug *Loha Bhasma*, Palm candy and Liquid glucose.

Apparatus Required: Weighing Balance, A large wide open mouthed vessel, wooden spatula, Metallic tray, vessels, Sieve, wooden fire, and long sized iron spatula /spoon.

As we used machinery support for the production of candy in bulk quantity, services were provided from a GMP Certified company in Kerala.

Procedure

11 Kg of accurately weighed Palm candy was taken in a wide open mouthed vessel. To this vessel sufficient quantity of water was added and boiled. Fire wood was used as the fuel. When the boiling process was initiated under moderate flame, continuous stirring was carried out. Then allowed to boil and melt completely. Waited for 15 minutes more and allowed to settle the froth produced during the process. Then to this mixture, accurately weighed 4 Kg of Liquid glucose was added. It served as a proper binding agent. Heating was continued with moderate flame until it reached a thicker thread like consistency. Then water content was removed with the aid of a vaccum machine. Weighed powdered herbal ingredients 90 g each of *Tila, Pippali and Kola Phala* along with 360 g of *Sunthi* and mineral drug 270 g of *Loha bhasma* was taken and mixed well in a medium sized steel vessel using a sieve and kept aside. After the complete removal of excess water, the contents were spread over a wide metallic tray. That was semisolid in nature. Soon to this tray containing the base ingredients, accurately weighed other ingredients were added and mixed well. Proper mixing was done with a long sized iron spatula. Homogeneous mixture was obtained. Then this mixture was loaded to candy making machine. After that, hard candies were produced and they were collected in a large tray. Batch wise productions of the candy were done. Packaging was done with airtight ziplock covers. The weight of one candy was 3 g and got more than five thousand candies in a single batch production. (Fig .1 and Fig.2)

Analytical study

This part played role in evaluation of the quality and safety of the formulation. Physico chemical characteristics of the raw drugs and the ETL Candy related to its standardization, were done in accordance with guidelines outlined in API[7] and General Guidelines for Drug Development of Ayurvedic Formulations by CCRAS, ministry of AYUSH, Government of India[8].

Standardization parameters of candy

Procedures were done at CARe KERALAM Limited.

Loss on Drying

The LOD is calculated by measuring the mass of a sample before and after the water is removed by the means of evaporation.

Procedure

Took 10 g of drug (without preliminary drying) after accurately weighing it in a LOD bottle. After placing the above said amount of the drug in the tired LOD bottle, dry at 105 degree Celsius for 5 hours. Then weigh and continue the drying and weighing done at one hour interval until difference between two successive weighing corresponds to not more than 0.25 per cent. Constant weight is reached when two consecutive weighing after drying for 30 minutes and cooling for 30 minutes in a desiccators which show not more than 0.01 g difference.

Calculation:

Percentage of LOD= (W-W1×100)/W

W = Weight of sample (air dried)

W1 = Weight of sample after drying

Total Sugars

Invert sugar reduces the copper in Fehling-A solution to a brick red coloured cuprous oxide.

Procedure

Standardization of Fehling's Solution

Pipetted out accurately 5ml of solution A and solution B in to a conical flask. 20 milliliter of distilled water is poured to it. Heated this mixture to boil and added standard dextrose using burette. Added 1ml methylene blue indicator towards the end of reaction while keeping the solution heated. The titration was completed within 3 minutes, the end point being indicated by change of colour from blue to red. Calculations of the strength of $CuSO_4$ are carried out by using the volume of the sugar solution.

This gave the quantity of sugar required to reduce the copper in 5ml of $CuSO_4$ Solution.

