

Estimation of Sodium Benzoate in Ayurvedic Formulation: *Kashaya* (Water Decoction)

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Sodium benzoate, the food grade preservative, is the most commonly used preservative in *kashaya*-the water decoction of ayurvedic formulation. No standard procedure was known for the estimation of sodium benzoate in *kashaya*. The titrimetric estimation of benzoic acid using NaOH can be used as a standard method for its estimation. The amount of sodium benzoate observed in the commercial samples of *nayopayam kashaya* were many fold than that of maximum level allowed for food samples.

Key Words: Estimation, Sodium benzoate, *Kashaya*.

INTRODUCTION

Ayurveda and other traditional medicines are gaining popularity, particularly for the treatment of a variety of chronic diseases¹. The ayurvedic formulations *asava* and *arista* are resistant to deterioration because of the removal of starch materials by fermentation and large proportion of alcohol in them. The low growth rate of microbes in oil enhances the shelf life period of oil preparations like *ghrita* and *taila*. The low water activity resists the growth of microbes in formulations like *vati*, *gutika*, *churna*, etc. However they cannot be stored for many years. The water preparations like *kashaya* (water decoction) are least resistant to microbial attack and it is the most common formulation in Kerala/South India. Traditionally *kashaya* has to be consumed before cooling down to normal temperature (35-40°C)². Similarly the *kudineer*, the water decoction of siddha system of medicine has to be consumed within 3 h of preparation³.

The *kashaya* is easily prone to microbial attack and thus can be marketed only by the addition of suitable preservatives. Large number of natural preservatives like organic acids, terpenes and phenolic acids were suggested especially of herbs origin⁴. The studies of these natural preservatives are in primitive level^{5,6} and commercialization requires elaborate studies in different branches of science. Law does not allow the addition of non-herbal substances in herbal formulations. The Drugs and cosmetics rules, 1955 is amended to prevent the addition of allopathic drugs to the herbal products⁷. The addition of preservatives to Ayurvedic drugs are

supported by the draft national policy on ISM 2001, under section 7, states, industry would be encouraged to adopt modern dosage form and follow reasonable shelf life periods⁸.

Each producer had their own combinations of preservatives and kept them as their secrets know how. Even then, the most common preservative used in ayurvedic formulations is sodium benzoate, the food grade preservative and generally recognized as safe (GRAS). There is no standard method for the estimation of sodium benzoate (or similar compounds) in *kashaya*. Number of methods using sophisticated instruments was available for its estimation in food⁹⁻¹¹. The volumetric method is adopted in food chemistry¹² since most of the Ayurvedic drug manufacturers are small-scale industrialists and cannot afford costly instruments. More over with the suggested laboratory equipments for GMP certification¹³ only volumetric method is possible.

EXPERIMENTAL

Preparation of *kashaya*

Standardization of procedure for the estimation of sodium benzoate is conducted in two common *kashaya*'s containing least number of components. *Nayopayam kashaya* containing dried roots of sida (*Sida retusa* L. sanskrit - *bala* [In north India *Sida cordifolia* is usually used as *bala* but in south India *sida retusa* is used], malayalam-*kuruthotti*), dry ginger (*Zingiber officinale* Rose., sanskrit - *sringa veram*, malayalam - *chukku*) and cumin (*Cuminum cyminum* Lin., sanskrit - *geera*, malayalam-*geerakam*) and *amrithotharam (amrithadi) kashaya* containing stem of heart leaved moonseed (*Tinospora cordifolia* Miers., sanskrit-*guluchi/madhuparni*, malayalam-*chittamrith*), dry ginger and seed coat of chebulic mirobalan (*Terminalia chebula* Retz., sanskrit - *harithikilabhaya/rohini*, malayalam - *kaddukka*). The *kashaya*'s were prepared as per the standard text¹⁴ with the help of a registered medical ayurvedic practitioner.

