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FORMULATION AND EVALUATION OF RASONA KSHEERAPAKA AS DISPERSIBLE POWDER

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ABSTRACT

Rasona Ksheerapaka is a classical preparation stated in Ayurvedic texts. Garlic Milk is considered as a highly useful remedy in Ayurveda for dyslipidaemia. The aim of the study is to preparation and evaluation Rasona Ksheerapaka using spray drying technique and to study the physicochemical properties. Rasona Ksheerapaka was prepared as per the reference textbook of Bhaisajya Kalpana text, Spray dried powder was prepared by using spray dryer unit, at standard. HPLC analysis was performed estimation of allicin. The result showed that the allicin present in the sample. The prepared ksheerapaka powder was evaluated for Physical, chemical, microbial and Nutritional value. Physical parameter like loss on drying, moisture content and total ash were found to be 3.8 %, 3.6 % and 4.54 % respectively. Titrable acidity as lactic acid was found to be 2.29%. microbial parameter like Total Aerobic Microbial Count and Total Yeast & Mold Count was found to be 34 Cfu/g and <10 Cfu/g respectively and pathogen test like Coliforms count, Staphylococcus aureus, Escherichia coli, Salmonella abony count was found to be all pathogen's absent in the sample. Nutritional Fact like Milk fat, Protein, Lactose and Carbohydrates was found to be 19.43 %, 21.10%, 18.21% and 51.33% respectively. It is necessary Rosana ksheerapaka to be prepared freshly and consumed. Currently there are no market products available. Hence, we have developed the rasona ksheerapaka dispersible powder by using spray drying technique.

KEYWORD: Rasona ksheerapaka, Dyslipidaemia, Spray drying.

INTRODUCTION

Ayurveda is not only the oldest system of medicine in India, but it claims to be the first systemic science ever evolved throughout the world. Pharmaceutics in Ayurveda were included under Bhaishajya Kalpana. Garlic Milk is considered as a highly useful remedy in Ayurveda for dyslipidaemia. It is highly effective & treats multiple conditions of the body including dyslipidaemia.

In industrialized nations, hyperlipidaemia is a prevalent condition. High blood fat levels are caused by anomalies in lipid metabolism, plasma lipid transport, or a malfunction in the production and breakdown of plasma lipoproteins. Elevations in blood triglyceride (TG), total cholesterol (TC), low-density lipoprotein (LDL), and HDL concentrations, as well as a reduction in LDL concentration, are possible symptoms. Cardiovascular diseases (CVDs) are the leading cause of mortality worldwide. Each year, more people die from CVDs than from any other cause. In 2008, 17.3 million people worldwide died from CVDs, accounting for 30% of all fatalities. An estimated 6.3 million of these fatalities were attributed to coronary heart disease, and 6.2 million to stroke. The impact is disproportionately seen in low- and middle-income nations: about 80% of fatalities from CVD occur in these regions and nearly equally affect men and women. By 2030, the number of deaths from CVDs—primarily from heart disease and stroke—will rise to 23.3 million. According to projections, CVDs will continue to be the top cause of mortality. By treating risk factors including tobacco use, poor nutrition and obesity, physical inactivity, high blood pressure, diabetes, and elevated lipids, the majority of cardiovascular illnesses may be avoided. 9.4 million High blood pressure is a factor in 16.5% of all fatalities, or one fatality per year10. This comprises 45% of fatalities from coronary heart disease and 51% of deaths from strokes. In order to identify and evaluate other significant variables and co-morbidities, it is imperative that all individuals diagnosed with hyperlipidaemia have a comprehensive clinical examination and appropriate therapy.

Ksheerapaka is processed milk which is naturally occurring form, it can be consumed in daily diet. It is necessary Rosana ksheerapaka to be prepared freshly and

consumed. Often, it is observed that patient do not adhere to the advice of the health care professional/doctor. Nonadherence is attributed to lack understanding of the treatment and laborious process involved in the preparation. Hence there is a need for the formulation that is patient/user friendly. We have developed the Rasona ksheerapaka powder using spray drying technique.

Methods

Materials

Raw material like Rasona(garlic) was collected from Local market Mysuru, Karnataka, India. Cow's milk was procured from FSSAI approved milk Product Company. Pharmaceutical preparation of Rasona Ksheerapaka was done at Sarada Vilas college of pharmacy, Mysuru, Karnataka, India.

Instruments

Spray dryer, High performance liquid chromatography.

Preparation of Rasona Ksheerapaka

Rasona Ksheerapaka was prepared as per the reference of Bhaisajya Kalpana text i.e. by taking concentration in proportion of 1:8:32 of Rasoana: Milk: Water. 1.25 kg of Garlic bulbs was treated with 10L of milk and 40L of Water. The mixture was heated on mild fire i.e. 90-95^{0}c until it reduced to half the total liquid. Ingredients and apparatus are mentioned in table no 1.

