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Research Article

STANDARDISATION OF *VILWADI LEHA* - A PROCESS VALIDATION BASED ON TOTAL SOLID METHOD

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ABSTRACT

Standardisation can be defined as a process of enforcing a level of consistency or uniformity in pharmaceutical preparations which are operated within the selected environment. *Vilwadileha* is a well-known Ayurvedic polyherbal formulation used for the management of various diseases such as *Chardi, Arochaka, Praseka, Agnimandhya* etc. It is described in *Sahasrayoga leha prakarana*. **Aim**: The objective was to develop the standard manufacturing procedure (SMP) and quality standards of *Vilwadi leha* based on total solid method. Total soluble solids content of a solution is determined by the index of refraction using either hand refractometer or Abbe refractometer. Brix is the term used when a refractometer equipped with scale, measures total soluble solids of a pure aqueous sucrose solution by the aid of refractive indices at 20°C and percentage by mass. **Materials and methods**: In present work, VL was prepared in three batches as per standard guidelines mentioned in AFI Vol 2. **Results:** *Samyak leha paka lakshanas* observed was compared with brix value and fix the brix value of VL prepared in 3 Batches. It took 10.40hr to completion of preparation. **Conclusion:** The current study opens a new concept to standardise *Avaleha*. This is a trial work to standardise the *Leha paka* with total solids analysis method or brix value. Brix for each preparation may differ based on sucrose concentration. It was found that *Leha* prepared with TS between 75 and 77 had parameters similar to *Samyak Leha paka*. Attempts were also made to develop analytical profile of final product.

INTRODUCTION

Standardisation in Ayurvedic formulations ensures the establishment of standards of quality and purity from the very stage of collection of raw materials to preparation of finished product, storage and its distribution. Classical reference of standardisation was mainly mentioned for small batches. During past, as *Vaidya*s prepare medicaments for their own patients the quality of the same are preserved to a greater extent. But today as a result of commercialization, bulk batch sizes are prerequisite. Therefore, stringent validation of quality is always a matter of concern. In this situation standardisation of pharmaceutical formulation has great relevance.

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Thus it becomes imperative to validate the standardisation techniques based on latest manufacturing situation. In addition to the effort to include criteria of standardisation, the study overview importance of improvements made to the conventional preparation processes with special reference to *Avalehakalpana.*

Degrees Brix is a measure of the total soluble solids (TSS) present in the preparation made up of sugars but also includes other compounds. Brix refractometers show the concentration of the soluble solids content (total solids) of a water-based solution. The soluble solids content is the total of all the solids dissolved in the water such as sugar, salts, proteins, and acids. The measurement reading value is the sum total. Brix values are important because they can be measured objectively and they relate to a subjective criterion that buyers and eaters use to assess quality-flavour or sweetness of a formulation containing sugar and its derivatives[(1)].

Avalehas are semisolid dosage form with jaggery or sugar as its base used internally for the cure of various ailments[1]. According to *Acharya Sharangadhara, Avaleha* can be considered as an *Upakalpana* of *Kwatha kalpana* (*Kwathadinam punahpakaat*)[2] *Avaleha*, is synonymous with dosage forms like *Leha*, *Khanda*, *Ghana*, and is prepared by the addition of *Prekshepa dravyas* to a concentrated syrup of sweetening agents like jaggery, sugar, sugar candy *Kwatha* and *Swarasa dravya*. It is prescribe with suitable *Anupanas* in variety of ailments[3].

Vilwadileha is a well-known Ayurvedic polyherbal formulation used for the management of various diseases such as *Chardi, Arochaka, Praseka, Agnimandhya* etc. It is described in *Sahasrayoga leha prakarana*[4]. The nomenclature is based on its one main ingredient *Vilwa.*

In conventional system *Avaleha sidhi lakshanas* are mainly followed to asses *Samyak leha paka*[5]. This is a trial work to standardise the *Leha paka* with total solids analysis method. It was found that *Leha* prepared with TS 75-77 had parameters similar to *Samyag leha paka*. Attempts were also made to develop analytical profile of *Vilwadi leha* (VL).

