

**STANDARD MANUFACTURING PROCEDURE (SMP) OF  
KUMKUMADI GHRITA: AN AYURVEDIC FORMULATION****PK Prajapati<sup>1\*</sup>, Amrutia A<sup>2</sup>, Rohit Sharma<sup>3</sup>, BJ Patigiri<sup>4</sup>**

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Article Received on  
26 August 2014,

Revised on 19 Sept 2014,  
Accepted on 14 Oct 2014

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**ABSTRACT**

**Introduction:** *Kumkumadi Ghrita* (KG) is one of the highly valued formulations among Ayurvedic physicians, commonly recommended in conditions like skin disorders especially *Mukhdushika* (Acne vulgaris). *Kesar* (stigma of *Crocus sativus* Linn) is a prime ingredient in the formulation. However due to high cost and increased adulteration trends in *Kesar*, another botanical '*Nagakesar*' (*Mesua ferrea* Linn.) is suggested by Ayurvedic experts as an substitute, which have relatively low cost and possess similar therapeutic attributes like *Kesar*. Recent studies also reveal equal efficacy of KG prepared with *Kesar* and KG prepared with *Nagakesar*'. In spite of wide utility of KG in Ayurvedic practice, no published work is available till date on manufacturing guidelines. **Aims and Objectives:** To develop SMP (Standard Manufacturing Procedure) for *Kesaryukta* (with *Kesar*)

*Kumkumadi Ghrita* (KKG) and *Nagakesar yukta* (with *Nagakesar*) *Kumkumadi Ghrita* (NKG). **Materials and Methods:** Total three batches of KKG and NKG each were prepared in the laboratory by adopting Ayurvedic classical guidelines. Pharmaceutical findings and observations during its preparation were systematically recorded. Prepared KKG and NKG were further subjected to organoleptic analysis. **Results and Conclusion:** The average

percentage loss in final product was 10.18 % in KKG and 7.58 % in NKG. Since, *Kesar* is costlier than *Nagakesar*, NKG can be preferred over KKG as per total yield is concerned. No difference was found on average duration for preparation of KKG and NKG i.e. 9.20 hrs and 9.21 hrs respectively. The study suggests that coarse powdered ingredients should be used instead of fine powders for pharmaceutical process to achieve maximum yield in expensive formulation, *Kumkumadi Ghrita*, and heating should be done only up to *Madhyama Paka* stage. NKG was found more cost effective than KKG, thus it can be preferred over KKG for future utilization in pharmaceutical companies. Data obtained by present study may be considered as standard for future researches.

**KEYWORDS:** *Kesar, Nagakesar, Kumkumadi Ghrita, Murcchana, Ghrita Paka.*

## INTRODUCTION

Quality products of SMP (Standard Manufacturing Procedure) with batch uniformity are needed to maintain quality assurance, which allow the patient to make safe use of them. Vast work is needed yet to develop globally accepted standards in the manufacturing process of Ayurvedic formulations. *Kumkumadi Ghrita* is a famous and commonly used Ayurvedic preparation in skin disorders especially *Mukhdushika* (Acne vulgaris),<sup>[1]</sup> having *Kesar* (stigma of *Crocus sativus* Linn) as a prime ingredient, which makes the formulation costly.<sup>[2]</sup> Since *Kesar* possesses wide range of therapeutic attributes, it is highly demanded and used herb in Ayurvedic medicines. Though it is expensive, its demand far exceeds than the production. Therefore, adulteration of this herb is much common in herbal drug industry and makes challenging task for consumers to find out the original, finest *Kesar*.<sup>[3],[4]</sup> *Nagakesar* (*Mesua ferrea* Linn.) is another highly recommended herb in Ayurvedic medicines; though, it is costly too, but is comparatively cheaper than *Kesar*. As per Ayurvedic classics, it can be used as a substitute of *Kesar*, as it is supposed to possess similar therapeutic qualities.<sup>[5],[6]</sup> Some texts have also considered *Kesar* as synonym of *Nagakesar*.<sup>[7]</sup>

