RESEARCH ARTICLE

Standardization of Babbularishta - A Marketed Ayurvedic Formulation as per WHO Guidelines

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Received: 10th August, 2023; Revised: 28th October, 2023; Accepted: 18th November, 2023; Available Online: 25th December, 2023

ABSTRACT

Ayurveda is the world's oldest continuous medicinal tradition. Ayurveda's discovery of the long-lasting single-dose forms of Asava and Arishta is a boon to modern medicine. Diarrhea, colitis, chronic cough, asthma, tuberculosis, and improved digestive function are only a few of the conditions for which the ayurvedic formulation Babbularishta is utilized. Gallic acid is one of the active ingredients in babbularishta, a commercially available ayurvedic medicine. The purpose of this study was to develop a standard for the quality of commercially available Babbularishta by measuring its alcohol content and pH. To meet World Health Organisation (WHO) standards, an high-performance liquid chromatography (HPLC) and ultraviolet (UV) method was devised for quantifying the main component, gallic acid, in babbularishta. Gas chromatography and redox titrimetry were used to confirm the accuracy of the formulation determined during the development process. The formulation was further tested for pharmacological activity, elemental makeup, pesticide traces, and heavy metal concentration.

Keywords: Babbularishta, Standardization, Ultraviolet, High-performance liquid chromatography.

International Journal of Drug Delivery Technology (2023); DOI: 10.25258/ijddt.13.4.10

How to cite this article: Gosavi S, Jadhav P, Kulkarni A, Jagtap S, Joshi S. Standardization of Babbularishta - A Marketed Ayurvedic Formulation as per WHO Guidelines. International Journal of Drug Delivery Technology. 2023;13(4):1183-1185.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Thirty-seven Asavas and Arishta are included in the Ayurvedic Formulary of India (AFI). For over 3000 years, people have turned to arishta and asava for both medicinal and recreational purposes.[1,2] The Sri Lankan ayurvedic pharmacopeia officially recognizes 34 distinct Arishta variations for both manufacturing and retail sale. Babbularishta is a brown, fermented ayurvedic herbal formulation.[3,4] It contains 5 to 10% self-generating alcohol, which serves as a medium for the formula's activity. It's useful for treating a wide variety of illnesses.[5]

The primary component of babbularishta is babbula, a tree native to India that is used to make gum in Arabic. It is made using babbula steam bark. Tanning compounds and others have a significant role in this.[6] Many beneficial effects, including those against cancer, fungus, fever, asthma, diabetes, spasms, platelet aggregation and hypertension, have been attributed to this plant. Asthma, bronchitis, tuberculosis, and other lung diseases can all be helped by taking babbularishta. It helps with coughing by acting as an expectorant, and it also stimulates digestion.[7]

MATERIALS AND METHODS

Ethanol Content Determination (Redox titration)

Ethanol concentration in the water is determined by redox titration. In concentrated sulphuric acid, ethanol is oxidized to ethanoic acid via a reaction with excess potassium dichromate.

Determination of Ethanol Content (Gas chromatography)

The ethanol concentration in the commercially available formulation was calculated by subjecting it to rotational vacuum evaporation at a temperature not exceeding 45%. All the liquid was evaporated during the evaporation process. The collected liquid is now a water and ethanol hybrid. Gas chromatography was used to determine how much ethanol was in the condensate. The accuracy of the retention time used to measure ethanol concentration was checked against a reference standard (99.9). It was determined that the procedure was exact, linear, and accurate.[8]

Phytochemical Screening

Carbohydrates, flavonoids, tannins, phenols, alkaloids, saponins, glycosides, anthraquinones, and amino acids were

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among many classes of compounds that might be identified using methanolic extract.[9]

Extraction of Tannins from the Formulation

There are a variety of tannins in babbularishta, including methyl gallate, ethyl gallate, chebulinic acid, chebulinic acid, and penta-o-galloyl-B-D glucose. After 10 hours of hydrolysis in 5M sulphuric acid at reflux, the formulation was discarded. This resulted in the disintegration of tannins into their constituent monomeric units. After being reduced to this more elementary form, it was purified by passing it through a column of silica (column grade, 60–80 mesh). The HPLC analysis could then proceed with the sample.[9]

Gallic Acid in the Formulation by UV Spectrophotometry and HPLC

Ultraviolet spectrometry was used to determine the concentration of gallic acid in hydrolyzed commercialized babbularishta formulation. The hydrolyzed formulation was compared to a standard gallic acid sample using UV spectrophotometry to determine gallic acid content. The linearity, accuracy, robustness, and roughness of this approach were all verified. Gallic acid's retention time was measured in relation to the standard. After the chemical was purified, it underwent high-performance liquid chromatography (HPLC) to check for gallic acid.

