



Research Article

**MICROBIAL STABILITY OF NAYOPAYAM PRAVAHI KWATHA**

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**ABSTRACT**

*Pancha vidha kashaya kalpana* are five basic medicinal preparations mentioned in Ayurveda pharmaceuticals, which includes *Swarasa, Kalka, Kwatha, Hima and Phanta*. They are the different set of extraction procedures. Among them *Kwatha Kalpana* is most significant and widely used dosage form. This is prepared by boiling of drugs with water in a specific proportion. *Pravahi kwatha* is concentrated *Kashaya* obtained by boiling the ingredients in a given amount of *Jala* (API part 2 volume 4). Addition of preservatives in *Pravahi kwatha* is permitted as per API. *Nayopayam Pravahi kwatha* is a decoction prepared with *Bala, Jiraka, Shunti* in a ratio 10:2:2 (API Part 2 volume 4). *Kwatha Kalpana* has more chance to get contaminated with microbes as it is an aqueous preparation. Preservatives help to prevent microbial contamination. As per previous researches it was noted that the amount of preservatives in *Kwatha* preparation is more than the permitted limit. To determine the microbial stability of *Nayopayam Pravahi Kwatha*, a long-term shelf life study was conducted. Analytical parameters such as microbial contamination, colour, odour, taste, pH, specific gravity, and total solid content were assessed at specified interval. An online survey was conducted among the GMP certified companies in Kerala preparing concentrated *Kashayas* to collect the details of preservatives in concentrated *Kashaya*. As per the study it was observed that *Pravahi kwatha* with double the permitted amount of preservatives was stable only upto 3 months.

**INTRODUCTION**

*Kwatha* is obtained by boiling the drugs in water. *Kwatha* is the fundamental formulation for other *Kalpanas* such as *Sandhana Kalpana, Sneha Kalpana, Rasakriya*, and *Avaleha*. It's made in an aqueous media, so there is a chance of microbial contamination. Due to a lack of time, self-preparation of *Kwatha* is difficult in today's life. As a result, more stable and convenient pharmaceutical products that may be accepted by customers are required. In this condition *Pravahi kwatha*<sup>[1]</sup> plays an important role as it is meant for instant use after diluting with water.

*Pravahi Kwatha* is concentrated *Kashaya* prepared by boiling the ingredients in 16 times of water and then reducing the *Jala* to 1/8th of its original volume. The decoction thus obtained is filtered and again boiled to reduce further to 1/4th and preservatives are added. Addition of preservatives in *Pravahi kwatha* is permitted as per API. Preservatives in *Pravahi kwatha* prevent microbial growth and maintain its shelf life. According to drug and cosmetic rules 1945, rule no: 161 B, the shelf life of *Pravahi kwatha* is 3 years. Generally used preservatives in Ayurvedic products are benzoic acid, sodium benzoate, Propyl paraben, Methyl paraben, bronopol etc. In concentrated *Kashayas* pharmacies are adding preservatives in combination, while it is restricted in drug and cosmetic rule 1945 (rule number 169). Long term shelf life studies helps to analyse the physical, chemical, biological, biopharmaceutical and microbiological characteristics of a drug, during and beyond the expected shelf-life. So there is a need of research and pharmaceutical survey to study the

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microbial stability of preservatives in *Pravahi kwatha* by analysing microbial stability and basic parameters like colour, odour, taste, pH value, specific gravity and total solid content through Long term shelf life study.

#### AIMS AND OBJECTIVES

- To find out the microbial stability of *Nayopayam pravahi kwatha*<sup>[2]</sup> through long term shelf life study
- To analyse the changes in physico chemical parameters of *Pravahi kwatha* at specified intervals
- To find out the types and concentration of preservatives in *Pravahi kwatha* used by different pharmacies by an online survey

#### MATERIALS AND METHODS

##### Ingredients of *Nayopayam Pravahi kwatha*

S.No	Ingredients	Botanical name	Part used	Ratio	Quantity taken
1	<i>Bala</i>	<i>Sida cordifolia</i>	Root	10	1000 gm
2	<i>Jeeraka</i>	<i>Cuminum cyminum</i>	Fruit	2	200 gm
3	<i>Shundi</i>	<i>Zingiber officinale</i>	Rhizome	2	200 gm
4	water			16	22400 ml



**Bala Root**



**Jeeraka Seeds**



**Shunti Rhizome**

#### Preparation of *Pravahi Kwatha*

Good quality raw materials were procured from reputed pharmacies. *Sida cordifolia* variety of *Bala* was collected from Thripunithura. *Shunti* and *Jeeraka* were collected from local market in Trivandrum. Raw materials were cleaned washed and dried. The physico chemical analysis of raw drugs such as identity, purity, strength, and powder microscopy were done to ensure its genuinity. Total 3 batches were prepared. In the first batch raw drugs were manually crushed. In the second and third batch raw drugs were crushed using disintegrators. From each batch *Kashaya*, *Pravahi kwatha* with permitted amount of preservatives<sup>[3]</sup>, *Pravahi kwatha* with double the permitted amount of preservatives were taken in sterilised bottles.