*Ghrita Kalpana* (medicated ghee preparations) is one of the commonly used dosage form in Ayurvedic pharmaceuticals, aimed: to extract the lipid soluble active principles from the plants and minerals, to make use of therapeutic values of ghee, to preserve the drug/drugs for longer time (enhanced shelf life), and to enhance and hasten the absorption of drugs, when used topically in fatty medias.<sup>[8]</sup> *Kumkumadi Ghrita* (KG) is one of such *Ghrita* based widely used formulation, published information on its SMP is lacking among manufacturers, hence posing a challenge to establish an acceptable processing method. The data compiled after several (at

least three) repetitions of the same procedure is to be compared to generate a standard protocol for any formulation. Taking a note of this, present study has been planned to establish SMP of *Kesar yukta* (with *Kesar*) *Kumkumadi Ghrita* (KKG) and *Nagakesar yukta* (with *Nagakesar*) *Kumkumadi Ghrita* (NKG).

## MATERIALS AND METHODS

The whole pharmaceutical procedure is arranged in the following two unit processes i.e. (1) *Murcchana* of *Go Ghrita* (ghee of Indian cow- '*Bos Primigenius Indicus*') and (2) Preparation of KG. Pharmaceutical Performa was prepared for maintaining SMPs during pharmaceutical study. Total 3 batches of KKG and NKG each were prepared by adopting classical method. Before dealing with main pharmaceutical study of the formulation, three pilot studies were carried out for each KKG and NKG to investigate the possible common problems which may impact the process. The crude drugs used in KG preparation with their botanical identities and parts used are enlisted in table 1. The main pharmaceutical steps involved are mentioned as follows.

### Identification and Authentication

The raw material was procured in coarse form from Pharmacy, Gujarat Ayurved University, Jamnagar, Gujarat, India, and authenticated by Pharmacognosy laboratory from same institute. Necessary equipments like SS (Stainless Steel) vessel, SS ladle, cotton cloth, measuring jar, SS spoon, gas stove, L.P.G. cylinder, thermometer, etc. were arranged prior to beginning of the pharmaceutical procedure.

### Preparation of Murcchita Ghrita

*Murcchana* was carried out as pretreatment of *Ghrita*, before main process of KG preparation, by adopting Ayurvedic classical guidelines.<sup>[9]</sup> One litre of *Ghrita* was taken in a non-reactive SS vessel and heated on mild heat till it becomes moisture free (free from froth, at 141°C) and ghee portion remains. After slight cooling (at 80°C), *Kalka* (coarse herbal paste, each herb equal parts i.e. 56.37 g) was added in prescribed quantity followed by water (quantity 4 times to ghee). Then the mixture was subjected to continuous mild heat (temperature at boiling stage- 120°C). First, a stage came called *Mridu Paka* stage (at 122°C), wherein the *Kalka* becomes '*Tulye Kalken Niriyase*' (gum like consistency) and sticky on touch and produces cracking sound when kept on fire (due to remained moisture contents). Moderate heating was applied and *Ghrita Paka* was carried out till attainment of *Siddhi Lakshana* of *Madhyama Paka* (confirmatory signs of completion of process/chief desired

characters, achieved at 130°C) such as: (1) *Sanyav Eve Niriyase* (*Kalka* consistency resembles to electuary), (2) *Madhye Darvi Vimunchati* (*Kalka* does not stick to stirring ladle) (3) *Shabda hino agni nikshipta* (No sound produced if a part of *Kalka* is put into the fire) (4) *Phenshanti* (foam disappears) and (5) *Gandh Varna Rasotpatti* (desired color, odor and taste ingredients become appreciable).<sup>[10, 11]</sup> Then it was filtered by single layer cloth and further subjected for preparation of KG. Obtained results of *Ghrita Murcchana* at different batches of KKG and NKG are detailed in Table 2.

