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Standardization of Arjuna tablet for safe and effective use

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Abstract
The current study focuses on the preparation, standardization, and assessment of tablets of Arjuna (*Terminalia arjuna*), a popular herbal remedy in Ayurveda that has cardioprotective properties. Establishing scientific guidelines to guarantee the uniformity, security, and effectiveness of commercially available and lab-produced Arjuna tablets was the goal of the study. Thorough organoleptic and physicochemical analyses were conducted after the bark of
arjuna was verified, processed, and made into tablets. Tests for hardness, friability, weight variation, and disintegration guaranteed acceptable pharmaceutical quality. The standardized tablets demonstrated consistent therapeutic potential by meeting the necessary quality parameters. The study promotes the safe use of Ayurvedic medicines and their scientific acceptance by offering a validated framework for quality assurance in herbal formulations.

Keywords: Standardization, Arjuna tablet, *Terminalia arjuna*, ayurveda

Introduction
Herbal medicines are the earliest type of therapy that people have ever encountered, using whole plants or plant parts to treat a variety of illnesses or promote overall health. There are numerous herbal formulations that have been demonstrated to reduce the symptoms of a broad spectrum of diseases, from flu and cold to depression. WHO has set clear standards for assessing the efficacy, quality of natural remedies [1].
Using herbal treatments to treat a range of illnesses is expanding rapidly on a global scale. People's acceptance in natural remedies has significantly increased in both industrialized and poor nations. Nowadays, both drug and supermarket stores provide herbal cures.Their primary source of medical care is herbal remedies. India has an advanced conventional healthcare system. Mostly all systems, including Ayurveda, Unani, homeopathy, and Sidha use herbs. Modern medications and dietary supplements for food and drink are being developed using natural herbal ingredients. Traditional medicines have therefore provided a high level of confidence in their efficacy and safety due to their hundreds of years of use [2].

2. Materials and Methods
2.1. Collection, identification and authentication of raw materials
The plant (Terminalia arjuna) was gathered from the Sangli neighborhood and verified by Dr. Sanjay Sathe sir, Dept. of Botany, Sangli.The bark of the plant was selected for study, sliced to little fragments, and then dried properly. Once dried, using a mortar, pestle, and mixer it was crushed into a fine powder [3].

2.2 Preparation of Arjuna tablet
Preparation of granules
A mortar and pestle were used to thoroughly combine all of the components once they had been precisely weighed. The accurate amount of Terminalia arjuna extract was added to above mixture and mixed them throughly. To make the granules, a moist mixture was created and sent through sieve number 16. After that, at 65°C oven was used to dry the granules. Once drying is done the granules are prepared [4].

Evaluation of prepared granules
Granules were evaluated by using following parameters, determination of moisture content, Angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio [5].

Preparation of Arjuna tablet

Table 1: The Formula of Arjuna tablet

Sr. No.	Ingredients	Quantity(mg)	Use
1	Terminalia arjuna extract	250	API
2	Methyl cellulose	180	disintegrant
3	Magnessium stearate	20	Lubricant
4	Lactose	55	Binder
5	Talc	10	Glidant
6	Sodium alginate	5	Diluent

3. Procedure

Evaluation of prepared granules [5]

Determination of moisture content

- A Moisture Analyzer device was used to measure the moisture content.
- Exact 0.2 gm of powder was taken and poured into the moiture analyzer plate and heated at 104oC for 55 sec. and moisture content was determined.

Angle of repose

The angle of repose was calculated using the fixed funnel method. Produced 15.62 g grains were transferred into a glass funnel. The glass funnel's lower tip was 2 centimeters above the ground. Following measurements, the pile's height (h) and radius (r) were computed by equation as follows. Tan θ - h/r

Bulk Density

Squeezed. Granule volume was then measured, computed using following formula. Bulk density (BD) = granules mass / unsettled apparent volume

Tapped density

The tapped density was tested using a 100 ml glass cylinder containing 15.62 g of granules. It was tapped for 100 times. The following formula was used to determine the volume of tapped granules:

(TD) = granules weight / final tapped volume.