- 1000gm of *Bala*, 200gm of *Shunti*, and 200gm of *Jeeraka* were taken and crushed into small pieces.
- Boiled the crushed ingredients in 16 times of water and reduced to 1/8.
- *Kashaya* was filtered through a cloth and collected in 6 sterilized bottles for checking microbial contamination at specified intervals.
- To prepare *Pravahi kwatha*, the remaining *Kashaya* was concentrated to 1/4th.
- After cooling, permissible amount of methyl paraben (0.1%) and propyl paraben (0.01%) were added to the *Pravahi kwatha*, which was then stored in 6 sterile bottles.
- After that, double the permitted amount of methyl paraben and propyl paraben were added to the *Pravahi kwatha* and stored in 6 sterile bottles.
- It was stored under controlled environment at the microbiology lab in Drug standardisation unit, Government Ayurveda college, Trivandrum.

The study comprised of 3 stages

1. Online survey
2. Preparation of *Nayopayam pravahi kwatha*
3. Evaluation of changes in analytical parameters of *Nayopayam pravahi kwatha* at specified interval

#### Survey

10 GMP certified companies in Kerala were randomly selected and an online survey was conducted through Google forms. Out of them, 6 pharmacies were responded. The main areas covered in the questionnaire were preparation of *Kwatha*, preservation, packing, and marketing.

Ingredients boiled in water and reduced to 1/8

It was filtered and *Kashaya* without preservatives was collected in 6 sterilised bottles

Remaining *Kashaya* was again boiled and reduced to 1/4 to prepare *Pravahi kwatha*

Permitted amount of preservatives were added and *Pravahi kwatha* was collected in 6 sterilised bottles

Double the permitted amount of preservatives were added and *Pravahi kwatha* was collected in 6 sterilised bottles



***Kashaya* collected in sterilized bottles**

### Organoleptic Features

Organoleptic characters were assessed on first day, third month and sixth month

#### pH

pH<sup>[4]</sup> of *Kwatha* were assessed on first day, third month and sixth month. 5ml of the *Kwatha* was dissolved in 100ml of distilled water. Then the pH of the solution was measured using a pH meter. pH of the samples were assessed as per the method mentioned in API.

#### Total Solids

Total solids<sup>[5]</sup> of the samples were assessed as per the method mentioned in API.

#### Specific Gravity

The specific gravity<sup>[6]</sup> of a liquid is the weight of a given volume of the liquid at 25°C (unless otherwise specified) compared with the weight of an equal volume of water at the same temperature, all weighing being taken in air. Specific gravity of the samples were assessed as per the method mentioned in API.

#### Microbial Contamination

The pour plate technique<sup>[7]</sup> was used to detect the microbial growth of the sample. The culture media was prepared with nutrient agar, MacConkey agar, Peptone water and sabouraud dextrose agar.



**Culture media**

**RESULTS****Organoleptic Features**

The taste and odour of the samples were not evaluated after they were contaminated with microbes.

Sample	Colour
K1,K2,K3	Initially- Light brown 1 month - Dark brown
3 batches of <i>Pravahikwatha</i>	Dark brown from time of preparation till 6 months

Sample	Taste, Odour
K1	<i>Katu tiktha rasa</i> and characteristic smell till 1 month
K2,K3	<i>Katu tiktha rasa</i> and characteristic smell till 1 week
P1	<i>Katu tiktha rasa</i> and characteristic smell till 3 months
P2,P3	<i>Katu tiktha rasa</i> and characteristic smell till 1 month
D1,D2,D3	<i>Katu tiktha rasa</i> and characteristic smell till 3 months

K1 - *Kashaya* sample 1

K2 - *Kashaya* sample 2

K3 - *Kashaya* sample 3

P1 - *Pravahi kwatha* sample 1 with permitted amount of preservatives

P2 - *Pravahi kwatha* sample 2 with permitted amount of preservatives

P3 - *Pravahi kwatha* sample 3 with permitted amount of preservatives

D1 - *Pravahi kwatha* sample 1 with double the permitted amount of preservatives

D2 - *Pravahi kwatha* sample 2 with double the permitted amount of preservatives

D3 - *Pravahi kwatha* sample 3 with double the permitted amount of preservatives

**pH**

Sample	At the time of preparation	3 <sup>rd</sup> month	6 <sup>th</sup> month
K1	5.42	5.13	4.8
P1	5.41	5	4.91
D1	5.45	5.21	4.94
K2	5.51	5.16	4.82
P2	5.54	5.34	4.84
D2	5.57	5.254	4.85
K3	5.46	4.98	4.72
P3	5.52	5.49	4.93
D3	5.57	5.124	4.99

**Total Solids**

Sample	At the time of preparation	3 <sup>rd</sup> month	6 <sup>th</sup> month
K1	9.23	9.13	8.31
P1	28.56	28.426	27.89
D1	28.936	28.121	27.756
K2	11.56	11.32	10.41
P2	33.63	32.934	31.21
D2	33.926	33.345	32.31
K3	13.42	13.18	12.43
P3	35.521	34.143	34.542
D3	35.768	35.547	34.654