Total Sugar Calculation

Carefully measured 5-10g of the specimen in a beaker. Mixed it with 50 ml of water. Poured 1ml of hydrochloric acid into it. Boiled the solution by heating it. Allow the solution to sit overnight to invert. Following inversion, neutralized the solution with sodium carbonate solution. Poured the solution into a volumetric flask with a capacity of 100ml.Prepared a solution with distilled water up to a volume of 100 ml. Retrieved the solution using the burette. Carefully pipetted 5 ml of solution A and 5 ml of solution B into a conical flask. Added a small amount of solution with

the burette and 20 milliliter of water. Bought the solution to a boil. Include 1ml of Methylene blue indicator at the conclusion of the reaction. Finished the titration in three minutes, with the endpoint marked by a color change from blue to red. Took note of the solution's volume in milliliters needed for the titration.

Mathematical computation

$$\text{Total Sugar percentage by mass} = \frac{100 \times \text{strength of Fehling's Solution} \times 100}{\text{weight of sample (g)} \times \text{titrevolume (ml)}}$$

The formula for calculating the Total Sugar percentage by mass is: (100 times the strength of Fehling's Solution * 100) divided by (weight of the sample in grams times' titre volume in milliliters).

Reducing sugars

Procedure

Measured precisely 5-10g of the substance in a beaker. Mixed it with 50 ml of water, then poured it into a 250 ml volumetric flask and top up to 250 ml with distilled water. Use the solution from the burette. Transferred 5 ml of solution A and B into a conical flask with a pipette. Poured approximately 20 ml of water and a small amount of solution from the burette. Bought the mixture to boil. Towards the final part of the reaction, 1milliliter of Methylene blue indicator is included. Finished the titration in three minutes, identified the endpoint by the transition of color from blue to red. Took note of the quantity in milliliters of the solution needed for the titration.

Mathematical computation

Formula for calculating the strength of Fehling's Solution: (titration volume of standard dextrose (ml) multiplied by weight of dextrose (g)) divided by the volume of Fehling's Solution

$$\text{Reducing Sugar percentage by mass} = \frac{250 \times \text{strength of Fehling's Solution} \times 100}{\text{weight of sample (g)} \times \text{titrevolume (ml)}}$$

Disintegration time

Filled the tank of the disintegration apparatus with distilled water up to the mark. Took 750 ml of distilled water in each of the 1000 ml beaker. Set the temperature of water to 370c ±0.50c. Introduced one candy into each tube of apparatus. Added a disc to each tube. Suspended the assembly in the beaker water and operate the apparatus. Noted the time duration at which the candy disintegrates.

Weight variation

Weighed 20 candy selected at random. Calculated the average weight. Then maximum and minimum weights were noted.

Friability

Friability was determined in a friability tester to determine the physical strength of tablet or candy. De-dusted the candies carefully. Weighed accurately ten numbers of candy or tablets. Placed the candy in the drum and rotate 100times.Candies are removed, also remove any loose dust from them and weighed accurately. Friability is the difference in weight.

Value of pH

Took buffer solutions of different pH 4, 7 and 9. Switched on the instrument. Leaved it for some time unless or on the board requirement of different pH solutions appears. The electrode was dipped in the buffer solution. Carried out the same exercise for another buffer solution also, after washing electrode thoroughly with distilled water. Took the test sample (10% aqueous solutions for solid preparations) then noted the value of pH. This method outlines how to calculate the level of salt in the sample.

Sodium Cloride Content

The quantity of salt in the sample is established through back titration with excess silver nitrate using potassium thiocyanate.

Accurately measured approximately 5.0g of the substance in a container and collected the complete ash. Mixed the ash in boiling water. Rinse and scrub the dish and residue with hot water until all chlorides are removed completely. Gathered the filtrate and rinsed in an Erlenmeyer flask, then combined with a measured amount of standard silver nitrate solution, slight excess, 5ml of ferric indicator solution, and a few ml of nitric acid. Added the standard potassium thiocyanate solution to the excess silver nitrate until a permanent light brown color is achieved.

Mathematical computation

The percentage mass of salt is calculated as 5.85 times the difference between volumes V1 and V2 multiplied by concentrations N1 and N2, all divided by molarity M.

Salt content by % mass = $5.85(V_1N_1\text{-}V_2N_2)/M$

V1 is the volume of standard silver nitrate measured in milliliters.