Carr's index

Since it indicates a powder's compressibility, it is sometimes referred to as the compressibility index. The compressibility index was computed utilizing the data from BD and TD.

Hausner's ration

The ratio of the TD to the BD is called as Hausner's ratio. It is computed using TD and BD data. And this is formula,

Hausner's ratio = TD/ BD

Compatibility study of drug and excipients [6]

The compatibility study was carried out through utilizing FTIR method. Drug and Excipient Compatibility Study Using FTIR-ATR.

Procedure

Preparation of sample

a) A tiny amount (~1-5 mg) of pure drug was taken.
b) Physical mixture of excipients was taken.
c) Physical Mixture of Drug and Excipient(s): A formulation-based mixture of drug and excipients was used. To guarantee even mixing, it was softly ground using a mortar and pestle.

2. FTIR-ATR Analysis

a) **Instrument Setup:** The ATR accessory and FTIR spectrometer were switched on. To prevent contamination, each sample was placed after the ATR crystal (typically diamond or germanium) had been washed with ethanol and soft tissue and dried.
b) **Sample Application:** The ATR crystal was immediately coated with a tiny quantity of the sample powder. To guarantee that the sample and the ATR crystal made good contact, a firm pressure was applied using the pressure arm.
c) **Obtain Spectra:** Gather spectra between 4000 and 400 cm^{-1}. Prior to every sample measurement, get a background spectrum (clean ATR crystal without sample). For a better signal-to-noise ratio, set the resolution (generally 4 cm^{-1}) and number of scans (usually 16-32 scans) appropriately.

3. Data Analysis: Identify typical peaks. Seek out variations in distinctive peaks (such as shifts, broadening, disappearance, or new peaks) that might point to interactions.

4. Post-analysis cleaning: Use ethanol to completely clean the ATR crystal and get rid of any remaining powder. All spectra of samples were superimposed, and a compatibility analysis was conducted.

Evaluation of prepared tablet and marketed tablet

Weight variation test: To maintain consistency in the weight of tablets in a batch, it is performed. To conduct the weight variation test, 20 tablets were first chosen at random for calculating total weight of the twenty tablets, then determining the mean, then determining weight of each tablet separately. The SD of tablet weight was calculated from this data to measure the how much individual tablet weights varries from the average (mean) weight, indicating spread or variability of the data. A lower SD suggests the weights are clustered closer to the average, while a higher SD indicates greater variation [7].

Friability test

Friability refers to weight loss of tablets due to the detachment of fine particles from their surface during handling. The test examines a tablet's resistance to abrassion against during packaging, transport, and handling. To determine friability, a Roche friabilator was utilized. Twenty tablets were put it in friabilator after being weighed individually, which rotated at 25 rpm for 4 minutes. Afterward, tablets were de-dusted and weighed again. The friability percentage was then determined using following formula [7].

% Friability = [(W1 - W2) × 100] / W1

Hardness test

The resistance of the tablet to the applied force until it breaks is known as hardness. Tablet's hardness was assessed utilizing Monsanto Hardness Tester. Usually, tablets are positioned between two platens, one of which moves to give the tablet enough force to fracture it. The tablet was compressed till it exploded [8].

Disintegration test: A disintegration test was used to determine the active pharmaceutical ingredient's (API)

solubility in the digestive system's gastric juices. The USP disintegrating device, comprising six glass tubes with a bottom 10-number mesh, was used to measure the breakdown of tablets. These six tubes were put in a one-liter jar with a medium that mimicked the disintegration environment, which was kept at 37 oC +/- 2 oC. This system was designed to oscillate between 28 and 32 cycles per minute. After that, it was noticed how long it took for the tablets to dissolve [8].

Organoleptic evaluation [9]

- The color, taste, and odor of tablets were examined in the organoleptic evaluation process.
- Color - The sample was visually examined to ascertain the tablet's color.
- Odor- After carefully taking a small amount of an Arjuna tablet, the material's odor was assessed by repeatedly inhaling air over it.
- Taste- A tiny amount of the Arjuna tablet was placed on the tongue to assess its flavor or taste.

Physical evaluation [10]

Determination of extractive value

The solvent extractive value can be calculated using the following methods to measure the water soluble extractive and the alcohol soluble extractive values using water and ethanol as extraction solvents, respectively.

