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PHARMACEUTICAL-ANALYTICAL STANDARDIZATION OF KUKA COUGH SYRUP: AN AYURVEDIC POLYHERBAL MEDICINE

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ABSTRACT

The concept of standardization evolved which became a necessity in the present times to ensure the safety and quality of the product. Standardization is an essential tool for establishing quality control methods for Ayurvedic drugs. **Objectives:** The study was planned by keeping in view the following objective: 1. To develop SMP for Kuka Cough Syrup. 2. To assess and standardize Kuka Cough Syrup analytically. **Methods:** A thorough and detailed screening of classical literature was done to formulate the composition, and method of preparation and for testing all three batches analytically. **Result & Conclusion:** The SOP of Kuka syrup developed in this paper yields for the production of a batch size of 5 litres. The end product so obtained is at par with all the laid standards.

Key words: Kuka Cough Syrup, Polyherbal, Standardization

INTRODUCTION

From ancient times, herbs have been processed to make them into suitable forms compatible with the human body for the desired therapeutic activity. This practice of manufacturing medicine by the practitioner has evolved over the course of time owing to increased population size which has led to more demand for medicines across the globe. Hence, the industrial sector came into existence and has boomingly expanded in a short course of time. But due to the mushroom growth of manufacturers, different

manufacturing processes were being adopted for the same composition leading to different final products in terms of their organoleptic and analytical profile, thus raising the quality and safety concerns for the consumers. Thus, the concept of standardization evolved, which became a necessity in the present times to ensure the safety and quality of the product. Standardization is an important step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for the production and manufacturing of herbal formulations[1]. In Ayurvedic formulations, it ensures the establishment of standards for the quality and purity of raw materials, quality control during the drug manufacturing process, production of a good quality finished product, storage, and distribution to maintain the quality of the final product. It is an essential tool for establishing quality control methods for Ayurvedic drugs[2]. Modification of pre-existing traditional dosage forms to other forms such as granules, lotions, syrups, shampoo, etc. took place in view of better shelf life, increased patient compliance, lesser and specific dose requirement, reduced manpower, targeted drug delivery, etc. Hence, in the present study development of a modified dosage form i.e., syrup is undertaken. Kuka Cough Syrup, an Ayurvedic proprietary medicine, is a poly-herbal preparation that is found to be very efficacious in all types of coughs, sore throat, chest congestion, etc. It was developed and standardized both pharmaceutically and analytically to ensure safe, effective, and quality products.

Material and Methods

The syrup is prepared in three batches under similar conditions to develop SOP at Multani Pharmaceuticals Ltd, Uttarakhand. Further, all the raw herbs as well as prepared batches were subjected to complete analysis at Drug Testing Laboratory Multani Pharmaceuticals Ltd, Uttarakhand.

The formulation composition of the Kuka Cough Syrup is given in Table 1.

Table 1: Ingredients along with quantities of Kuka Cough Syrup

Ingredients	Botanical Name	Part used	Quantity
Tulsi	*Ocimum sanctum*	Leaf	25 g
Vasaka	*Adhatoda vasica*	Leaf	200 g
Kulanjan	*Alpinia galangal*	Rhizome	200 g
Yashtimadhu	*Glycyrrhiza glabra*	Stem/Root	200 g
Pippali	*Piper longum*	Fruit	100 g
Satpudina	*Mentha spicata*	Leaf extract	1 g
Sugar			3 kg
Citric acid			55 g
Propylene glycol			360 g
Methyl paraben			100 g
Propyl paraben			1 g
Purified water			Q. S

Three batches each of 5 litres were prepared under similar conditions to develop a standard manufacturing procedure (SMP). All the raw materials used in the composition were collected from the authorized vender of the company.

Equipment used.

1. Mortar and pestle
2. Decoction vessel
3. Extract collecting vessel.
4. Syrup preparation vessel
5. Muslin cloth

Preparation of Syrup

After proper identification and authentication of all the raw herbs as per API standards used in the composition, they were further subjected to processing. The preparation of syrup formation can be divided into the following steps:

- **Disintegration process-** *Kulanjana*, *Mulethi*, and *Pippali* after weighing in required amounts were subjected to a mortar-pestle to obtain the desired coarse

particle size. On average, a 2.375% loss was observed during the pulverizing process (Table 2).

Table 2: Quantity of herbs before and after pulverizing

Name of Herbs	Quantity in gm						Loss		
	Before			After					
	1	2	3	1	2	3	1	2	3
Kulanjan	200	200	200	195.25	195.36	195.16	4.75	4.64	4.84
Yashtimadhu	200	200	200	195.25	195.36	195.16	4.75	4.64	4.84
Pippali	100	100	100	97.625	96.680	97.580	2.375	2.32	2.42

- **Extraction process-**

a) The coarse powder of disintegrated herbs was taken in desired quantity and soaked in 6 litres of water.
b) After proper soaking, the material was transferred to the decoction kettle and boiling is started.
c) Boiling was continued till the desired volume of liquid was left.
d) The extract was passed through nylon cloth in an extract measuring tank.
e) This herbal extract was held up for 20 minutes for sedimentation.

- **Syrup preparation-**

a) The above-prepared extract was added to the syrup manufacturing tank.
b) Stirrer was started and 3 kg of sugar was added to it and heated up to 90-100°C.
c) 55g of citric acid was dissolved in 10 ml of purified water and added to the above mixture under continuous heating and stirring.
d) Then, 100 g of methyl paraben was dissolved into 125ml of water and added to the above mixture.
e) Further, the desired amount of propyl paraben was dissolved in water and added to the mixture.

- **Cooling-**

a) Cooling of syrup up to 40°C was done.
b) 1g of *Satpudina* in an SS vessel was taken and 360 g of propylene glycol was added to it and then dissolved well.
c) This solution was added to the main bulk and mixed properly.