The HPLC mobile phase is acetonitrile:water (30:70), with ortho-phosphate added to keep the pH at around 3. The linearity, precision, and accuracy of the procedure were all verified.[10]

RESULT AND DISCUSSION

The ethanol level was determined to be 10.70% v/v using the redox titration method, with a standard deviation of 0.828. Calibration curve for ethanol concentration versus standard peak area by gas chromatography (Figure 1). Over a l to 3% v/v concentration range, the calibration curve was determined to be linear (R = 0.992Using a calibration graph in which peak area was plotted against concentration, we were able to determine that the ethanol concentration in the sample was 10.70% v/v. Both approaches result in ethanol concentrations that are within the range specified on the bottle. The average formula pH was determined to be 3.89 µg/mL. Initial phytochemical analysis revealed the presence of Anthraquinone glycoside as well as reducing sugar, ketose, fructose, sucrose, glucose, glycogen, and tannins. Gallic acid concentration was determined from the formulation using UV spectrophotometer at 258 nm (Figure 2). Lambert-Beer's law was followed with a regression coefficient of 0.995 over a concentration range of 2 to 12 µg/mL. The concentration of gallic acid in the sample formulation, whose exact value is unknown, is 1.75 mg/mL. The RSD for this approach is 1.75%, while the standard deviation is 0.0076%. Low, medium, and high levels of recovery were examined, with results ranging from 98.37 to 103.25%. Absorbance measurements using a two-solvent system and two different instruments yielded standard errors of 0.002 and 0.0018, respectively. A 0.223 µg/mL LoD and a 0.67 µg/mL LoQ were determined. Gallic acid was measured quantitatively from the formulation using HPLC at 227 nm. Peak areas were linearly related to values above 2 to 8 µg/mL using the HPLC technique (r = 0.996). The concentration of the sample formulation, which was not disclosed, was equivalent to 1.7 mg/mL of gallic acid. The threshold for detection was set at signal strength three times that of the background noise. Values of 0.099 and 0.3 µg/mL were determined to be the LoD and LoQ, respectively. Analysis of the gallic acid quality in the formulation was used to establish the injection's repeatability in terms of quantity. RDS readings of 0.785 indicate a high degree of consistency.[11]

Analysis of the %recovery of marker constituents was used to calculate the accuracy (expressed as recovery) of the technique. Accuracy was good, as evidenced by high recovery values (90.87–106.93%) attained. Finally, the method's robustness was investigated by varying mobile phase, with the results summarized in Table 1 showing that tiny shifts in mobile phase had no influence on peak resolution (Figure 3). Pesticide residues, including organophosphate and carbamate, were not detected in the final formulation. None of the halogens (chlorine, bromine, iodine) were detected in the formulation, nor were nitrogen or sulfur. Lead levels were found to be within

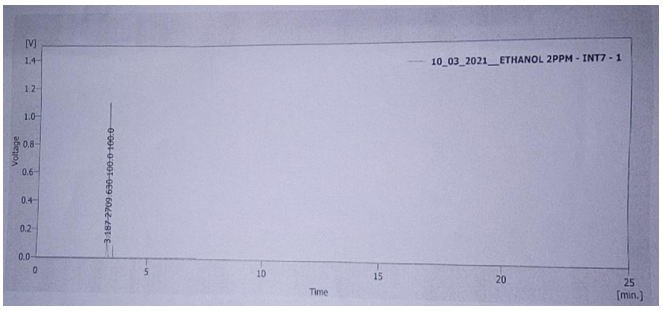

Figure 1: Standard ethanol gas chromatograph (2% v/v)

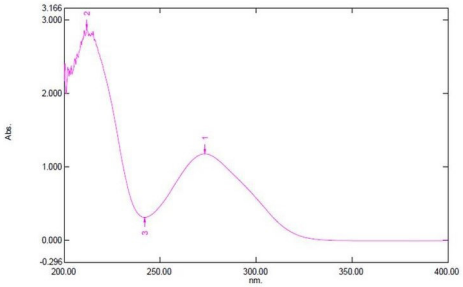

Figure 2: Gallic acid UV spectrum

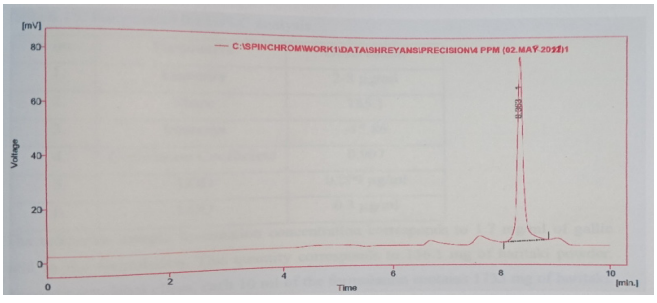

Figure 3: Standard Gallic acid HPLC chromatogram

Table 1: Parameter of UV and HPLC

Parameter	*UV*	*HPLC*
Linearity	2–12 µg/mL	2–8 µg/mL
Slope	0.045	185.1
Intercept	-0.0295	-15.86
Correlation coefficient	0.995	0.997
LoD	0.223	0.099 µg/mL
LoQ	0.676	0.3 µg/mL

Table 2: Heavy metal contamination of formulation

Elements	*Observation*	*Permissible limit*
Lead	0.8	10 µg
Cadmium	Nil	0.4
Arsenic	Nil	4µg
Mercury	Nil	-

Table 3: Permissible limits for different microorganisms

Parameter	*Observation*	*Permissible limits*
Aerobic viable bacteria	150 cfu/mL	10^7/g
Escherichia coli	Absent	100/g
Salmonellae's sp.	Absent	Absent

the allowable range, and cadmium, arsenic, and mercury were not discovered in the formulation, as indicated in Table 2. Results for the maximum allowable concentration of various harmful bacteria, as specified by WHO recommendations, are reported in Table 3.[12]

CONCLUSION

According to World Health Organisation (WHO) standards, we analyzed marketed Babbularishta. The sample's alcohol concentration was under the permitted threshold. To determine how much gallic acid is in the marketed ayurvedic formulation, routine analysis of gallic acid from the formulation using the suggested HPLC and UV procedures is possible. The UV method is less precise, sensitive, and selective than the HPLC approach. Additionally, the formulation passes the tests for microbiological load, heavy metal contamination, and pesticide residue.

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