Determination of water soluble extractive value

In a conical flask, 50 ml of water was poured separately to a carefully weighed 2 g sample of powdered arjuna tablet. After that, the sample was left to macerate for 24 hours, shaking regularly diring initial 6 hours, then leaving it alone for the remaining 18. After a short filtering, 25 milliliters of filtrate were placed in a water bath to evaporate until it was completely dry. We calculated water-soluble extractive value based on the solid residue weight.

Determination of alcohol soluble extractive value

A conical flask was filled using two grams of carefully weighed powdered arjuna tablet material. After adding fifty milliliters of ethanol separately, the combination was allowed to macerate for twenty-four hours. The first six hours were spent shaking the mixture often, and the remaining eighteen hours were spent letting it stand. After rapidly filtering the mixture, 25 milliliters of the filtrate were placed in a water bath to evaporate until they were completely dry. The weight of the alcohol-soluble residue was used to calculate its extractive value.

Determination of Ash value

Any organic material's ash is made up of its non-volatile inorganic constituents. Three methods can be used to measure the amount of ash: total ash, acid-insoluble ash, and water-soluble ash.

Determination of Total ash

One gram of powdered arjuna tablet was added to the precisely weighed and tared silica crucible in order to determine the total amount of ash. The sample was ignited by progressively raising the heating upto 500-600°C till it turned white, signifying lack of carbon, after the crucible containing the powdered arjuna tablet had been placed in a muffle furnace. Following a half-hour cooling period in a desiccator, the residue was moistened with roughly two milliliters of water, dried on a water bath, ignited to constant weight. After then, the total amount of ash was determined.

Determination of acid insoluble ash value

The whole ash from the previous step was cooked with 25 milliliters of 2M HCl for five minutes in order to determine the acid insoluble ash value. After passing the ash through ash- less filter paper, the insoluble substance was gathered in a previously tared crucible. After being washed with hot water, the residue was burned for 30 minutes at 450°C in a muffle furnace. After that, desiccator was used to cool the mixture. Then amount of acid-insoluble ash was calculated.

Determination of Water soluble ash

Ash that dissolves in water is known as water soluble ash.It was determined using following technique: crucible containing the full ash was filled with 25 milliliters of water, and it was then brought to a boil for five minutes.The insoluble particles were collected utilizing ash-free filter paper. After that, heated water was used to wash it and placed in a crucible to burn for fifteen minutes. Next, the weight of residue was deducted from the ash's overall weight.

Qualitative estimation of suitable biomarker [11]

Qualitative analysis of Quercetin as a biomarker from the ethanolic extract of Terminalia arjuna, including both marketed and laboratory-formulated tablets, using the HPTLC method.

Sample Preparation

- Preparation of working standard solution of Quercetin
- Ten milligrams of quercetin were dissolved in ten milliliters of ethanol.
- Preparation of sample solution of arjuna tablet and arjuna extract
- Stock solutions were made by dissolving 10 mg of the commercially available, laboratory- prepared Arjuna tablets and arjuna extract in 10 ml of ethanol. Since all samples were ethanol- soluble the final volume was composed utilizing ethanol to achieve concentration of 1000 µg/ml.

Chromatographic conditions

A silica gel G60 F254 (10 x 10 cm) HPTLC plate with a 0.2 mm thickness was used for the experiment, and no prewashing was done. Using an SPRAYLIN-VI automatic sample applicator, samples were arranged on plates in 5 mm bands, 10 mm from the plate's edges and 5 mm apart. In a Camag twin-trough glass chamber with a stainless steel top, the plates were grown using the ascending method to a distance of 80 mm, at 25±5°, with a relative humidity of 50-60%, using a mobile phase that included toluene, ethyl acetate, glacial acetic acid, ethanol, and formic acid [5:2:2:1:(5 drops)].Saturation time in the chamber was maintained at 10 minutes. Plates were dried after development and examined using Aetron Elite Mini Luminance.

Photodocumentation

The plate was examined in Aetron Elite Mini Luminance at 365 nm.