OBJECTIVES

1. Collection of raw materials
2. Authentication of raw materials
3. Preparation of *Vilwadileha* as per AFI Part 1 (Sahasrayoga reference)
4. Pharmaceutical study of *Vilwadileha*
5. Analytical study of *Vilwadileha*

MATERIALS AND METHODS

The raw drugs were procured from the RM store of pharmaceutical corporation. All the herbal ingredients were authenticated at the R and D lab.

Equipments used

Stainless steel vessel, stainless steel ladle, steel pan, clean cotton cloth (1.5x1.5 feet), measuring jar, sieve (10mm mesh size), weighing machine and gas stove.

Pharmaceutical Procedure

VL was prepared at formulation unit of department of Research and Development of Pharmaceutical corporation, Thrissur. Steps involved in its preparation are as follows.

***Kwatha* Preparation**

Vilwa moola in *Yavakuta* form (coarse powder 10#) was taken in a stainless steel vessel and added with eight times of potable water. The contents were heated (80-100°C) and reduced to one-fourth part. Decoction was filtered, measured and kept aside.

***Prekshaepa choorna* preparation**

Item 2 to 9 were powdered in a cutter mixer, pulverised and sieved through 80 mesh to obtain fine powder.

Preparation of *Avaleha*

Prepared *Kwatha* was added with 3.072kg *Guda* (Jaggery). The contents were subjected to mild heating over gas stove till the complete dissolution of jaggery in it. Later the jaggery dissolved in *Kwatha* is filtered to remove all physical impurities. Again the filtrate is subjected to heating under moderate flame. After getting one thread consistency, the TS (brix value) of preparation was noted and found to be at 76. The experiment was validated by checking brix in 2 more batches. The *Prekshepas* were added in *Kwatha*-jaggery syrup. Flame was turned off. They were mixed thoroughly into uniform consistency.

Table 1: **Ingredients of *Vilwadi leha***

Ingredients	**Quantity**
Vilwa Moola	6.14 Kg
Musta Root	48gm
Dhanyaka	48 gm
Jeeraka	48 gm
Ela	48 gm
Patra	48 gm
Twak	48 gm
Maricha	48 gm
Pippali	48 gm
Sarkara	3.072Kg
Water	49.152 L reduced to 12.288 L

Fig 1: Ingredients of *Vilwadi leha*

Vilwa moola

Musta

Dhanyaka

Patra

Jeeraka

Ela

Twak

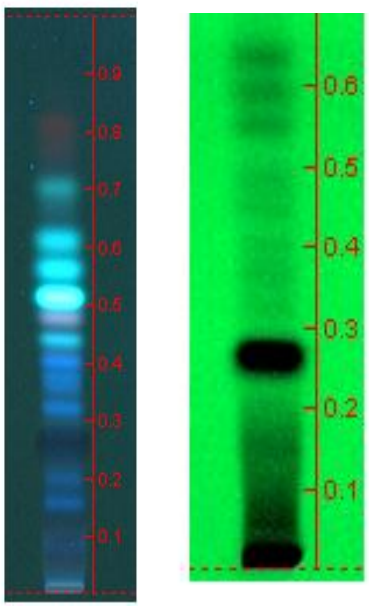
Pippali

Maricha

Guda

Fig 2: Manufacturing procedures of *Vilwadi leha*

a. Preparation of *Kashaya* b & c. Reduction d. Filtering e. Addition of *Guda* f. testing of *Leha paka* g. Adding *Prekshepa* at time of h. *Leha paka* and Mixing into uniform constituency. i. Testing total solids.