Table no. 1: Ingredients of rasona ksheerapaka.

Sl. No.	Drugs	Quantity used in each sample
1	Rasona	1.25kg
2	Milk	10L
3	Water	40L

Powder of arjuna ksheerapaka

Rasonsa Ksheerapaka was converted into the dried powder by using spray dryer, Ksheerapaka was kept in spray drying unit with standard setting of atomizer.

Preparation of spray dried powder of rasona ksheerapaka

Table no. 2: Spray dried powder of rasona ksheerapaka.

Quantity of Rasona Ksheerapaka	Temperature (°C)		RPM	Feed rate	Total yield (gm)	Duration (Min)
	Inlet	Outlet				
10 L	180°C	95°C	8000	30 ml/min	400 gm	60 min

Estimation of allicin using high performance liquid chromatography

Preparation of extract for high performance liquid chromatography

The extract prepared was diluted with distilled water. 196 mg of extract was taken and was diluted with 10 mL of distilled water. The extract was filtered with 0.45 filter pore and then used for HPLC.

Preparation of standard for high performance liquid chromatography

Allimax tablets were used as a source of allicin. One tablet consists of 195 mg of powdered allicin. This 195 mg was diluted with 10 mL of distilled water. The standard was filtered with 0.45 filter pore and then used as standard for high performance liquid chromatography.

Table no. 3: Quantitative Analysis (HPLC Conditions).

Stationary phase	C18 column (250 × 4.6 mm)
Mobile phase	Water: methanol
Solvent ratio	50:50
Flow rate	1 ml / min
Detector	UV detector
Wavelength	254nm
Run rate	10 min
Injection Volume	20 microliters

RESULTS

Powder of rasona ksheerapaka

Rasona ksheerapaka dispersible powder was prepared.

Figure no. 1: Rasona ksheerapaka powder.

Estimation of allicin using High performance liquid chromatography

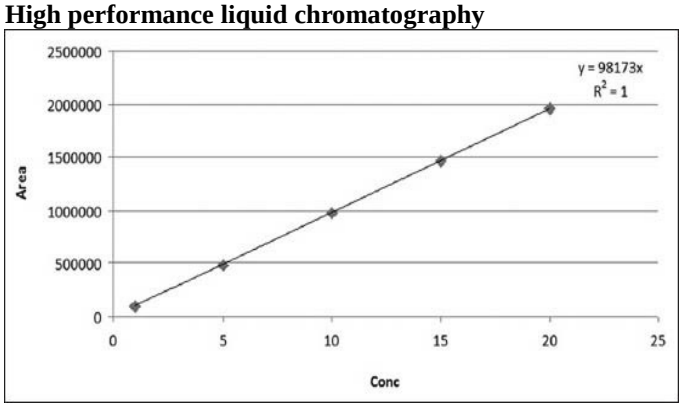

Figure 2: Calibration curve of standard allicin as obtained by HPLC.

The chromatogram obtained by analysing a solution of standard allicin was shown [Figure]. The response was linear in the range 1-20 µg/ml. The linear regression equation was: y = 98173x, (y = area in arbitrary units, x = concentration in µg/ml), with $R^2 = 1$.

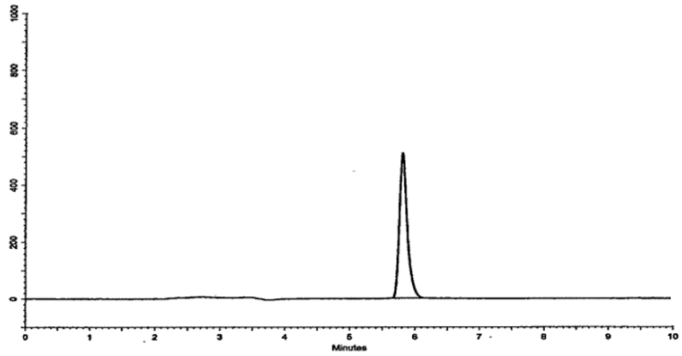

Figure no. 3: Chromatogram of standard solution of allicin as obtained by high performance liquid chromatography.

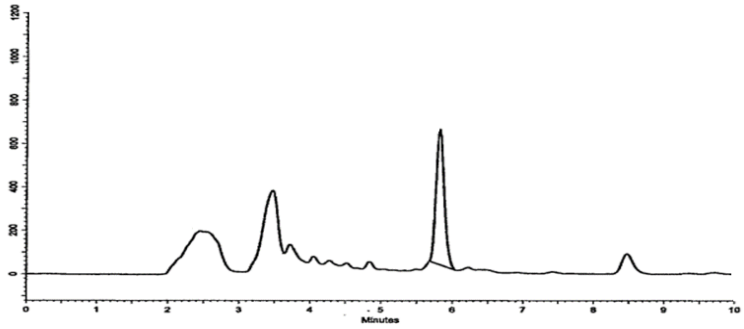

Figure no. 4: Chromatogram of sample rasona ksheerapaka as obtained by high performance liquid chromatography.

