

Identification, Optimization and Standardization of Various Process Parameters for the Industrial Production of Rasona Ksheerapakam- A Dairy Based Nutraceutical

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I. INTRODUCTION

THE nutraceuticals or the functional foods are majorly plant-based products and most of them being predominantly herbal. Hence clues to these nutraceutical products could be got from our ancient and traditional systems of medicine like Ayurveda and Siddha. Therefore there is ample scope for India to develop a range of nutraceutical/health food products based on our traditional knowledge base in Ayurveda. And to succeed, these products have to be standardized with scientific validation to ensure safety and efficiency so as to instill confidence in the customers to use them. In order to achieve this goal considerable research has to be carried out on these products. Thus India's own traditional knowledge base gathered from Ayurveda and Siddha can help out in research work on nutraceuticals.

Ksheerapakam is one of the most important and unique preparations found in Ayurvedic system, where milk is used as the medium of extraction of herbal medicinal components. Rasona Ksheerapakam, the product subjected in the present study is basically considered as a cardiac tonic.

II. ASSESSMENT OF THE EXISTING METHODOLOGY FOR MANUFACTURE OF KSHEERAPAKAM

As per the standard procedures mentioned in the ancient texts of Ayurveda, there are different types of methodologies available for the production of Ksheerapakam. In all these methods, the herbal ingredient is allowed to boil in milk with water, for the purpose of extraction. One method of medicated milk preparation consists of boiling one part of prescribed drug with 8 parts of milk and 32 parts of water (1:8:32). The ingredients are boiled on moderate heat till the total volume is reduced to that of the initial volume of milk. Another method of preparation of medicated milk is by providing one part of drug, 15 parts of milk and 15 parts of water (1:15:15). Here also the ingredients are boiled on moderate heat till the total volume is reduced to that of the initial volume of milk. Yet another method of preparation is in which the extraction of the medicinal components is done first and equal quantity of milk to that of extract is added. The mixture is then subjected to mild heating till the volume is reduced to that of the initial volume of milk.

III. LIMITED SHELF LIFE OF KSHEERAPAKAM

As the process of extraction is carried out by using milk as the extracting media, the Ksheerapakam preparations need to be prepared on a daily basis. While administering this drug for various ailments, Ayurveda physicians found it relatively impractical, as the patients in the modern busy world are unwilling to carry out the lengthy and laborious preparatory procedures of the medicine. So far no authentic work is reported for the process standardization for the commercial production of Ksheerapakam preparations.

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Moreover no work is reported on the attempts on increasing the shelf life and making the product available in user friendly dosage forms.

IV. MATERIALS AND METHODS

- *Identification of the Unit Operations Involved in the Preparation of Rasona Ksheerapakam*

The conventional method of preparation of Rasona Ksheerapakam was observed at some of the traditional Ayurvedic medicine preparation units. The method of preparation involves boiling milk along with the drug, in an open pan under direct flame using firewood. Manual scraping was carried out to get a uniform heating and also to prevent burning of the milk in the pan. The method of preparation was found both labour intensive and energy intensive. An alternative mechanism for boiling milk with less labour involvement and reducing energy requirement will help in getting a consistent uniform quality product and also enable mass production of the product. Boiling the milk along with the drug, forms one of the main unit operations involved in the preparation of the product. Since the product is milk based the storage of the product under ambient conditions is difficult. In order to improve the keeping quality of the product under ambient conditions converting the product into powder form by employing some drying technique is the only alternative. Hence concentration and drying forms the two unit operations involved in the preparation of the product on industrial scale for long term storage.

- *Selection of Equipment and Machinery for the Industrial Production of Rasona Ksheerapakam*

All the Kashaya preparations in ayurveda are basically made out of extraction processes, where the herbal raw material is subjected to water extraction under boiling temperature. In Ksheerapakam preparations, the most commonly adopted method is to boil the raw drug in milk and water. For the present study, the medicated milk was prepared following the standard procedure by adding 1 part of prescribed drug, Garlic with 8 parts of milk and 32 parts of water (1:8:32). Since boiling forms the main unit operation involved in the preparation of the product, the mixture was subjected to boiling using two different methods. In order to provide uniform heating and continuous stirring trials were carried out in the following methods.