366nm **254nm**

Fig 2: TLC plate views of *Vilwadi leha* samples at 366nm and 254 nm

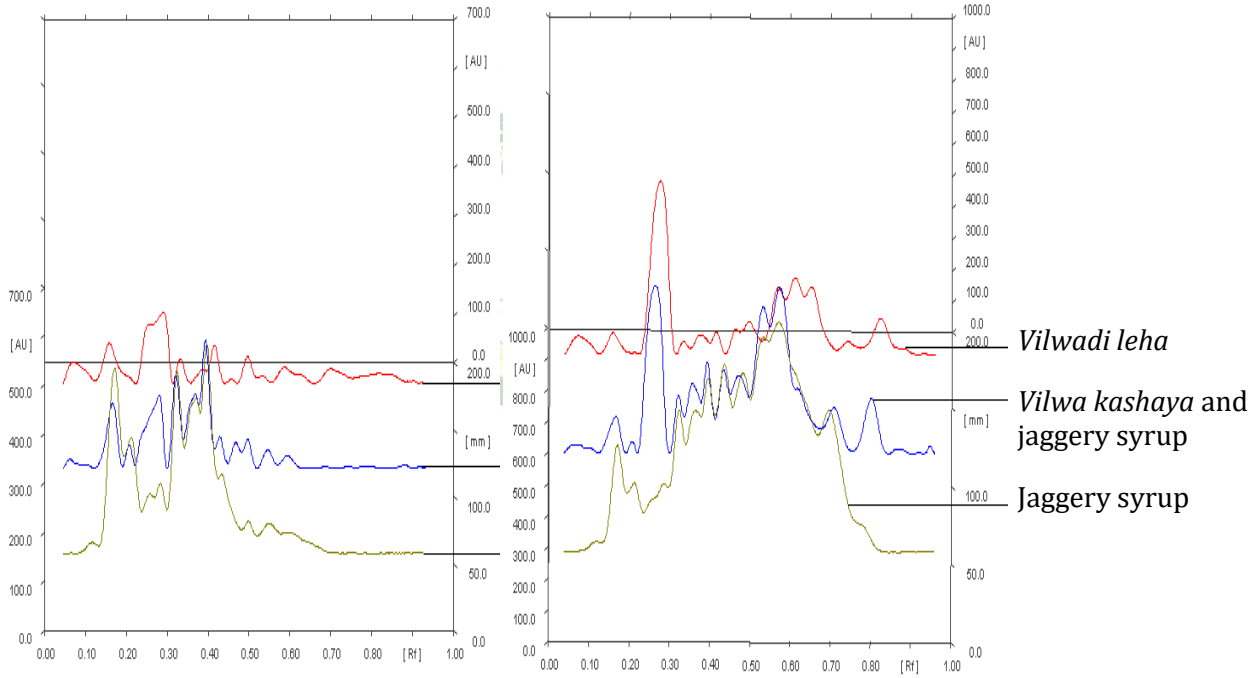


Fig 3: Overview image of *Vilwadi leha* at 254nm and 366nm

RESULTS AND DISCUSSION

Analytical Study

The following analytical parameters of *Vilwadi leha* were analysed and tabulated at department of R and D section of Pharmaceutical Corporation.

- Determination of pH
- Moisture
- Total ash
- Acid-insoluble ash value
- Alcohol-soluble extractive value
- Water-soluble extractive value
- Total solid content
- Total sugar estimation
- Microbial limit test

Table 2: Physico-chemical analysis of 3 batches of *Vilwadi leha*

Parameters	Batch 1	Batch 2	Batch 3
Colour	Dark brown	Dark brown	Dark brown
Loss on drying	4.862	4.751	4.538
pH	4.51	6.86	6.20
Presence of Hydrose	Nil	Nil	Nil
Colour of Hydrose	Nil	Nil	Nil
Total sugar	88.13	87.57	88.27
Extraneous Matter	0.66	0.62	0.64
Total Ash	0.3243	0.3684	0.3543
Total bacterial count	$5.7X10^4$	$5.1x10^4$	$4.8x10^4$
Total yeast and mould count	TFTC	TFTC	TFTC
Total solids	76	76	77

Average percentage yield of *Prakshepa* was 88.67%. During the procedure of *Avaleha*, the temperature was maintained in-between 90°C and 100°C and observed *Darvi pralepatvam* at 94°C, *Tantumatvam* at 95°C, *Apsumajjanam* at 97°C, and *Sthiratvam* at 97°C. Average yield was found as 5745 g. It took altogether 10.40 hr to complete the preparation of *Avaleha*. Details of desired characteristics of VL are placed at (Table 3).

