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# Evaluation of in-process quality control parameters of Ayurvedic preparation kankasava

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## ABSTRACT

*In-process quality control parameters were performed for Ayurvedic preparation, kankasava. Kankasava was prepared by fermentation process and KS-1, KS-2 and KS-3 coded for laboratory prepared kankasava. During preparation each step was monitored like specific gravity was found 0.9914±0.67, viscosity was 2.54±0 .41, alcohol content was found 4.80±0.06, total solid content was 5.11±0.13 and pH was estima ted 3.76±0.16 respectively, for KS-1, KS-2 and KS-3.*

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## INTRODUCTION

Comparing with the conventional preparation, herbal products represent a number of unique problems when quality aspects are considered. These are because of the nature of the herbal ingredients present therein, which are complex mixture of different secondary metabolites that can vary considerably depending on environment and genetic factors. Furthermore, the constituents responsible for the claimed therapeutic effects are frequently unknown or only partly explained and this precludes, the level of control which can routinely be achieved with synthetic drugs so much with conventional pharmaceutical preparations. These complex positions of quality aspects of herbal drugs are further complicated by the use of combinations of herbal ingredients as are being used in traditional practice. It is not uncommon to have as many as five different herbal ingredients in one product.

Standards of any drug relate to the uniformity in quality, which are numerical quantities by which the quality of commodities may be assessed. The information upon which standards may be based is obtained by a study of the genuine drug. While proposing the standards for crude drugs, several aspects are to be considered as pharmacognostical standards, to find out a well consistent quality formulation, the standards for formulation development during in-process quality control parameters are discuss in this paper [1, 2].

## MATERIALS AND METHODS

### Development of Formulations

The pharmaceutical product development requires a variety of scientific expertise to build-in quality, efficacy and safety, which are the hallmarks of a successful drug product. Understanding of the drug development process and the myriad tasks and milestones that are vital to a comprehensive development plan can only ensure scientific and commercial success of a product in the market. Key steps on the path of product development include pharmaceutical analyses, which include in-process quality control studies are required to determine and assure the identity, potency and purity of ingredients as well as those of the formulated products [3, 4, 5]

### Preparation of Kankasava

The required quantity of water, to which sugar as prescribed in the formula (Table +1) was added, boiled and cooled. This was poured into the fermentation pot. Fine powder of the drugs mentioned in the formula was added. The container was covered with a lid and edges were sealed with clay-smeared cloth winded in seven consecutive layers. The container was kept in an underground cellar to ensure fermentation for 45 days. After 45 days, the lid was removed and the content was examined to ascertain whether the process of fermentation has been completed. The fluid was first decanted and then strained after two or three days. When the fine suspended particles settled down, it was again strained and bottled. Kankasava was prepared in three batches and coded as KS-1, KS-2 and KS-3.

**Table 1 Ingredients of Kankasava**

| S. No. | Common | Botanical name | Family | Part used | Quantity taken |
|---|---|---|---|---|---|
| 1. | Datura | *Datura stamonium* | Solanaceae | Panchang | 50 gm |
| 2. | Vasaka | *Adhatoda vasica* | Acanthaceae | Root | 50 gm |
| 3. | Mulethi | *Glycyrrhiza glabra* | Leguminoceae | Root | 25 gm |
| 4. | Pippali | *Piper longum* | Piperaceae | Fruit | 25 gm |
| 5. | Nagkeshar | *Mesua ferrea* | Guttifereae | Flower | 25 gm |
| 6. | Ginger | *Zingiber officinalis* | Zingiberaceae | Rhizome | 25 gm |
| 7. | Chhoti kateri | *Solanum xanthocarpum* | Solanaceae | Aerial part | 25 gm |
| 8. | Bharangi | *Clerodendron serratum* | Verbenaceae | Bark | 25 gm |
| 9. | Talish patra | *Abies webbiana* | Pinaceae | Leaf | 25 gm |
| 10. | Dhai phool | *Woodfordia fruticosa* | Lythraceae | Flower | 200 gm |
| 11. | Munnaka | *Vitis venefera* | Vitaceae | Fruit | 250 gm |
| 12. | Honey | | | | 625 gm |
| 13. | Sugar | | | | 1250 gm |
| 14. | Water | | | | 6400 gm |

### Formulation Variables [1, 4, 6, 7,8]

Selection of formulation variables and their control is called the process optimization. During manufacturing, in-process quality control was performed on these formulations and number of methods and parameters were developed for further reference. All these steps were subjected for quality assurance tests.