N1 = Standard silver nitrate's normality.

Volume of the standard potassium thiocyanate solution used is represented by V2 in milliliters.

N2 is the standard potassium thiocyanate solution's normality.

M represents the weight in grams of the sample used in the experiment.

Total Aerobic Plate Count

To describe about Total Aerobic Plate Count in the given sample. This is applicable for the enumeration of microbes in the given sample.[9]

Total Yeast and Mold Count

Weighed 10g of the sample and dispense into 90 ml of Buffered sodium chloride peptone solution (PH-7) Serial dilution was carried out till10-5 dilution. Dispensed 1 ml each of sample homogenate into duplicates of appropriately labeled Petri plates. Add

15-20 ml of Sabouraud dextrose agar, cooled to 45 Degree Celsius, into Petri dishes. Quickly without any delay mixed the sample homogenate/dilutions and agar well by alternate rotation of the plates on a level surface. Allowed the agar to solidify. Do not stack the plates while the agar is solidifying. Incubated the solidified agar plates in the dark at 20-25°C for 5 days. A Negative control is also done as a part.

Heavy metal Analysis

Atomic absorption spectroscopy was employed. For Lead and Cadmium detection,1% HCl was used. 20 % HCl in case of Mercury and Arsenic.

OBSERVATIONS AND RESULTS

PHYSICO CHEMICAL ANALYSIS

Results of physico chemical evaluation of raw drugs are shown in Table 1

Table 1: Result of Quantitative Evaluation of Raw drugs

Quantitative Evaluation of Raw Drugs						
Parameter	***Tila* (%) w/w**	***Pippali* (%) w/w**	***Sunthi* (%) w/w**	***Kola phala* (%) w/w**	***Loha bhasma* (%) w/w**	**Palm candy (%) w/w**
Foreign matter	-	-	-	-	-	-
Total Ash	3.7	1.3	2.9	4.1	99.91	0.1
Acid insoluble ash	0.27	0.14	0.31	0.1	86.51	0.2
Alcohol soluble extractive	58	39	29	24	2.44	8.7
Water soluble extractive	21	24	32	46	1.36	98.4
Fixed oil	62	-	-	-	-	-

Results of standardization parameters of EtL Candy shown in Table no.2

Table 2: Standardization parameters of ETL Candy

Physico - Chemical Evaluation of E T L Candy			
S.No.	**Parameters**	**Unit**	**Result**
1.	Disintegration	minutes / hour	10.0
2.	Friability	%	-
3.	Hardness	Kg/m2	6.0
4.	Loss on Drying	%	4.14
5.	Reducing sugar	% (w/w)	13.06
6.	Total Sugar	% (w/w)	45.1
7.	Water soluble Extractive	% (w/w)	94.45
8.	Alcohol soluble Extractive	% (w/w)	40.28
9.	Acid Insoluble Ash	% mass	0.067
10.	Sodium chloride content	% mass	0.0016
11.	PH	-	6.30

Microbial Testing and Safety Evaluation

To ensure the safety of the candy, the microbial load was tested according to the guidelines-

- **Total Aerobic Count**: To ensure the candy is free from harmful bacterial contamination, the total aerobic count was measured and kept within permissible limits.
- **Yeast and Mould Count**: A yeast and mould count was also performed to ensure that the candy remained free from fungal contamination.