Estimation of benzoate

Kashaya's containing requisite concentration of sodium benzoate were prepared by the addition of calculated amount of A.R. sodium benzoate (Glaxo) in 100 mL samples of freshly prepared *kashaya*. The benzoate was dissolved completely by stirring and kept for 1 d for attaining stabilization. The amount of sodium benzoate was estimated by titrimetric method by the estimation of benzoic acid using standard sodium hydroxide solution.

Pipette 50 mL spiked *kashaya* in to 250 mL standard flask. Add 8 g powdered sodium chloride and dissolve with constant stirring. Using satu rated sodium chloride solution diluted to 150 mL and made alkaline to litmus with 10 % NaOH solution. The solution is made up to the mark

with saturated sodium chloride solution. The solution is kept for 2 h with occasional shaking (preferably overnight). 100 mL of the solution is transferred in to 500 mL separating funnel. Add dil. HCl (1:3) drop by drop till the solution is slightly acidic. Add 2 mL HCl in excess. The solution is kept for 0.5 h for the complete conversion of benzoate to benzoic acid. The solution is washed with 50, 40 and 30 mL of chloroform successively and the washings are collected together in an R.B. flask. The formation of emulsion is occasionally observed. If emulsion is formed, dilute with more water and centrifuged if necessary. The complete break down of emulsion is required. It is observed that 90 % benzoic acid is found with the formed emulsion. If a colour or opaqueness is developed in chloroform fraction, washed with water till a clear solution is obtained. Excess washings were avoided to reduce the removal of benzoic acid with water. The chloroform was distilled off keeping the R.B. flask in a water bath. If there is a possibility of simple organic acids like acetic acid in kashaya sample then the complete evaporation of chloroform is required. The residue is dissolved in minimum amount of ethyl alcohol or acetone and diluted to 20 mL with water and titrated against standard 0.05 N NaOH solution taken in a burette using phenolphthalein as indicator.

$$\text{The amount of sodium benzoate in percentage} = \frac{\text{Titre} \times \text{Normality of NaOH} \times 144 \times \text{Volume made up} \times 100}{\text{Volume taken for estimation} \times \text{Volume of kashaya pipetted} \times 1000}$$

If the above procedure is followed using the same volumes of the solutions as discussed then the equation is simplified to,

$$\% \text{ sodium benzoate} = 0.72 \times \text{Titre} \times \text{Normality of NaOH}$$

(To estimate as benzoic acid use 122 in place of 144 in the above equation)

RESULTS AND DISCUSSION

The estimation of sodium benzoate in *kashaya* is based on the high solubility of sodium benzoate in water (556 g dm^{-3} at 20°C) and the low solubility of benzoic acid in water (2.91 g dm^{-3} at 20°C). In chloroform a reversal in solubility is observed. The procedure for the estimation of benzoate and benzoic acid were established by estimating their concentrations in prepared samples of 0.1 % solutions in water. 100 % recovery by the solvent chloroform is observed (Table-1). Estimation of acids in freshly prepared samples of *kashaya* revealed that there are no natural acid constituents in them. The amount of sodium benzoate estimated in spiked samples of *kashaya* after 24 h of its addition is given in Table-1. The reproducibility of the method is confirmed by repeating the estimation in

different spiked samples at least by two different persons. The data showed that this method is suitable for these *kashaya*'s and can be extended to other *kashaya*'s after the standardization of the technique. This method even though tire some, it can be employed in any ordinary laboratory with a graduate in Chemistry.

The recovery of added sodium benzoate by the solvent chloroform can be affected if there is strong interaction of preservative with any phytochemical component present in the *kashaya*. A reversible interaction and ionization does not affect the recovery since the procedure adopted converts the whole preservative to sodium benzoate and then to benzoic acid. The possible variations in the quantitative estimation of sodium benzoate with time are studied in different spiked samples. Estimations were conducted once in 10 d for a period of 60 d. No variations are noticed, the values obtained are within the error limits as shown in Table-1.