1. The ingredients were boiled in a steam jacketed kettle of 80 liters capacity under a steam pressure of 2.5 Kg/cm². The product temperature was maintained at 102^o C by regulating the steam pressure. The contents were constantly agitated manually by using a stainless steel ladle. The heating was continued till the total quantity of the product was reduced to the initial volume of milk taken.
2. The ingredients were boiled in a LPG fired stainless steel motorized kettle of 40 liters capacity. A temperature of 102^o C was maintained by controlling the flame of the burner. The kettle was provided with a stationery scrapper and the base of the kettle was rotated by a drive motor of 1.5 HP. Two numbers of stationery LPG burners were provided beneath the rotating base. This arrangement enabled to provide uniform heating and automated scrapping of the surface of the vessel. Agitation of the ingredients was also uniform.

- *Selection of Method of Drying for Increasing the shelf-life of the Product*

The conventional product obtained by boiling the mixture of milk and the drug is in liquid form and hence the keeping quality of the product under ambient conditions is very poor. Converting the product into powder form will be an ideal solution to improve the keeping quality and also the marketability of the product.

Preliminary trials were carried out for selecting the method of drying. Product was subjected to drying in a Twin Drum Roller Drier, Cabinet Drier, and Spray Drier. Product parameter such as uniformity of the product, better reconstitution, and overall acceptability of the prepared product were analysed.

- *Optimization of Various Processing Parameters of the Method of Drying of Rasona Ksheerapakam*

From the preliminary trials conducted for selection of the method of drying for improved keeping quality and consumer acceptability of the product spray drying was selected as the best method of drying of the product.

After the selection of spray drying as the appropriate process for drying, detailed investigations were carried out for the optimization of process parameters of spray drying process. In order to carry out the scaling up of the process further trials were carried out in a pilot spray drier plant (Make: Anhydro, Denmark) having a capacity of 5 kg/hr of water evaporation rate. Three major factors such as speed of the atomizer (rpm), inlet temperature (°C), feed rate (lph) were selected as the parameters for optimization. Based on machine specifications, available literature and results obtained from preliminary trials, the speed of atomizer was varied from 15,000 to 22,000 rpm, inlet air temperature from 170 to 200 °C and feed rate from 3 to 5 LPH. The Central Composite Rotatable Design (CCRD) for these three independent variables was used for studies leading to the optimization of the process variables. As per the design outcome, 20 trials were carried out, by keeping the variables as nearly as possible to the values prescribed by the software and the product was subjected to sensory evaluation and estimation of moisture content. The evaluated scores were further subjected to statistical analysis and final equations in terms of actual factors such as flavour, colour and appearance, mouth feel and overall acceptability were obtained. After conducting the diagnostic check of the quadratic model for the sensory characteristics and moisture content, results were obtained.

- *Preparation of the Product using the Optimized Process Variables and Verification of the Predicted Values*

After obtaining statistically viable optimized process variables, studies were carried out for the validation of predicted values. Three trials were carried out for the purpose of validation and the data thus obtained was statistically analyzed using t-test (assuming equal variance) with the corresponding predicted value.

V. RESULTS AND DISCUSSIONS

- *Selection of Equipment and Machinery for the Industrial Production of Rasona Ksheerapakam*

In order to select an efficient method of extraction of the medicinal component in milk, trials were carried out in an open pan steam jacketed vessel and LPG fired motorized kettle with stationery scrapper. The major disadvantage of the steam jacketed kettle was that, continuous and vigorous scrapping of the contents is required through out the extraction process. Other wise the product may get burned on the surface of the kettle. As the process should be supported by the uninterrupted supply of steam at a minimum pressure of 2.5 Kg/cm², the paraphernalia of a steam boiler must be provided. On the other hand, the LPG fired system was more user-friendly as the system was provided with a motorized vessel and scrapper. Thus the necessity for continuous stirring was avoided, and labour component was reduced. On the end product side also, better uniformity was obtained in the second method. A tabulation regarding various parameters under consideration is shown in table.1.