Total flavonoids content [12, 13]

Colorimetric analysis is a popular technique for figuring out the total flavonoid content (TFC)

Procedure

1. A quercetin stock solution (1 mg / ml) was prepared in methanol.
2. Create a standard quercetin calibration curve.
3. Combine 0.1 ml of 10% aqueous aluminum chloride and 1.5 mL of 95% ethanol, 0.1 ml of 1M potassium acetate, distilled water 2.8 ml, and 0.5 mL of standard solution.
4. Let it sit at room temperature for half hour. Using a UV spectrophotometer, determine the reaction mixture's absorbance at 445 nm.
5. Use the same volume of distilled water and 10% aluminum chloride to create a blank solution.
6. In a similar manner, use aluminum chloride to treat 0.5 ml of powdered turmeric tablet samples in order to determine the flavonoid concentration utilizing calibration curve.

4. Result and Discussion

The plant (Terminalia arjuna) was gathered from Sangli neighborhood, verified by Dr. Sanjay Sathe, Dept. of Botany, Sangli, to ensure accurate identification. The bark of the plant was selected for study, sliced to little fragments, and then dried properly. Once dried, using a mortar, pestle, and mixer it was crushed into a fine powder. This prepared plant material was stored for further experimental analysis.

Table 2: Evaluation of granules.

Sr. no.	Parameters	Mean values	±SD
1	Moisture content	5.45`%	0.0208
2	Angle of repose	29.06 0	0.0152
3	Bulk density	0.34 gm/ml	0.0057
4	Tapped density	0.39 gm/ml	0.0057
5	Carr's index	11.11`%	0.0251
6	Hausner's ratio	1.125	0.0010

Several criteria, including moisture content, angle of repose, bulk density, tapped density, Carr's index and hausner's ratio were used to satisfactorily evaluate laboratory prepared granules. Moisture content of the granules was found to be 5.45`%, which is within the acceptable range for granule stability and flow. The angle of repose was measured at 29.06°, indicating excellent flow properties. The bulk density and tapped density were observed to be0.34 g/ml and 0.39 g/ml, respectively. These values are used to calculate the Carr's index of 11.11`% and Hausner's ratio of 1.125 which are key indicators of flowability and compressibility. The Carr's index was found to be 11.11%, which falls in the range of 10-15`%. Likewise, the Hausner's ratio of 1.125 was observed. Overall, the evaluation results confirm that the prepared granules exhibit satisfactory physical characteristics for tablet manufacturing, with appropriate flow and compressibility properties.

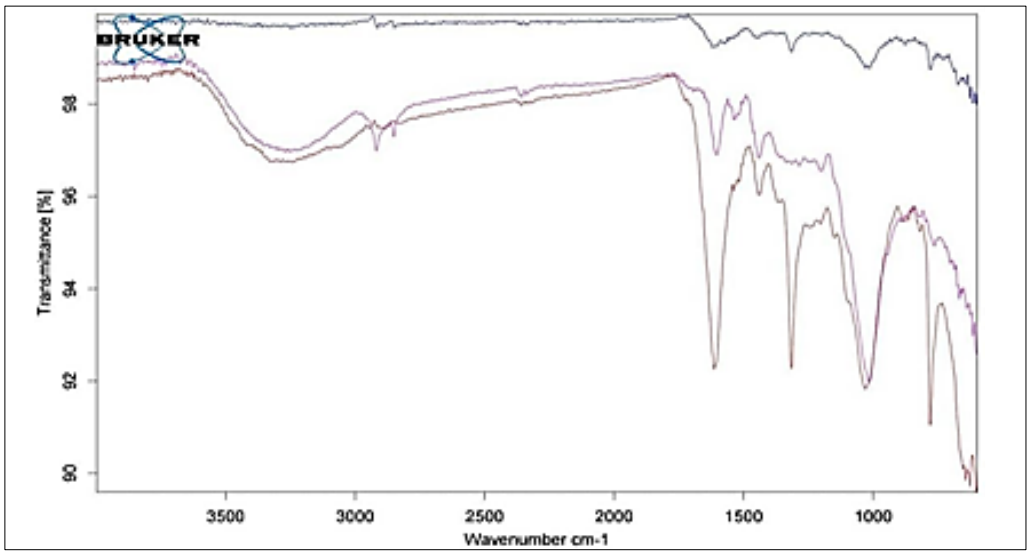

Fig 1: Overlay of drug-excipients FTIR spectrum.