### Preparation of KG

The pharmaceutical process for KG preparation was conducted as per classical method.<sup>[11]</sup> Quantities of ingredients for both KKG and NKG are stipulated in Table 7. Initially, decoction of *Chitrakmoola* (roots of *Plumbago zeylanica*) was prepared as per Ayurvedic guidelines.<sup>[12, 13]</sup> Subsequently, decoction was filtered through a single layer cotton cloth. Then, all *Kalka dravya* in prescribed quantity were made into paste by adding small quantity of *Chitrakmoola Kwatha*. *Murcchita Ghrita* was taken in a SS vessel and heated over *Madhyama Agni* till complete evaporation of moisture content, and after slight cooling (at 80°C), the bolus of *Kalka* were added into *Ghrita* followed by *Chitrakmoola Kwatha*. The whole mixture was again heated with intermittent stirring. The heating duration was adjusted so that *Ghrita Paka* was completed in five days. The heating was carried out till attainment of *Siddhi Lakshana* of *Madhyama Paka* (like *Ghrita Murcchana*). These are the characteristic features of *Madhyama Paka*, which desired to declare completion of any *Ghrita* preparation. The finally prepared KG was filtered with muslin cloth, collected, weighed and stored in dry airtight glass jars under sterile conditions. Total three batches each of KKG and NKG were prepared to ensure SMP by following similar process. Observations on quantity of ingredients, temperature, duration, and obtained results of *Kumkumadi Ghrita* preparation (KKG and NKG) are detailed in Tables 3-6.

### RESULTS AND DISCUSSION

Ayurveda has also given utmost importance to quality of drug, maturity of plant, standard preparation methods, and its mode of usage in logical manner.<sup>[14, 15, 16, 17]</sup> Initially the raw materials were authenticated and analyzed before processing as the good quality products mainly depend upon genuine raw materials. Before preparation of DKG, few pilot batches were prepared to find out the possible difficulties in preparation and to maintain the standard uniformity of the process. It was observed that coarse powder of ingredients should be taken

for *Kalka* preparation in *Ghrita Paka* instead of fine powders to achieve maximum yield. Kesar showed quick miscibility and imparted color to *Ghrita* only when it was added by making a paste by adding some water. So instead of dry form, wet paste of Kesar was used for *Ghrita Paka*. To develop SMP, 3 batches each of KKG and NKG were prepared. *Go Ghrita* was used, as it is advocated the best among all lipids to prepare *Ghrita* preparations, and it possess *Sanskaranuvartana* (the quality of a substance which when added with another substances does not change its original property and also imparts the quality of added substances) and other highly nourishing properties.<sup>[18]</sup> Initially, *Ghrita Murcchana* was carried out. It is a unique pharmaceutical procedure wherein raw Ghee is boiled with coarse powder of selected medicinal drugs and desired quantity of water, before subjecting it to *Ghrita Paka* (main cooking procedure of *Ghrita*).<sup>[19]</sup> *Murcchana* is supposed to enhance the appetite of Ghee for drug absorption. So, *Murcchita* Ghee incorporates the medicinal properties far better than raw Ghee processed without *Murcchana* procedure. *Murcchana* also helps in refinement of Ghee, and is aimed at removing un-dissolved solids from crude Ghee, moisture content/factor causing rancidity (*Ama dosha*), undesirable odour (*Gandha dosha*), free fatty acids, phosphatides etc which may alter the physico-chemical characters of Ghee. The process in turn potentiates the Ghee, induces antioxidant properties, inhibits lipid-peroxidation, make it lighter for digestion and drug absorbability, assimilability and shelf life are greatly enhanced.<sup>[20],[21],[22]</sup> The average temperature on completion of *Murcchana* was 130°C and 124°C in KKG and NKG respectively. More loss in *Ghrita Murcchana* was observed in KKG (8.8% loss) as compared to NKG (3% loss). Average time taken for *Ghrita Murcchana* in KKG and NKG was 8.83 hrs and 8.78 hrs respectively.