**Specific Gravity**

Sample	At the time of preparation	3 <sup>rd</sup> month	6 <sup>th</sup> month
K1	1.002	1.002	1.001
P1	1.04	1.04	1.03
D1	1.04	1.04	1.03
K2	1.004	1.004	1.002
P2	1.05	1.05	1.03
D2	1.05	1.04	1.03
K3	1.004	1.003	1.002
P3	1.05	1.05	1.03
D3	1.05	1.05	1.03

**Microbial Stability**

Sample	<i>Kashaya</i> without preservative	<i>Pravahikwatha</i> with permitted preservative	<i>Pravahikwatha</i> with double the permitted preservative
First batch (sample prepared with manually crushed drugs)	1 month	3 month	3 month
2 <sup>nd</sup> & 3 <sup>rd</sup> batches (sample prepared with disintegrated drugs)	1 week	1 month	3 month

**Microbial growth****DISCUSSION**

As per the survey, all pharmacies responded that *Kashaya* with the permitted amount of preservatives maintains their stability upto 3 years. The methods for industrial manufacturing of *Kwatha* differ significantly from the literature. The preservatives are chosen based on the pH of the *Kashaya*. Sodium benzoate is the commonly used preservative. All pharmacies use mixture of sodium benzoate, methyl paraben and propyl paraben. Neither of the pharmacies had mentioned the complaints of concentrated *Kashayas*. Only one pharmacy opined that they are reducing *Kashaya* into 1/32. All other pharmacies responded that reduction ratio depends upon the capacity of drug boilers.

Non-parametric Wilcoxon's signed rank test was used to assess the variations in pH, total solids, and specific gravity. There was no significant variation

noted in pH, total solids and specific gravity from day 1 to third month and third month to sixth month in each group.

**Microbial Growth Detection**

- First batch *Kashaya* prepared without adding preservative was free from microbial contamination upto 1 month.
- Second and third batch *Kashayas* prepared without adding preservatives were free from microbial contamination upto 1 week.
- First batch *Pravahi kwatha* with permitted amount of preservatives (0.1% Methyl paraben, 0.01% Propyl Praben) and double the permitted amount of preservatives were free from microbial contamination upto 3 months. But the total microbial plate count in *Pravahi kwatha* with

double the permitted amount preservative was less than that in permitted amount.

- Second and third batch *Pravahi kwatha* with permitted amount of preservatives were free from microbial contamination upto 1 month.
- Second and third batch *Pravahi kwatha* with double the permitted amount of preservatives were free from microbial contamination upto 3 months.
- The first batch of *Kashaya* was prepared with manually crushed drugs. The second and third batches were prepared from disintegrated drugs. Second and third batches were less stable than first batch. It may be due to the entry of more starch contents and phyto constituents into the *Kashaya*. While utilizing disintegrators to reduce size, instead of crushing, breaking occurs. More starch and other phyto constituents enter into the solution when the size of raw materials is too small. All the 3 batches of *Pravahi kwatha* with double the permitted amount of preservatives were stable only up to 3 months. Pharmacies are adding preservatives in combination, even though it is prohibited by drug and cosmetic rules. Under the PFA acts and rules, Rule no: 54, the addition of more than one class II preservative is prohibited. Benzoic acid and a wide range of its derivatives are commonly used as preservatives. Adverse reactions to benzoates has been reported. Addition of preservatives in *Pravahi kwatha* or concentrated *Kashaya* is permitted as per API. As per D&C rule shelf life of *Pravahi kwatha* is 3 years. Based on these rules related with *Pravahi kwatha* pharmacies are adding preservatives in concentrated bottled *Kashayas* and they opine that shelf life of bottled *Kashaya* is 3 years. But the pharmacies are not following the exact method of preparation for concentrated *Kashaya* mentioned in API. In API *Pravahi kwatha* or concentrated *Kashaya* is prepared by reducing the initial water content into 1/32. But only one pharmacy opined that they are reducing the water content into 1/32. A common procedure for the preparation of *Kvatha* must be employed by all pharmacies, that is a Standardized procedure which is mentioned in API. Lack of uniformity in the choice of preservatives is another concern. Along with standardizing the procedure, the concentration of preservative added should also be fixed in such a way that it does not

cross the permitted level. Even though all the samples were kept in sterilized bottles, the sample with double the permitted amount of preservatives maintained its stability only up to 3 months. As a result, the three-year shelf life of *Pravahi kwatha* under the D&C rules must be revalidated.

## CONCLUSION

In comparison to textual references, the procedure for preparing *Kwatha* in an industrial scale differs significantly. The type of the preservatives used by major pharmacies had variation. So the three-year shelf life for *Pravahi Kwathas* as per Drug and Cosmetic rule must be reviewed and revised. Proper authentication in regard to concentration and combination of preservatives must be done.

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