Results of Heavy metal analysis of ETL Candy shown in Table 3

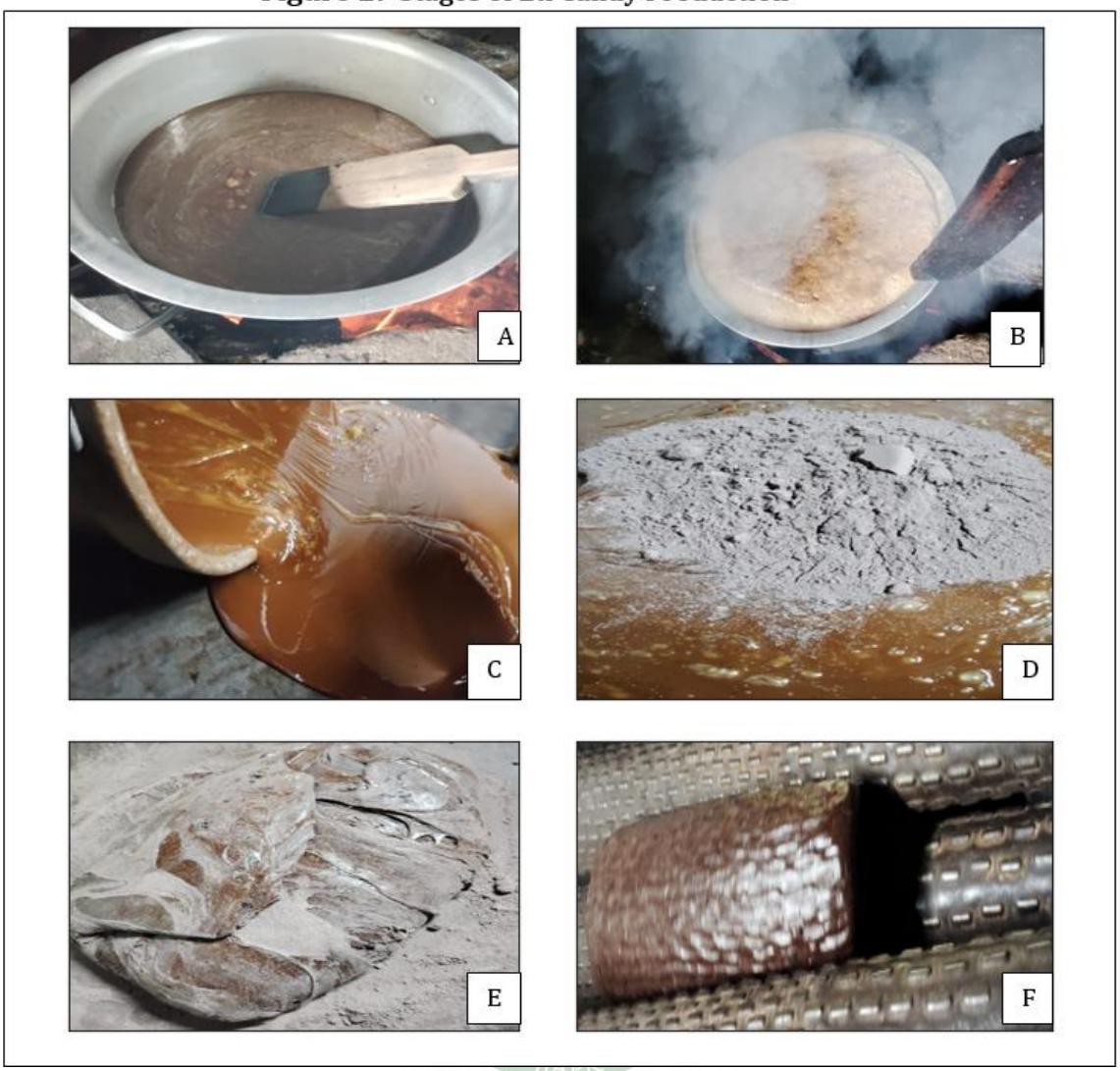
Table 3: Results of Heavy Metal Analysis

Metals	**Unit**	**Result**	**Permissible limits (API)**
Cadmium	Ppm	BDL	0.3
Mercury	Ppm	BDL	1
Lead	Ppm	0.69	10
Arsenic	Ppm	BDL	3

Figure 1 Raw Ingredients of *Ellumthippallyadi Lehya* Candy

A- *Tila*
B- *Pippali*
C- Loha Bhasma
D- *Sunthi*
E- Palmsugar candy

Figure 2: Stages of Etl Candy Production



A- Vessel with Palm Sugar candy and water
B- Process of Boiling
C- Spreading of base ingredients
D- Addition of base ingredients
E- Prior step of mixing of all ingredients
F- Loaded homogenous mass of ingredients to the machine