Table 1: Comparison of Steam Jacketed Kettle and LPG fired Motorized Kettle for Processing of Rasona Ksheerapakam

Description of parameter under consideration	Steam Jacketed Kettle	LPG Fired motorized Vessel
Initial Capital required	High(Rs 3.00Lakh for a minimum feasible capacity of 32 litres per day)	Low(Rs 1.50 Lakh for 32 litres per day capacity)
Cost of Utilities	High(40% higher than LPG fired model)	Low
Accessories required	Steam boiler and related paraphernalia	No additional accessories required
Cost of Labour	High(2 labourers/machine)	Low(1 labourer/machine)
Quality of the product	Poor (with burnt and grainy particles)	Better

Thus considering the merits of the LPG fired system, the system was selected as the appropriate methodology for further investigations in the study.

- *Selection of Method of Drying*

Dehydration or drying is the oldest and most important method of food processing and dehydrated foods are convenient, versatile and incur less handling cost (Loesecke, 1998; Hayashi, 2003). Various methods of industrial drying methodologies such as Cabinet drying, Roller drying, Spray drying etc are commonly used for drying of milk and milk products. The Rasona Ksheerapakam was subjected to three different types of drying such as Twin Drum Roller Drying, Cabinet Drying and Spray Drying. The products obtained by these methods were subjected for evaluation with respect to physical and sensory properties. The results are shown in Table 2.

Loesecke (1998) reported spray drying as one of the widely adopted dehydration techniques for preparation of value added products, especially powder formulations. Spray drying helps to produce a powder of specific moisture content and particle size. In a continuous operation spray drying delivers a highly controlled powder quality with relatively easy manipulation. The objective of the spray drying is to produce a spray of high surface to mass ratio droplets and then to evaporate the water uniformly and quickly. Evaporation keeps the product temperature to a minimum, which in turn reduces the chance of high temperature quality loss of the product. Further spray drying minimizes the loss of volatile flavors as against other dehydration techniques.

From the trials undertaken, it was evident that, the product obtained from spray drying technique resulted best quality since it possess a lower solubility index (maximum solubility), better sensory qualities compared to the product obtained from drum drying and cabinet drying methods. Hence spray drying method was selected for further studies in the investigation.

Table 2: Comparative Physical and Sensory Characteristics of Spray Dried, Drum Dried and Cabinet Dried Rasona Ksheerapakam Powder

Method of Drying	Solubility Index(ml)	Flavour	Mouth feel	Colour and Appearance
Spray Dried	1.0	Clean, rich and free from burnt flavour	Same as that of whole milk	Creamy white
Drum Dried	14.5	Distinct cooked flavour	Slightly grainy feel	Slightly darker shade
Cabinet Dried	18.5	Burnt flavour	Pronounced grainy feel	Darker shade

- *Preliminary Trials on the Selected Method of Drying of the Product*

After conducting a series of trials by using Laboratory Model Spray drier JISL/LSD-48, acceptable quality dried powder was obtained with the following process parameters- Inlet air temperature 180° C, Aspirator rate 50%(59 m³/h), Feed pump rate 20%(200ml/h). As further studies were planned to carry out in a pilot scale ANHYDRO spray drying plant with centrifugal atomizer, it was necessary to select the range of feed rate and speed of the atomizer. Various research workers (Rao and Mathur, 1987 and Ganesan 1996) suggested a feed rate ranging from 3 to 4 LPH and speed of the atomizer ranging from 15000 to 22000 rpm, in a pilot scale ANHYDRO spray drier for getting acceptable quality product. Hence the inlet air temperature ranging from 170 to 200° C, speed of the atomizer ranging from 15000 to 22000 and feed rate ranging between 3 and 4 lph were selected for further optimization.