Procedure of KG preparation was followed similar as *Murcchana* procedure. *Chitrakmoola Kwatha* was filtered at slightly hot condition and squeezing was necessary to get maximum extraction. Specific smell of *Chitrakmoola Kwatha* was felt and color of *Kwatha* was dark brown. As the liquid media used for *Ghrita* preparation is *Kwatha*, *Ghrita Paka* was completed in five days as per classical guidelines.<sup>[11]</sup> Probably nature of *Kwatha* material to impart chemical constituents may take this much longer period.<sup>[23]</sup> The cooking method followed same as in *Murcchana* upto *Madhyama Paka* stage, probably during this stage the drug activity will be at optimum level. Overheating (up to next *Khara Paka* stage) is not recommended to avoid burning of active constituents and it may produce burning sensation in stomach on therapeutic administration.<sup>[24],[11]</sup> In context of *Ghrita Paka* which contains Kesar as ingredient, Ayurvedic texts have advocated not to go beyond *Madhyama Paka*,

presumably to retain active constituents level in the drug. Therefore, *Madhyama Paka* heated KG (approx heat range for KKG: 129°C and for NKG: 138°C) is recommended for external application in *Mukhdushika*. *Ghrita siddhi Lakshana* observed during *Ghrita Murcchana* and *Kumkumadi Ghrita* preparations are mentioned in Table 7. Average duration for preparation of KKG and NKG was 9.20 hrs and 9.21 hrs respectively. The average temperature on completion of *Murcchana* was 129°C and 138°C in KKG and NKG respectively. Average loss in final product was 10.18 % in KKG and 7.58 % in NKG.

Organoleptic characters which correspond to the *pancaijnanendriya pariksha* (perception by five sense organs) of *Ayurveda*, were documented at two stages of preparation (for *Murcchita Ghrita*, and KKG and NKG), [Table 8] because these parameters can change at different stages. Significant difference was found in color of finally prepared KKG and NKG (dark orange and dark yellow in color respectively). In clinical study, KKG and NKG have shown highly significant results in *Mukhdushika*, with no major difference in results. <sup>[25]</sup>

## Appendix

### I Equipments and their specifications in KKG and NKG preparation

1. Stainless steel vessel: –      Depth              9.5 inch  
    Diameter              18 inches  
    Circumference              56 inches  
    Capacity              40 L
2. Stainless steel ladle: -      Length              21.5 inches
3. Gas stove:              Jumbo burner  
    Diameter:              04 inches  
    Circumference:              12 inches
4. L.P.G. cylinder:              14.5 kg capacity
5. Thermometer:              360°C
6. Weighing balance:      Maximum Capacity - 2.2 kg  
    Minimum Capacity - 10 g  
    Error              - 200 mg
7. Measuring jar:              Maximum Capacity - 2.0 L
8. Cotton cloth:              1 x 1 meter



Table-1: Ingredients and their quantities for *Ghrita Murcchana* for KKG and NKG.

S. N	Ingredients	Latin name/English term	Part used	Quantities
1	Go Ghrita (litre)	Cow Ghee	-	1
2	Kalka (g)*	Coarse paste of herbs	As prescribed below	338.25
3	Haritaki (g)	Terminalia chebula Retz	Dried fruit's pericarp	56.37
4	Amalaki (g)	Embllica officinalis Gaertn	Dried fruit's pericarp	56.37
5	Bibhitaki (g)	Terminalia belerica Roxb	Dried fruit's pericarp	56.37
6	Musta (g)	Cyprus rotundus Linn	Rhizome	56.37
7	Haridra (g)	Curcuma longa Linn	Rhizome	56.37
8	Matulung Juice (g)	Citrus medica Linn	Juice of fruit	56.37
9	Jala (litre)	Potable water	-	4

\*Ingredients 3-8 are *Kalka Dravya*

Table 2: Results obtained during *Ghrita Murcchana*.

Observations	KKG				NKG			
	Batches				Batches			
	1	2	3	Avg	1	2	3	Avg
Initial quantity of Ghrita (ml)	1000	1000	1000	1000	1000	1000	1000	1000
Quantity of Ghrita obtained (ml)	880	916	940	912	960	975	965	966.66
Initial quantity of Kalka (g)	338.25	338.25	338.25	338.25	338.25	338.25	338.25	338.25
Obtained quantity of Kalka (g)	570	550	520	546.66	550	537	531	539.33
Loss of Ghrita (ml)	120	84	60	88	40	25	35	30
Loss of Ghrita (%)	12	8.40	6.00	8.8	4.00	2.50	3.50	3.33
Total time required for Murcchana (hrs)	8.50	9.00	9.00	8.83	9.12	8.75	8.48	8.78
Total time required for Murcchana (days)	3	3	3	3	3	3	3	3

Table-3: Quantities of ingredients for both KKG and NKG.