The investigation of the drug's and excipients's compatibility was performed employing Fourier Transform Infrared (FTIR) Spectroscopy. Method is widely used for detecting any possible chemical interactions that may occur between a drug and the formulation excipients. Both the physical mixture of the drug with excipients and the pure drug's FTIR spectra were captured and overlaid for comparison. The absence of new peaks, no disappearance of existing peaks, or no significant peak shifts shows that there was no chemical interaction between the drug and the formulation's excipients. This confirms that selected excipients are compatible with API and are suitable for further formulation development.

Table 3: Evaluation of prepared and marketed tablet.

Sr. No.	Parameter	Sample	Mean	± SD	%RSD
1	Weight Variation	Marketed Tablet	519.3	1.154	0.2222
		Laboratory Prepared Tablet	517	1.7320	0.3350
2	Friability Test	Marketed Tablet	0.106	0.0010	0.9433
		Laboratory Prepared Tablet	0.118	0.0010	0.8474
3	Hardness Test	Marketed Tablet	7.433	0.0577	0.7762
		Laboratory Prepared Tablet	7.366	0.0577	0.7833
4	Disintegration Test	Marketed Tablet	24.11	0.1040	0.4313
		Laboratory Prepared Tablet	24.32	0.1662	1.6833

The evaluation of both tablets, that is, marketed tablets and laboratory-prepared tablets, was done by using various evaluation parameters like Weight variation, Friability test, Hardness test and Disintegration test. The weight variation of marketed tablet and laboratory prepared tablet were found to be 519.3 and 517 respectively. The marketed tablet had friability of 0.106%, while the laboratory- prepared tablet exhibited a friability of 0.118%. Both values are significantly below the maximum allowable limit of NMT 1%, indicating good mechanical strength. As per the results, the marketed tablet exhibited a hardness of 7.433 kg/cm², while the laboratory-prepared tablet showed 7.366 kg/cm².The marketed tablet indicated disintegration time of 24.11 minutes, while the laboratory-prepared tablet displayed 24.32 minutes.

Table 4: Organoleptic evaluation of tablets.

Sample	Color	Odor	Taste
Laboratory prepared tablet	Brown	Aromatic	Bitter and astringent
Marketed tablet	Brown	Aromatic	Bitter and astringent

The organoleptic evaluation of both marketed and laboratory-prepared Arjuna tablets was carried out to assess their physical characteristics. As shown in the table, both tablet types exhibited similar properties in terms of color, odor, and taste. The tablets were brown in color, the aromatic odor observed in both samples and the bitter and astringent taste was observed.

Table 5: Determination of extractive values and ash values.

Sr. No.	Parameter	Weight of Sample (g.)	Mean	%W/W	± SD	% RSD
1	Water Soluble Extractive Value	4	0.964	24.1%	0.0035	0.3630
2	Alcohol Soluble Extractive Value	4	0.844	21%	0.0040	0.4739
3	Total ash	2	0.104	5.2%	0.0015	1.4423
4	Acid - insoluble ash value	2	0.025	1%	0.0005	2
5	Water Soluble ash value	2	0.056	2.5%	0.0010	1.7857

To evaluate the quality and purity of pure Arjuna, its extractive and ash values were determined. Good solubility characteristics were indicated by the water-soluble extractive value of 24.1% and the alcohol-soluble extractive value of 21%, both of which are within the standard range. The sample's total ash content was 5.2%, whereas the water-soluble and acid- insoluble ash contents were 2.5% and 1%, respectively. The purity and low level of inorganic or extraneous matter in the sample were confirmed by the fact that all ash values fell within the acceptable ranges.