- *Optimization of Various Processing Parameters of the Method of Drying of Rasona Ksheerapakam by Response Surface Methodology*

Samples of Rasona Ksheerapakam powder were prepared by spray drying technology by subjecting the process through selected range of inlet air temperature, rpm of the atomizer, and the feed flow rate. A five level-three factor CCRD was adopted for the optimization. The coded and actual levels of the three factors (design factors) are given in Table 4.3 and design matrix representing different combinations of the three

factors as generated by the software are presented in Table 4.4. The product samples prepared out of the trials were subjected to sensory evaluation, and the obtained values are presented in table.5

Table 3: Coded and Real Values of Speed of the Atomizer, Inlet Temperature and Feed Rate

Coded level Factor	Lower limit	Factorial point	Centre coordinate	Factorial point	Upper limit
	-2	-1	0	+1	+2
A: Speed of Atomizer, rpm	15000.00	16418.89	18500.00	20581.11	22000.00
B: Inlet air Temp. °C	170	176.08	185.00	193.92	200.00
C: Feed rate LPH	3.0	3.41	4.00	4.59	5.00

Table 4: The Central Composite Rotatable Design for Three Independent Variables: Speed of the Atomizer, Inlet Temperature and Feed Rate

Standard Order	Block	Factor 1	Factor 2	Factor 3
		Atomizer speed rpm	Inlet temperature °C	Feed rate lph
1	Block 1	16418.89	176.08	3.41
2	Block 1	20581.11	176.08	3.41
3	Block 1	16418.89	193.92	3.41
4	Block 1	20581.11	193.92	3.41
5	Block 1	16418.89	176.08	4.59
6	Block 1	20581.11	176.08	4.59
7	Block 1	16418.89	193.92	4.59
8	Block 1	20581.11	193.92	4.59
9	Block 1	15000.00	185.00	4.00
10	Block 1	22000.00	185.00	4.00
11	Block 1	18500.00	170.00	4.00
12	Block 1	18500.00	200.00	4.00
13	Block 1	18500.00	185.00	3.00
14	Block 1	18500.00	185.00	5.00
15	Block 1	18500.00	185.00	4.00
16	Block 1	18500.00	185.00	4.00
17	Block 1	18500.00	185.00	4.00
18	Block 1	18500.00	185.00	4.00
19	Block 1	18500.00	185.00	4.00
20	Block 1	18500.00	185.00	4.00

VI. EFFECT OF DIFFERENT LEVELS OF PROCESS PARAMETERS ON THE SENSORY SCORES AND MOISTURE CONTENT OF RASONA KSHEERAPAKAM POWDER

- *Diagnostic Check of the Quadratic Model*

The quadratic model for sensory scores and moisture content was obtained through successive regression analysis. The dependence of these responses with respect to three factor levels in the form of correlations is presented in Table 4.6. The model F value for all sensory attributes was more than F Table value at 5% level of significance, except for moisture content where it was found not significant. The R² values were more than 0.73 for all sensory responses except for moisture content, which indicates that the fitted quadratic models accounts for more than 73% of the variation in experimental data. For moisture content, the R² value was 0.49, which indicates that the fitted quadratic model is accounted for less than 50% of the variation in experimental data and hence the observed value cannot be explained by the chosen (Quadratic) model. The lack of fit test, which measures the fitness of the model obtained, did not result in a significant F value, indicating that the

model is sufficiently accurate for predicting the sensory characteristics of the product with any combination of factor levels within the range evaluated.

In case of moisture content, the model F value is less than F Table value and hence model F value is not a significant term. The model is not sufficiently accurate for predicting the moisture content in the product with any combination of the factor levels within the range evaluated. The response surface equations developed to predict the changes in each sensory characteristic are described below.

Table 5: Moisture Content and Sensory Score of RKP Powder with Different Process Variables