Table 3: **Characteristic features of *Vilwadi leha* during *Siddhi lakshana***

S.No	*Siddhi lakshana*	Time of appearance after adding *Guda* in *Kashaya*	Temperature in (^oC)
1	*Darvi pralepa*	9.50	94
2	*Tantumatwa*	10	95
3	*Apsumajjanam*	10.15	97
4	*Sthiratwa*	10.40	97

DISCUSSION

Standardisation at each step right from the beginning of collection of raw materials to the preparation of finished product is very much essential to confirm quality. *Avaleha* is a semisolid formulation which involves *Drava dravya*, sweetening agent like *Guda*, sugar or sugar candy and *Prekshepa dravyas* in its preparation. The amount of water to be added with the raw material differs depending on the quantity and quality of the raw material. In the present study, VL was prepared as per the reference *Sahasrayoga Leha prakarana* quoted in AFI part 1. Before the processing of *Prekshepas,* physical impurities were removed manually and cleaned thoroughly. A loss of 8.32% loss was observed during preparation of *Prakshepa*. *Kwatha dravya* was made into coarse powder for proper extraction of the active principles. The pharmaceutical procedure mentioned in *Sahasrayoga* and Ayurvedic Formulary of India (AFI) are same. The final result thus obtained is validated by preparing two more batches.

During *Avaleha* preparation when syrup achieved one thread consistency, TS was noted and found to be 76. Degrees Brix is a measure of the total soluble solids (TSS) present in the preparation made up of sugars but also includes other compounds. Brix refractometers show the concentration of the soluble solids content (total solids) of a water-based solution. The soluble solids content is the total of all the solids dissolved in the water such as sugar, salts, proteins, and acids. The measurement reading value is the sum total. Brix values are important because they can be measured objectively and they relate to a subjective criterion that buyers and eaters use to assess quality-flavour or sweetness of a formulation containing sugar and its derivatives. *Prekshepas* were added after obtaining appropriate TS. Heating process was stopped and vessel was removed from fire and mixed thoroughly to ensure uniform consistency. 5.745kg VL was obtained.

The *Avalehasiddhi lakshanas* such as *Darvipralepatvam*, *Tantumatvam*, *Apsumajjati*, and *Patitastunashiryate* are noted at each stage. These parameters, indicates the time to remove the vessel from the fire, and addition of the *Prakshepas*. Among the *Asanna Paka Lakshana* of *Avaleha*, first *Darvipralepatvam* could be noticed, and then, the *Tantumatvam* stage appeared. *Appsumajjati* stage was the third.

The consistency of the final product depends mainly on the TS at which it is prepared. It was found that *Leha* prepared with TS 75-77 had parameters similar to *Samyak lehapaka*. TS above 80 make the formulation to change in *Khanda* stage. Two more trial batches were prepared to confirm final result. Analytical study validates that the three batches were almost similar in their monograph. The physio chemical parameters of three batches are also within specified limit and helped to obtain a blue print of VL. Physico chemical values obtained are in par with API. pH shows the formulation is acidic. Total sugar was estimated at 89.32. HPTLC fingerprinting reveals 11 spots of rf values respectively at 0.01, 0.17, 0.2, 0.32, 0.36, 0.38, 0.41, 0.43, 0.48, 0.58, 0.72. in long wave uv at 366nm and 7 spots of rf values respectively at 0.01, 0.25, 0.33, 0.36, 0.45, 0.55, 0.58 in short wave uv 254nm (Fig 3).

CONCLUSION

As a traditional practice, *Avaleha sidhi lakshanas* are mainly depend to assess *Samyak leha paka*. This is a trial work to standardise the *Leha paka* with total solids analysis method. It was found that *Leha* prepared with TS 75-77 had parameters similar to *Samyak lehapaka*. Attempts were also made to develop analytical profile of *Vilwadileha* (VL). When the traditional knowledge gets blended with modern scientific validation it helps in better appreciation to existing Ayurvedic principles. The developed SMP may be taken in further pharmaceutical study and also, it will be helpful in further scientific research.

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