S. N	Observations	Latin name/English term	Part used	KKG				NKG			
				Batches				Batches			
				1	2	3	Avg	1	2	3	Avg
1	Murcchita Ghrita (ml)	Pre-treated Ghee	-	880	916	940	912	960	975	965	966.66
2	Kalka (g)*	Coarse paste of herbs	-	220	229	235	228	240	243.75	241.25	241.66
3	Kesar (g)	Crocus sativus Linn	Stigma	55	57.25	58.75	57	-	-	-	-
4	Nagakesar (g)	Mesua ferrea Linn	Flower bud	-	-	-	-	60	60.90	60.30	60.40
5	Haridra (%)	Curcuma longa Linn.	Rhizome	55	57.25	58.75	57	60	60.90	60.30	60.40
6	Daruharidra (g)	Berberis aristata DC	Stem	55	57.25	58.75	57	60	60.90	60.30	60.40
7	Pippali (g)	Piper longum Linn	Fruit	55	57.25	58.75	57	60	60.90	60.30	60.40
8	Chitrakmoola Kwatha (litre)	Plumbago zeylanica Linn	Decoction of root	3.52	3.66	3.76	3.64	3.84	3.90	3.86	3.86

\*Ingredients 3-7 are *Kalka Dravya*, 8 is *Kwatha Dravya*.



**Table-4: Observations on temperature at different stages of *Kumkumadi Ghrita* preparation.**

Observations		KKG				NKG			
		Batches				Batches			
		1	2	3	Avg	1	2	3	Avg
Temperatures during Kumkumadi Ghrita preparation (°C)	On loss of moisture of Ghrita	142	144	142	142.66	140	146	150	145.33
	On adding Kalka	80	88	78	82	82	74	78	78
	On adding Chitrakmoola Kwatha	60	64	56	60	60	52	60	57.33
	At boiling stage	116	118	120	118	122	120	118	120
	At Phenshanti	118	120	118	118.66	124	128	124	125.33
	On mridu Paka stage	122	126	128	125.33	126	130	138	131.33
	On Madhyama Paka stage	126	130	132	129.33	134	138	142	138
	At filtration time	80	84	88	84	76	80	72	76

**Table 5: Duration of Kumkumadi Ghrita Preparation in Different Batches.**

Observations	KKG				NKG			
	Batches				Batches			
	1	2	3	Avg	1	2	3	Avg
Total duration to obtain moisture free condition (min)	18	15	20	17.66	20	22	20	21.33
Time when Kalka added (min)	30	24	35	29.66	34	45	44	41
Time when water added (min)	34	28	38	33.33	38	50	54	47.33
Duration of Phenshanti (hrs)	7.15	7.30	8.00	7.48	8.12	7.70	7.20	7.67
Duration of mridu Paka stage (hrs)	8.50	8.20	8.55	8.41	8.68	8.50	8.22	8.46
Duration of Madhyama Paka stage (hrs)	9.20	9.00	9.40	9.20	9.10	9.25	9.30	9.21
Total time required for Ghrita Paka (hrs)	9.20	9.00	9.40	9.20	9.10	9.25	9.30	9.21
Total time required for Ghrita Paka (days)	5	5	5	5	5	5	5	5

**Table 6: Results obtained during *Kumkumadi Ghrita* Preparation.**

Observations	KKG				NKG			
	Batches				Batches			
	1	2	3	Avg	1	2	3	Avg
Initial quantity of <i>Murcchita Ghrita</i> (ml)	880	916	940	912	960	975	965	967
Quantity of <i>Ghrita</i> obtained (ml)	780	818	860	819	880	910	890	893
Quantity of <i>Ghrita</i> obtained (%)	88.63	89.30	91.4	89.78	91.66	93.33	92.22	92.40
Initial quantity of <i>Kalka</i> (g)	220	229	250	223	240	243	241	241
Obtained quantity of <i>Kalka</i> (g)	360	400	380	380	384	370	377	377
Loss of <i>Ghrita</i> (ml)	100	98	80	92.7	80	65	75	73.33
Loss of <i>Ghrita</i> (%)	11.36	10.69	8.51	10.18	8.33	6.66	7.77	7.58

