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COMPARATIVE PHARMACEUTICO-ANALYTICAL STUDY OF GANGADHA KWATH, GHANAVATI WITH SPECIAL REFFRENCE TO ITS ANTI-BACTERIAL ACTIVITY

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INTRODUCTION

One of the main strategies in Ayurvedic medicine is to increase body'snatural resistance to the disease. Ayurveda is being practiced since ancient times as an important speciality aiming at rejuvenation and geriatric care. It is considered to be one of the oldest of healthcare systems, and is based on sound scientific principles. It literally meansthe Science of Life. It is not just a medicinal system, but also a way of life. Ayurveda deals with the physical, as well as spiritual health. Ayurvedic compound formulations too have reached extensive acceptability as therapeutic agents for several diseases. Ayurveda isattracting modern scientists in finding out solutions for many challenging diseases.

Diarrhoea is a disease with bowel disturbances during which one passes more frequent, loose, watery stools. More than 90%cases of acute diarrhoeal disease are caused by infective agents. Most of thepeople have experienced diarrhoea at some point in his and her life.In developing countries and under developed countries, where healthcare is scarce, diarrhoea is a major health concern because of its potential to cause severe life-threatening dehydration. Infants and elderly are more prone to dehydration from diarrhoea.

Diarrhoea is an uncomfortable condition that can have many causes. This is usually caused by the intake of stale food and drinking contaminated water. Although the vast majority of bacteria are harmless or beneficial, a few pathogenic bacteria can cause infectious diseases. Infection is classified short term infection (acute) & long-term infection (chronic). Common organisms that cause acute bacterial diarrhoea are Escherichia coli, Bacillus cereus, Staphylococcus etc.

Increasing use of antibiotics by practitioners is resulting into increased resistance against the antibiotics. This demands to the higher use of higher antibiotics to counteract the disease. This approach by the practitioners is costly treatment and ultimately causes

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permanent resistance to the antibiotics also.

All dhatus and updhatus (fluid tissues such as rasa, lasika, sharirjala, mutra etc.) getting increased greatly, decrease the effect of the agni and mix with the faeces, thus making it watery, goes out of body in large quantities, many times forced out by vata. This dreadful diseaseis called as Atisara. In Ayurveda, it has been written that atisara means discharge of frequent watery stool from anus.

The concept of alternative system of treatment notably herbal and Ayurvedic medicines therapy is gaining ground, attraction & attentionworldwide. There is more and more scientific research being conducted in our country for treatment of various diseases byAyurvedic and herbal therapy.

Ayurvedic medicines are based on plants, animals extract and minerals both in single ingredient drugs and compound formulations. In Ayurvedic pharmacology, Kalpavijnana (pharmacy) is a well-advanced branch. Crude drugs are rarely administered. Various formulation ranging from simple Arks (distillates), Kwath (decoctions), Leha, Avaleha (linctus) and Churna (powders) to elaborate pharmaceutical preparations like Vati, Guti, Modaka (pills of different sizes) and taila and Ghrita (medicated oils) are available.In liquid formulations too, a wide range exists. These are Swarasa (fresh juice), Kwath (decoction), Phanta (infusion in hot water), Ksirapaka (decoction in milk). Acharya have mentioned many secondary formulations in samhitas like Churna, Kwath, Vati, Ghanvati, Avaleha according to their particular therapeutic use. Aacharya Bhava Mishra has given asystematic and scientific description of many pharmaceutical preparations. Bhava Prakash is an important treatise on Ayurveda, being counted as one of the “Laghu Trayi”. In Bhava Prakash volume II, Atisaraadhikara chapter, Gangadhara kawth is given in Atisara (Diarrhoea).

But dispensing Kwath is convenient because it is most of the time notpalatable to patient and it must be prepared daily. Kwath (Decoction) is the process in which the water soluble and heat stableconstituent of hard and woody crude drugs are extracted out. Here water is used as menstrum for the stated time. A freshly prepared Kwath should only be dispensed and the same must be consumed within 24 hours without reheating.

The Kwath material with the help of heat is set in to processed; whichultimately converted into semisolid and solid form that is called as Ghana. After this process; Ghana manually

converted in to Vati thatis Ghanavati.