Standard Run	Moisture content,%	Sensory Score			
		Flavour	Mouth feel	Colour and appearance	Overall acceptability
1	3.26	7.56	7.47	7.43	7.29
2	3.54	7.92	8.11	8	8.06
3	3.25	7.23	7.25	7.26	7.43
4	3.52	7.89	7.87	7.95	7.99
5	3.26	7.53	7.44	7.45	7.42
6	3.45	7.59	7.62	7.62	7.86
7	3.58	7.68	7.54	7.56	7.38
8	3.49	7.72	7.68	7.69	7.68
9	3.29	7.49	7.41	7.42	7.61
10	3.52	7.58	7.83	7.85	7.95
11	3.28	7.48	7.38	7.31	7.53
12	3.38	7.36	7.21	7.25	7.49
13	3.49	7.62	7.31	7.36	7.46
14	3.26	7.75	7.77	7.82	7.93
15	3.51	7.42	7.39	7.41	7.38
16	3.26	7.36	7.36	7.39	7.46
17	3.26	7.49	7.46	7.42	7.38
18	3.28	7.56	7.46	7.48	7.54
19	3.28	7.28	7.32	7.28	7.39
20	3.61	7.52	7.68	7.65	7.66

*Score in each cell is the average of four judges

Table 6: Regression Coefficients and ANOVA of Fitted Quadratic Model for Moisture Content and Sensory Characteristics

Partial coefficients	Moisture content %	Sensory characteristics			
		Flavour	Mouth feel	Colour and appearance	Overall acceptability
Intercept	3.365099	7.435532	7.434637	7.440639	7.469452
A- Speed of Atomizer (rpm)	0.075919	0.093093*	0.167181**	0.167414**	0.193442**
Inlet Temp. °C	0.036478	-0.02064	-0.01032	-0.0429	-0.01591
B- Feed rate LPH	-0.01295	0.010151	0.033216	0.025894	0.026393
AB	-0.03625	0.035	0.01	-0.0075	-0.04375
AC	-0.05625	-0.115*	-0.12	-0.1175	-0.07375
BC	0.04875	0.08	0.05	0.0775	-0.03625
A ²	0.023798	0.052486	0.093693*	0.090376	0.10288*
B ²	-0.00272	0.011827	-0.03182	-0.02453	0.007421
C ²	0.013191	0.105519	0.077783	0.062091	0.072828
Lack of fit	ns	ns	ns	ns	ns
Model F value	1.108312 ^{ns}	3.67*	3.54*	3.04*	3.25*
R ²	0.499369	0.767425	0.761066	0.732208	0.745331
Press	0.542417	0.777931	1.357535	1.596326	1.695543
Adeq. Press	3.830309	7.250504	7.290214	7.082737	6.74808

** Significant at 1 per cent level

*Significant at 5 per cent level

^{ns} Non- significant at 5.0%

Table 7: Goal Set for Constraints to Optimize the Rasona Ksheerapakam Powder

Constraints Name	Goal set for RKP	Lower Limit	Upper Limit
Speed of the atomizer, rpm	is in range	16418.89	20581.11
Inlet temperature, °C	is in range	176.08	193.92
Feed rate, LPH	is in range	3.41	4.59
Flavour	maximize	7.23	7.92
Mouth feel	maximize	7.21	8.11
Colour & appearance	maximize	7.25	8.00
Overall Acceptability	maximize	7.29	8.06

The values obtained were further analysed with the help of Design expert software. Table 8 shows 29 solutions and their desirability while predicted values for all the sensory responses are depicted in Table 4.9. It was noticed that solution no: 1 had higher desirability value of 0.851. Hence solution no: 1 was selected as optimum combinations. The predicted value as listed for different responses in solution no1 was considered while validating the optimized combinations.

Table 8: Suggested Solutions from the RSM Analysis for the Rasona Ksheerapakam Powder

Solution No	Solutions			% Desirability
	Atomizer Speed (rpm)	Inlet temp. °C	Feed rate, LPH	
1	20581.11	176.08	3.41	0.851
2	20581.11	176.15	3.41	0.850
3	20581.11	176.53	3.41	0.847
4	20581.02	176.08	3.41	0.847
5	20581.11	176.30	3.42	0.840
6	20556.95	176.08	3.42	0.836
7	20581.11	178.19	3.41	0.835
8	20581.11	176.08	3.51	0.792
9	20581.11	183.91	3.41	0.788
10	20581.11	186.47	3.41	0.763
11	20581.11	187.82	3.41	0.749
12	20581.11	176.08	3.65	0.714
13	20581.10	191.45	3.41	0.709
14	20581.11	176.08	3.97	0.587
15	20581.11	193.36	4.59	0.577
16	20581.11	193.50	4.59	0.577
17	20581.10	193.92	4.59	0.576
18	20581.11	192.21	4.57	0.570
19	20581.10	186.76	4.59	0.566
20	20581.11	190.57	4.55	0.564
21	20581.11	185.86	4.58	0.561
22	20581.11	193.92	4.50	0.554
23	20581.11	183.56	4.59	0.554
24	20581.11	176.08	4.10	0.553
25	20581.11	185.99	4.36	0.538
26	16418.89	193.92	4.59	0.448
27	16436.41	193.91	4.59	0.446
28	16418.89	191.45	4.58	0.439
29	16418.89	177.86	4.59	0.405