G - Final ETL Candy obtained
H- Candy in packed form

DISCUSSION

The candy format provides an enjoyable and easy-to-administer dosage form, improving adherence to the supplementation regimen [10]. In line with the guidelines set forth by the Central Council for Research in Ayurvedic Sciences (CCRAS), various parameters were considered to standardize the candy formulation ensuring its consistency and safety. Standardizing properties of the candy was essential to ensure that it remains uniform in composition and potency across different batches. The following parameters were specifically assessed.

Organoleptic characteristics of ETL Candy, it was evaluated for colour, shape, and texture. It was visually appealing and uniform in shape and size. The formulation was processed to achieve a smooth texture with no cracks or irregularities. The candy appeared as dark brown, round-shaped units weighing 3g each with predominance of sweet taste and predominant odor of *Pippali.*

The visual appearance of the candy is important not only for consumer appeal but also for its quality and consistency. According to the CCRAS guidelines, the weight of the candy should not exceed 5-6 grams. The 3g weight of the candy falls well within this specified range, ensuring proper dosage per unit and facilitating ease of administration. The round shape and uniform color also confirm the consistency in the production process, which is essential for ensuring the accurate delivery of active ingredients in each dose. Weight Uniformity: Each candy was designed to have a total weight of 3 gram, with 50 mg of *Loha Bhasma* incorporated into the formulation. The weight of individual candies was measured to ensure that the dose of *Loha Bhasma* remained consistent across each batches, and the deviation from the mean weight was within permissible limits. The moisture content of the candy was measured to ensure its stability and shelf life. Excess moisture can lead to microbial growth or alteration in the physical properties of the candy, while insufficient moisture can affect texture and palatability. No further shelf life studies are done in this study.

The disintegration time, which is the time required for the candy to break down and release its contents, was recorded at 10 minutes per hour. This is an acceptable value, as it indicates that the candy will dissolve and release its active ingredients in a controlled manner, without prolonged delay[11].

The fact that the friability is nil, indicates that the candy is stable and robust, which is crucial for maintaining the integrity of the dosage form during handling and storage. It also ensures that the candy remains intact during transport and is easy for the consumer to handle without risk of breakage[12].

Reducing Sugar (13.06%) and Total Sugar (45.1%): The sugar content of the candy is an important consideration in terms of both its palatability and its impact on the efficacy of the formulation. The reducing sugar content of 13.06% and the total sugar content of 45.1% confirm that the candy has a balanced sweetness, which aids in improving patient compliance, especially for the adolescent population. High sugar content may also serve as a stabilizer for the candy, preventing crystallization and enhancing the mouth feel[13].

These Extractive values reflect the solubility and extractability of the herbal ingredients in the candy. The high water-soluble extractive value (94.45%) indicates the presence of water-soluble bioactive compounds from the herbs, which are important for enhancing iron absorption and digestive health. The alcohol-soluble extractive (40.28%) confirms the presence of herbal constituents that are soluble in alcohol, which may include compounds that contribute to therapeutic effect.

The pH value of the candy was found to be 6.3, which is slightly acidic but within the acceptable range for oral dosage forms. The pH of the candy can influence the solubility and bioavailability of the active ingredients, as well as their gastrointestinal tolerance. The mildly acidic pH is ideal for supporting the absorption of iron and other nutrients.[14]

CONCLUSION

ETL candy was developed, Standardized as per the guidelines and ensured its quality and saftey. The results of the standardization and quality control tests confirm that the ETL candy meets all the necessary criteria for consistency, safety, and efficacy. The physicochemical parameters, including appearance, disintegration time, friability, moisture content, and sugar content, align with the regulatory guidelines for herbal dosage forms.

With its convenient and palatable form, it could be a valuable addition of the *Ellumthippallyadi lehya*. With further research and increased awareness, this product could make a significant contribution to public health.

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