**Step 1:** Amount of sugar (Table 1) was dissolved in distilled water, boiled, cooled and then specific gravity (by pycnometer)) and viscosity (with the help of Ostwald viscometer) of syrup was determined.

**Step 2:** Preparation of step 1 was poured into fermentation pot and all the fine powder drugs and honey were added, sealed and kept at room temperature. After 45 days lid was removed fluid was decanted and bottled. The kankasava so formed was subjected to determination of alcohol content [9] and pH (by digital pH meter).

**Step 3:** The volume of Kankasava so formed was measured accurately and 25 ml was taken to carry out total solid content by drying in an oven at 105 ºC.

All the observations and results obtained for kankasava during in-process quality assurance are recorded in Table 2.

**Table 2 In-process quality assurance of kankasava**

| Parameters | Kankasava | | | | |
|---|---|---|---|---|---|
| | KS-1 | KS-2 | KS-3 | Mean±SD | Coefficient of variance |
| Specific gravity (g/cm$^3$) | 0.9914±0.01 | 0.9915±0.01 | 0.9914±0.03 | 0.9914±0.67 | 0.811 |
| Viscosity (cps) | 2.53±0.03 | 2.56±0.01 | 2.54±0.04 | 2.54±0.41 | 0.207 |
| Alcohol content (%v/v) | 4.80±0.07 | 4.80±0.001 | 4.80±0.003 | 4.80±0.06% | 0.357 |
| Solid Content (%w/v) | 5.12±0.11 | 5.11±0.10 | 5.11±0.11 | 5.11±0.13% | 0.417 |
| pH (10% v/v solution) | 3.78±0.17 | 3.76±0.13 | 3.76±0.19 | 3.76±0.16 | 0.308 |

## RESULTS

During preparation of anti-asthmatic Ayurvedic formulation kankasava, formulation variables for a number of in-process quality assurance parameters were developed. Table 2 reflects in-process quality assurance of kankasava. All the values are Mean ± SD of KS-1, KS-2, and KS-3. During in-process quality assurance specific gravity (g/cm$^3$) of kankasava was found 0.9914±0.67 and batch-to-batch coefficient of variance was found 0.811. Viscosity (cps) was estimated 2.54±0.41 and coefficient of variance was found 0.207. Alcohol content (% v/v) was found to be 4.80±0.06% and coefficient variance was estimated as 0.357. Total solid content (% w/v) was 5.11±0.13 while pH (10% v/v) was found 3.76±0.16 and batch-to-batch coefficient of variance was found 0.417 and 0.308 respectively for solid content and pH. All these coefficient of variance values are in low limit indicating the higher reproducibility.

## DISCUSSION

Modern synthetic drugs are prepared by using synthetic materials. Reproducible manufacturing techniques and acceptable chemical assays for these drugs are given in pharmacopoeias to have adequate quality control. In contrast, herbal medicines are prepared from materials of plant origin and they are prone to contamination, deterioration and variation in compositions, thus posing problems for quality control of herbal formulations. In the light of this the work was concentrated on develop and evaluate ayurvedic formulations. Formulations were developed and prepared methods, which are described in The Ayurvedic Pharmacopoeia, and Bhaisajratanawali and in-process quality control parameters were developed.

Three batches of kankasava (KS-1, KS-2 and KS-3) were prepared. Quality assurance parameters for optimization of process were developed to set up standards by performing coefficient variance among the batches.

During the preparation of ayurvedic formulation kankasava, formulation variables including process optimization was estimated.

Table 2 reflects the result of formulation variable (in-process quality control parameter) of kankasava. Specific gravity ($g/cm^3$) was found (Mean ± SD of KS-1, KS-2, KS-3) 0.9914±0.67. Viscosity (cps) was estimated (Mean ± SD of KS-1, KS-2, KS-3) 2.54±0.41. Alcohol content (%v/v) was found (Mean ± SD of KS-1, KS-2, KS-3) 4.80±0.06. Total solid content (%w/v) and pH (10% v/v) was estimated (Mean ± SD of KS-1, KS-2, KS-3) 5.11±0.13 and 3.76±0.16 respectively. Batch to batch coefficient variance among three batches were found very low 0.811, 0.207, 0.347, 0.417 and 0.308 respectively for specific gravity, viscosity, alcohol content, solid content and pH. These low coefficients of variance are indicative of reproducibility of process. Hence the developed parameters and their values may be considered as standard value for further reference.

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