TABLE-1
ESTIMATION OF SODIUM BENZOATE (%) IN DIFFERENT SAMPLES

Solution estimated	Amount added	Amount estimated*
Benzoic acid in water	0.10	0.10 ± 0.001
Sodium benzoate in water	0.10	0.10 ± 0.003
Sodium benzoate in <i>amrithotharam kashaya</i>	0.10	0.10 ± 0.004
	0.25	0.26 ± 0.005
	0.50	0.52 ± 0.008
	1.00	0.99 ± 0.010
Sodium benzoate in <i>nayopayam kashaya</i>	0.10	0.11 ± 0.004
	0.25	0.24 ± 0.006
	0.50	0.51 ± 0.009
	1.00	1.02 ± 0.010

*Recovery of sodium benzoate from spiked samples with 3 replicate determinations.

Even though sodium benzoate is a common preservative of food, the drugs and cosmetic act of India does not allow its addition to Ayurvedic formulations⁷. As per the recommendations of the task force submitted to the Government of India, Excipients which are already approved as pharmaceutical aids in modern medicines industry and standard monographs are available in various pharmacopoeias like IP, BP, USP, NF, *etc.*, should be permitted for use as long as the manufacturer can provide rationality for their usage and quantum used⁸. A daily intake of < 0.5 g is tolerable to humans¹⁵. No accumulation of benzoic acid occurs in body (up to 4 g/day) because it is metabolized and eliminated in urine as hippuric acid or glucuronic acid for higher levels of intake¹⁶. The maximum allowed

concentration in food as per FDA is only 0.1%¹⁵. But it is observed that there is indiscriminate addition of sodium benzoate or similar preservatives, which can be estimated as benzoic acid equivalents.

There is no direct evidence for the toxicity of sodium benzoate or benzoic acid within the approved levels, only allergic interactions are noticed¹⁷. The *nayopayam kashaya* is prescribed for the treatment of allergic ailments such as *kasa* (bronchial asthma, etc.)¹⁴. The *kashaya* provided for allergic interactions if spiked with proved allergens like benzoate or benzoic acid, whatever may be the reasons for their addition, it might have adverse effect on the curative ability of this medicine. The precipitation of allergic interactions cannot be avoided in such situations. The amount of benzoate is thus estimated in commercial samples of *nayopayam kashaya* (Table-2).

TABLE-2
ESTIMATION OF SODIUM BENZOATE IN COMMERCIAL
SAMPLES OF *Nayopayam kashaya*

Manufacture	Batch No.	Date of Manufacture	Benzoate* (%)
Arya Vaidya Sala, Kottakal	64018	9/2003	1.31
The Arya Vaidya Pharmacy, Coimbatore	46676	8/05/2002	0.65
Oushadi, Trichur	0901	13/9/2000	0.38
Nagarjuna Herbal Concentrates (Ltd.), Trichur	CKAK	11/2002	2.11
Sreeram Herbal Remedie (P) Ltd., Tichur	5776	7/2002	0.49
Vaidyaratnam Oushadasala Ollur, Trichur	1634	9/2004	0.83

*Estimated by volumetric method as benzoic acid equivalent.

The drug and cosmetics act of India¹³ (Rule 161) insists, a conspicuously displayed label on the container or package of an Ayurvedic (including siddha) or Unani drug, with the true list of all the ingredients used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard text and *adikarana*, as are prescribed in the authoritative books specified in the first schedule of the act. None of the commercial packages we received contain a list of ingredients added to the *kashaya*. Only a reference sahasrayoga is given. The commonly used sahasrayoga in Malayalam did not have the *nayopayam kashaya* formulation in it¹⁸.

The study is not meant for ascertaining the quality of *kashaya* but to show that the preservative that has proven record of allergic interaction is used in a *kashaya* given for allergic interaction. More over the amount of preservatives added is 10 to 50 times more than the internationally accepted level for food.

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