The HPLC data given in Table clearly suggested that the allicin was not degraded by the effect of spray drying technique. Even, from the different area and peak height, it was easily visible that the amount of allicin was there in the sample.

Table no. 4: HPLC output of allicin.

Component	Rt value (min)	Peak area	RSD (%)	Peak height
Standard allicin	5.8	959856	0.43925	1863
Rasona ksheerapaka sample	5.803	827369	0.51728	1984
HPLC: High performance liquid chromatography; RSD: Relative standard deviation				

Organoleptic properties

Table no. 5: Organoleptic properties of Rasona ksheerapaka dispersible powder.

Characteristics	Specification	Results	Method
Colour	Creamish white	Complies	Sensory
Odour	Characteristics odour	Complies	
Taste	Milkey taste, slightly sweet	Complies	
Texture	Smooth and powdery	Complies	

The organoleptic evaluation of Rasona ksheerapaka dispersible powder revealed the following:

- **General description:** The powder is creamish-white in color with a characteristic odor.
- **Taste:** It has a milky, slightly sweet flavor.
- **Texture:** The texture is smooth and powdery.

Physical properties

Table no. 6: Organoleptic properties of rasona ksheerapaka dispersible powder.

Parameters	Specification	Results	Method
Identification	Spherical shape, Gram positive, spore-forming	Complies	Microscopy
Loss on Drying	NMT 6.0%	3.8 %	FSSAI manual method
Moisture content	NMT 6%	3.6 %	
Total ash	NMT 5%	4.54 %	
dispersibility test	partially dispersed	Complies	Visual

The bacteria were identified as spherical, Gram-positive, and spore-forming. Loss on drying and moisture content were 3.8% and 3.6%, respectively. Total ash content was 4.54%. Rasona ksheerapaka showed partial dispersion after 2 minutes. Titrable acidity, measured as lactic acid, was 2.29%.

Determination of microbial parameters

Table no. 7: Microbial parameters of Rasona ksheerapaka.

Parameter	Media	Result	Acceptance Criteria	Conclusion
Total aerobic microbial count	SCDA	3400 Cfu/g	NMT 5000 Cfu/g	Pass
Total Yeast & Mold Count	RBCA	< 10 Cfu /gm	NMT 100 Cfu /gm	Pass

Pathogen testing				
Escherichia coli (E. coli)	Mac Conkey media	Absence	Must be absence	Pass
Staphylococcus aureus	Streptococcus selective media (SS).	Absence	Must be absence	Pass
Salmonella abony	Bismuth sulfite agar (BSA)	Absence	Must be absence	Pass
Total shigella count	Streptococcus selective media (SS).	Absence	Must be absence	Pass

Total aerobic microbial count

TAMC is calculated with SCDA medium, and the results were obtained with the help of microbial plate counts of 10^5 for formulation and it's expressed in cfu /gm using the formula.

TAMC calculation of SCDA medium

MEB	Dilutions	No. of Colonies	TAMC Cfu/g	Standard Limit Cfu/g
F-1	10^5	34	3400	NMT 5000

Total Yeast & Mold Count

TYMC is calculated with RBCA medium, and the results are noted down with the help of microbial plate counts of 10^{-1} and it's expressed in cfu /gm using the formula.

TYMC calculation of RBCA medium

MEB	Dilutions	No. of Colonies	Cfu /gm	Standard Limit Cfu/g
F-1	10^1	01	< 10	NMT 100

Figure no. 5: TYMC plates.

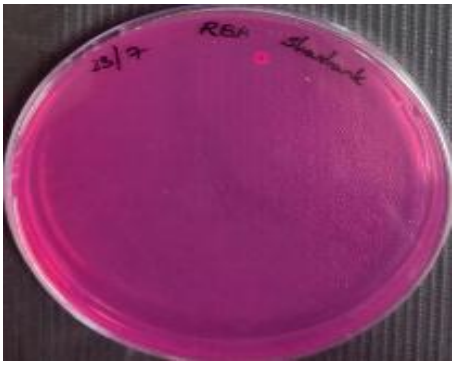

Figure no. 6: Total aerobic microbial count.