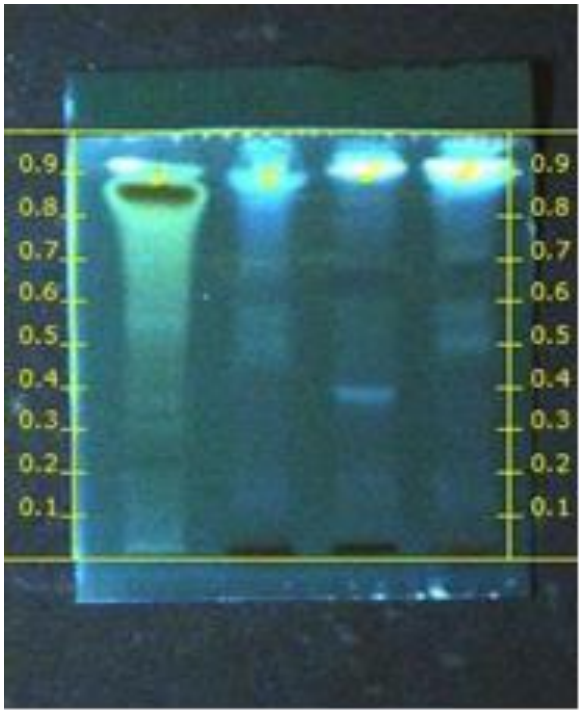

Fig 2: HPTLC plate scanned under 365 nm

Qualitative analysis of Quercetin as a biomarker using the HPTLC method was conducted.The HPTLC analysis was carried out utilizing a mobile phase made up of toluene, ethyl acetate glacial acetic acid, ethanol, and formic acid in the ratio of [5:2:2:1:(5 drop)].The Rf value for standard quercetin was discovered being 0.88. Quercetin existing in marketed Arjuna tablet, the laboratory prepared Arjuna tablet and plant extract showed Rf values of 0.89, 0.89, and 0.88 respectively. This close similarity in Rf values indicates the successful identification of quercetin in all the samples. The analysis was done under UV light at 365 nm, confirming presence of quercetin. These results support the reliability of the HPTLC method for qualitative analysis.

Table 6: Total flavonoid content of tablets

Sr. No.	Sample Name	Absorbance	Concentration of flavonoid in sample	Total Flavonoid Content (mg quercetin equivalent/g)
1	Marketed Arjuna tablet	0.285	330.42	165
2	Lab. Prepared Arjuna tablet	0.292	340.42	170

Following equation was utilized for determining the quercetin calibration curve based on the research findings,

$y = 0.0007x + 0.0537$ $R^2 = 0.997$.

The total flavonoid content (TFC) was conducted in both the marketed Arjuna tablet and the laboratory-prepared Arjuna tablet by using the aluminum chloride colorimetric technique, and quercetin as the reference compound. The total flavonoid content of Marketed Arjuna tablet and Laboratory prepared Arjuna tablet was discovered being 165 mg and 170 mg quercetin equivalent/g.

5. Conclusion

The current investigation was conducted with focus on formulation, standardization, and evaluation of Arjuna (Terminalia arjuna) tablets, a well-known cardioprotective herbal medicine in Ayurvedic practice. The primary objective was to establish scientific parameters that ensure the consistency, safety, and efficacy of Arjuna tablets, whether marketed or prepared in the laboratory. The goal of this thesis was to standardize Arjuna tablet based on a number of criteria in order to guarantee their steady therapeutic action and encourage their safe use.

The study began with the selection and authentication of Terminalia arjuna bark, followed by its proper processing and formulation into tablet form. To provide thorough standardized criteria, careful organoleptic physicochemical analyses were conducted. Organoleptic evaluation supported its sensory qualities. Physicochemical characteristics, including ash value and extractive value, were also conducted. To make sure the tablets fulfilled acceptable pharmaceutical requirements for dosage uniformity and stability, additional formulation factors were assessed, like tablet Hardness, Friability, Weight variation, and Disintegration test. Outcomes of every assessment showed that the standardized Arjuna tablets fulfilled the necessary pharmaceutical requirements, had the right range of active ingredients, and maintained constant quality. In conclusion, this study's effective standardization of Arjuna tablets provides a template for creating herbal formulations with guaranteed quality. It offers a scientific foundation that not only improves the safety and effectiveness but also helps herbal medicines become more widely accepted and used.

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