Table: 9 Predicted Values for the Sensory Parameters of Rasona Ksheerapakam Powder by the Design Expert RSM Software for the Suggested Optimized Solutions

Solution No.	Flavour	Colour & appearances	Mouth feel	Overall Acceptability
1	7.87	7.96	7.88	7.92
2	7.87	7.95	7.88	7.92
3	7.86	7.95	7.88	7.91
4	7.87	7.95	7.88	7.92
5	7.86	7.95	7.87	7.91
6	7.86	7.94	7.87	7.91
7	7.85	7.94	7.88	7.91
8	7.81	7.91	7.83	7.89
9	7.80	7.87	7.87	7.89
10	7.78	7.83	7.85	7.88
11	7.77	7.81	7.84	7.88
12	7.72	7.84	7.77	7.86
13	7.75	7.75	7.81	7.87
14	7.59	7.73	7.67	7.83
15	7.68	7.67	7.71	7.71
16	7.68	7.67	7.70	7.71
17	7.69	7.67	7.70	7.70
18	7.66	7.67	7.70	7.72
19	7.60	7.67	7.70	7.77
20	7.63	7.67	7.70	7.73
21	7.59	7.67	7.69	7.78
22	7.66	7.66	7.69	7.69
23	7.57	7.66	7.68	7.81
24	7.55	7.70	7.64	7.83
25	7.56	7.67	7.67	7.75
26	7.66	7.59	7.59	7.55
27	7.66	7.59	7.59	7.55
28	7.64	7.58	7.59	7.55
29	7.61	7.52	7.55	7.56

- *Verification of the Optimum Formulations*

The product was prepared using optimized combinations and was subjected to analysis for sensory characteristics. The data obtained are depicted in Table 10. They were analysed statistically using t-test (assuming equal variance) with the corresponding predicted value. It was observed that the values were not significantly different from the predicted value with respect to sensory attributes.

Table 10: Comparison of the Predicted and Observed Values of Quality Attributes of Rasona Ksheerapakam

Attributes	RKP		
	Predicted value	Observed value [#]	t _α value
Flavour	7.87	7.78 ± 0.08	0.25 ^{ns}
Colour and appearance	7.96	7.88 ± 0.01	0.11 ^{ns}
Mouth feel	7.88	7.87 ± 0.02	0.47 ^{ns}
Overall acceptability	7.92	7.87 ± 0.01	0.07 ^{ns}

[#] Figures are the Mean ± SE of three replications

VII. CONCLUSION

The present investigation aims at the process standardization of various unit processes involved in the commercial production of Rasona Ksheerapakam. Attempts were also carried out for increasing the shelf life of the product and making the product available in the user friendly dosage forms. As the process of Ksheerapakam preparation is basically an extraction process, different possible methods for industrial production were explored. Once the extract was prepared out of a standard industrial process, the next phase was aimed at selection of a method of drying, for increasing the shelf life of the product. Product was subjected to drying in a Twin Drum Roller Drier, Tray Drier, and Spray Drier and the product obtained was subjected to evaluation. The scaling up of the production spray drying process and optimization of the process parameters were carried out. The Central Composite Rotatable Design (CCRD) for three independent variables was used for studies leading to the optimization of the process variables. After obtaining statistically viable optimized process variables as 20581 rpm speed of the atomizer, 176°C inlet air temperature, 3.41 LPH feed rate, studies were carried out for the validation of predicted values.

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