- **Volume makeup and mixing-**

a) Stirring was stopped and the liquid level was allowed to settle at a constant level.
b) The make-up of the volume up to 5 litres was done with purified water by using a graduated and calibrated S.S dipstick.
c) The whole solution was again stirred for up to 30 minutes.

- **Filtration-**

a) The prepared final product was subjected to filtration to ensure the removal of any unwanted particles.
b) Then, the solution was stored in airtight containers.

A similar process was followed two more times by using raw material from the same source and using the same equipment to develop SOP and SMP for this product.

The average time taken for different processes included under the preparation steps is mentioned in Table 3:

Table 3: Time taken for different processes in the preparation of syrup.

S.no.	Process	Average time taken
1.	Disintegration of material	30 minutes
2.	Extraction process	2 hours
3.	Syrup preparation	1.5 hour
4.	Cooling process	1 hour
5.	Volume makeup	35 minutes
6.	Filtration process	20 minutes

Moderate temperate (90-120°C) was maintained throughout the process in various steps. The temperature conditions are listed down below (Table 4).

Table 4: Observation of temperature throughout the process

S.no.	Process	1st Batch	2nd Batch	3rd Batch	Maximum observed temperature
1.	Extraction process	104°C	103°C	103°C	103°C
2.	Syrup preparation	98°C	98°C	96°C	97°C

Analytical parameters

All three batches of the finished product were subjected to analysis to determine the quality of the product. The following testing parameters were conducted:

1. Organoleptic characteristics-
- Colour
- Taste
- Appearance
- Odour
2. pH
3. Specific gravity at 25°C
4. Heavy metal estimation- Detection of:
- Lead
- Arsenic
- Cadmium
- Mercury
5. Microbiological limit test-
- Total bacterial count
- Yeast and mould count
- *E. coli*
- *S. aureus*
- *P. aeruginosa*
- *Salmonella sp.*
6. Total sugars
7. Total soluble solids
8. Detection of Aflatoxins-
- B1
- B1+B2+G1+G2

Protocols for all the above tests were followed as per the methods described in API (Table 5) except for total soluble solids. In-house, the standard process for testing of total soluble solids was carried out.

Table 5: Analytical parameters for the three batches of Syrup

Parameters	1	2	3	Average
Organoleptic characters	Brown	Brown	Brown	Brown
Colour				
Odour	Menthol-like	Menthol-like	Menthol-like	Menthol-like
Taste	Sweet	Sweet	Sweet	Sweet
Appearance	Viscous liquid	Viscous liquid	Viscous liquid	Viscous liquid
pH[3]	4.69	4.27	4.67	4.54
Specific gravity at 25°C[4]	1.23	1.23	1.22	1.22
Total soluble solids (%)	51.6	50.7	50.0	50.76
Total sugars[5]	57.21	58.61	57.33	57.71
Heavy metal estimation[6]	1.48	1.50	1.04	1.34
Lead (Pb) ppm				
Arsenic (As) ppm	<0.50	<0.50	<0.50	<0.50
Cadmium (Cd) ppm	<0.01	<0.01	<0.01	<0.01
Mercury (Hg) ppm	<0.13	<0.13	<0.13	<0.13
Microbiological Limit Test[7]				
Total bacterial count (cfu/ml)	15	20	15	16.6
Yeast and mould count (cfu/ml)	<10	<10	<10	<10
E. coli	Absent	Absent	Absent	Absent
S. aureus	Absent	Absent	Absent	Absent
P. aeruginosa	Absent	Absent	Absent	Absent
Salmonella sp.	Absent	Absent	Absent	Absent
Aflatoxins[8]				
B1 (ppb)	Complies	Complies	Complies	Complies
B1+B2+G1+G2 (ppb)	Complies	Complies	Complies	Complies

DISCUSSION

Ingredients of Kuka cough syrup possess *Kaphahar, Katu-Tikta-Madhur rasa, Ushna, Snighda, Laghu, etc.* properties. *Kulanjana* is said to have properties such as *Kaphahar* (pacifies *Kapha dosha), Kasahar* (relives cough), *Pratishyay* (relieves cold), *Susvara* (improves voice quality), *Kanthya* (good for throat), *Mukhvishodhan* (cleans the mouth) etc[9]. *Vasa* is known to be excellent *Kasa-shwasahar* (relives from cough and dyspnoea), *Swarya* (improves voice quality) etc[10]. *Pippali* has *Kasahar, Shwasahar,* etc. properties. *Mulethi* possesses *Swarya, Kaphashamaka, Shothahar* (anti-inflammatory), *Kanthya, etc.* properties[11]. *Tulsi* is said to have *Kaphanihsarak* (expectorant), and *Kasahara* (relieves cough) properties[12]. Preservatives are added to prevent microbial contamination in the product. These are added to protect the product from undergoing any chemical change or microbial action. The menthol-like odour of the syrup is due to the presence of *Satpudina* in its ingredients. All the above said properties effectively relive the conditions of all types of *Kasa.* The end product was tested for the quality check and was found to be in accordance with the laid standards.

CONCLUSION

Kuka cough syrup is a poly-herbal formulation that is clinically proven very efficacious in all types of coughs. The SOP of Kuka syrup developed in this paper yields that for the production of a batch of 5 litres, 25 g of *Tulsi,* 200 g of *Vasa, Kulanjan, Yashtimadhu, Pippali, Satpudina* each, 3kg sugar, 55g citric acid, 360 g propylene glycol and for the preservatives 100g of methyl paraben and 1g of propyl

paraben is required. The end product so obtained is at par with all the laid standards. Hence, this can be considered the Standard Manufacturing Procedure of Kuka cough syrup for all future references.

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