Pathogen testing

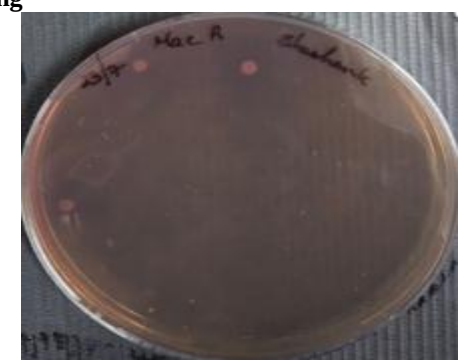

Figure no. 7: Escherichia coli.

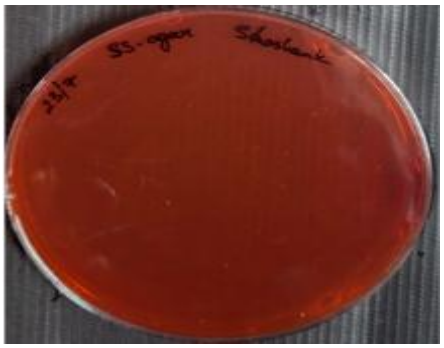

Figure no. 8: Staphylococcus aureus.

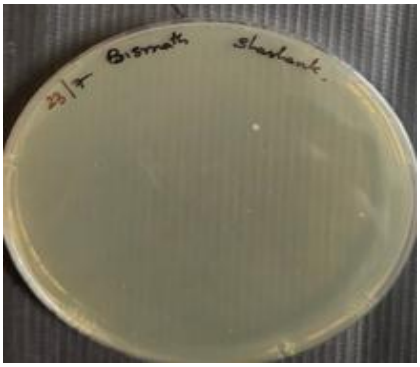

Figure no. 9: Salmonella abony.

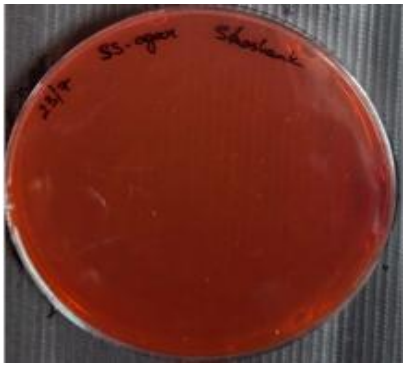

Figure no. 10: Total shigella count.

Pathogen Testing include Testing for *Staphylococcus aureus*, *Escherichia coli*, *Salmonella abony and* Total shigella by using different media such Mac Conkey media, Streptococcus selective media, Bismuth sulphite agar media and Streptococcus selective media was confirmed the absence of these pathogens in the powder.

Nutritional Fact of Rasona ksheerapaka

Table no. 8: Nutritional study data of rasona ksheerapaka.

Sl. No.	Tests	Unit	Results	Test Methods
1	Milk fat	% w/w	19.43	FSSAI manual of method
2	Protein	% w/w	21.10	
3	Lactose	% w/w	18.21	
4	Carbohydrates	% w/w	51.33	

The Milk fat content in Rasona ksheerapaka formulation was found to be 19.43% w/w. similarly Protien content in rasona ksheerapaka was found to be 21.1% w/w.

The lactose content in Rasona ksheerapaka formulation was found to be 18.21 % w/w. similarly carbohydrates content in rasona ksheerapaka was found to be 51.33 % w/w.

DISCUSSION

In this study, Rasona ksheerapaka dispersible powder was formulated and evaluated using the spray drying technique. This unique Ayurvedic liquid dosage form extracts both milk and water-soluble active principles. High-Performance Liquid Chromatography (HPLC) analysis confirmed that the allicin content remained stable during spray drying. The prepared powder underwent various evaluations, including physical, chemical, microbial, and nutritional assessments.

The physical parameters showed that the powder is creamish-white with a characteristic odour, milky and slightly sweet taste, and smooth, powdery texture. Microscopic examination identified the bacteria as spherical, Gram-positive, and spore-forming. Loss on drying was 3.8%, moisture content was 3.6%, total ash was 4.54%, and dispersibility tests indicated partial dispersion after 2 minutes. chemical analysis revealed a titrable acidity of 2.29% as lactic acid.

Microbial testing showed a total aerobic microbial count (TAMC) of 34 CFU/g and total yeast and mould count (TYMC) of less than 10 CFU/g, with no pathogens detected in the powder. Nutritional analysis indicated milk fat content at 19.43% w/w, protein at 21.10% w/w, lactose at 18.21% w/w, and carbohydrates at 51.33% w/w, demonstrating that the milk components were stable within the powder's nutritional profile.

CONCLUSION

It is necessary Rosana ksheerapaka to be prepared freshly and consumed. Currently there are no market products available. Hence, we have developed the rasona ksheerapaka dispersible powder by using spray drying technique. This Technique reduces the product bulk weight and size and spray drying minimizes handling. The process also preserves the product by reducing its water activity to a low level, required to stop bacterial degradation.

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