**Table-7: *Ghrita siddhi Lakshana* during *Ghrita Murcchana* and *Kumkumadi Ghrita* preparation.**

Ghrita siddhi Lakshana	Ghrita Murcchana		KKG and NKG	
	Kalka	Ghrita	Kalka	Ghrita
Sanyav Eve Niryase	+	-	+	-
Madhye Darvi Vimunchati	+	-	+	-
Shabda hino agni nikshipta	-	+	-	+
Phenshanti	-	+	-	+
Gandh Varna Rasotpatti	-	+	-	+

**Table 8: Organoleptic characters of *Murcchita Ghrita* and *Kumkumadi Ghrita*.**

Parameters	Observations		
	Murcchita Ghrita	KKG	NKG
Rupa (Colour)	Dark yellow	Dark orange	Dark yellow
Rasa (Taste)	Slight bitter and astringent	Slight bitter and astringent	Bitter and astringent
Gandha (Odour)	Aromatic like turmeric	Specific smell	Aromatic like turmeric
Sparsha (Touch)	Like Ghrita	Like Ghrita	Like Ghrita

**Evaluation of cost of KKG and NKG**

Nowadays availability of quality drug at reasonable rate to remove the burden on these classes is the need of time. Cost of the drug plays pivotal role while selecting the appropriate form of medicament. Raw drug and process costing affects the final cost of prepared formulation. So here an attempt is made to calculate the cost of KKG and NKG (Table 9). The retail price of the formulations was calculated in accordance with the formula set by the official gazette of India, under Drug (Price Control) Order, 1995, which is as follows<sup>[26]</sup>:

$RP = (MC + CC + PM + PC) \times (1 + MAPE/100) + ED$  [Where- RP: retail price, MC: material cost, CC: conversion cost, PM: packing material cost, PC: packing charges, MAPE: Maximum Allowable Post-manufacturing Expenses, ED: Excise duty]

As the total yield of finally prepared KKG was obtained as 819 g, the cost of which was calculated as per aforesaid formula was 17270 INR. Therefore the cost of 1 Kg of KKG would be 21086 INR. While, as the final yield of NKG was 893 g, which priced us 2915 INR. Therefore the cost of 1 Kg NKG would be 3264 INR. Thus, total cost to prepare KKG was much higher than NKG, and as clinically Therefore, NKG, which is more cost effective, and possess similar therapeutic activities as KKG<sup>[25]</sup>, can be preferred by large scale industries.

**Study Limitations and Future Directions**

Present study is preliminary attempt on small scale to develop SMP for KG. More studies are needed to evaluate the physico-chemical, qualitative and chromatographic profile of the

formulation, to ascertain the quality of both formulations KKG and NKG, and their comparative biological roles. Since stability is an essential criteria for development of a pharmaceutical product.<sup>[27]</sup> Further stability studies (Accelerated stability study and Real time stability study) are needed to ascertain the increased shelf life.

## CONCLUSION

Though in original reference, *Kesar* is mentioned as an ingredient in KG, NKG was prepared with *Nagakesar* as a substitute to overcome the scarcity and high cost of original *Kesar*. *Madhyama Paka* should be done for preparation of KG. Fine powdered ingredients should not be used for *Kalka* in *Ghruta Paka* to achieve maximum yield in expensive preparations like KKG. No major difference was found in average time taken for preparation of KKG and NKG. The average loss in final product was 10.18 % in KKG and 7.58 % in NKG. Since, clinically both NKG and KKG have shown similar results and NKG was found comparatively more cost effective, it can be preferred over KKG. The findings of present study ensure the uniformity in the operative procedures, thus the present SMP of NKG can be adopted by future utilization in pharmaceutical companies. As no published reports are available on the standardization of preparation of KG, the observations of present study can be considered as standards for further researches.

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