Due to busy schedule of working man now a days, it is easier to administer Ghanavati instead of Kwath i.e. easy dispensing, better palatability and lower dose and syrups can be easily administered in children & elderly so preparation of Ghanvati and syrup of same covers the entire age group.

The oral use of liquid pharmaceuticals has generally been justified on the basis of ease of administration to those individuals who have difficulty in swallowing solid dosage forms. Ayurvedic formulations are preferentially administered by oral route syrup preparation is equivalent to Sharkara kalpana. It is Upkalpana of Hima Kalpana according to Aacharya Yadavji Trikamji and in modern pharmaceutics, it called as syrup. Syrup is a thick, viscous liquid consisting primarily of a solution of sugar in water, containing a large amount of dissolved sugar but showing little tendency to deposit crystals. When purified water alone is used in making the solution of sucrose the preparation is known as syrup or simple syrup. When the preparation contains some medicinal-substance, it is known as medicated syrup. When the syrup does not contain any medicament but contains various aromatic or pleasantly -flavoured substances are known as flavouring syrups.

Ghanavati can be given in low doses, easy to dispensing, with exact dose and easy transport form and syrup dosage form can be give easy for children and hide to the taste & odour of unpleasant drugs.

Hence, this study is intended to prepare Gangadhar Kwath, Ghanavati, syrup and evaluate its anti-bacterial activity.

AIM AND OBJECTIVES

Aim

To prepare, analyze & evaluate anti-bacterial study of Gangadhara,kwath, ghanavati and syrup.

Objectives

1) Authentication of Raw material.
2) Preparation of Gangadhar kwath.
3) Prepararation of ghanavati from Gangadhar kwath.
4) Prepararation of syrup from Gangadhar kwath.

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5) Analytical study of Gangadhar kwath, ghanavati, and its syrup.

MATERIAL AND METHODOLOGY

MATERIAL-

A) Following herbs will be used for this research work with standardreference as mentioned in Bhava Prakash (Atisara Adhikara 2/29).

Table A: Drugs

Sr. No.	Drug Name	Part used	Ratio
1	Chaulai	Leaf	1
2	Dadim	Leaf	1
3	Jamboo	Leaf	1
4	Shrungataka	Leaf	1
5	Bilwa	Fruit	1
6	Bahristham	Root	1
7	Musta	Bulbous root	1
8	Shunthi	Rhizome	1
9	Potable water	-	Q.S.
10	Sugar	-	Q.S.
11	Methyl-p hydroxyl benzoate	-	0.25%
12	Propyl-4 hydroxyl benzoate	-	0.04%

B) **RAW DRUG COLLECTION**-

a) Three raw drugs (Chaulai, Dadim, Shrungataka) were collected fromfarms.

b) Five raw drugs (Jamboo, Bilwa, Bahristham, Musta, Shunthi) werecollected from GMP certified pharmacy.

c) All drugs were identified and authentified by botanist from scienceinstitute.

C) Equipment for Gangadhara kwath, Ghanavati and Syrup

1. weighing machine and digital weighing machine
2. measuring cylinder 2000ml., 500 ml., 100ml.,
3. Stainless steel vessels 10L. , 1L. ,
4. Heating device,
5. Spoons,
6. Thermometer,
7. White clean cotton cloth.

MATHODOLOGY

Quantity of raw drugs used for Gangadhara Kwatha, Ghanavati and Syrup-

Table B: Drug's Quantity

Sr. No.	Drug Name	Kwath	Ghanavati	Syrup
1	Chaulai	25 gm.	125 gm.	50 gm.
2	Dadim	25 gm.	125 gm.	50 gm.
3	Jamboo	25 gm.	125 gm.	50 gm.
4	Shrungataka	25 gm.	125 gm.	50 gm.
5	Bilwa	25 gm.	125 gm.	50 gm.
6	Bahristham	25 gm.	125 gm.	50 gm.
7	Musta	25 gm.	125 gm.	50 gm.
8	Shunthi	25 gm.	125 gm.	50 gm.
9	Potable water	1.6 lit.	8.0 lit.	3.2 lit.
10	Sugar	-	-	790gm
11	Methyl-p hydroxyl benzoate	-	-	2.47mg
12	Propyl-4 hydroxyl benzoate	-	-	0.39mg

GANGADHARA PRODUCTS PREPATION

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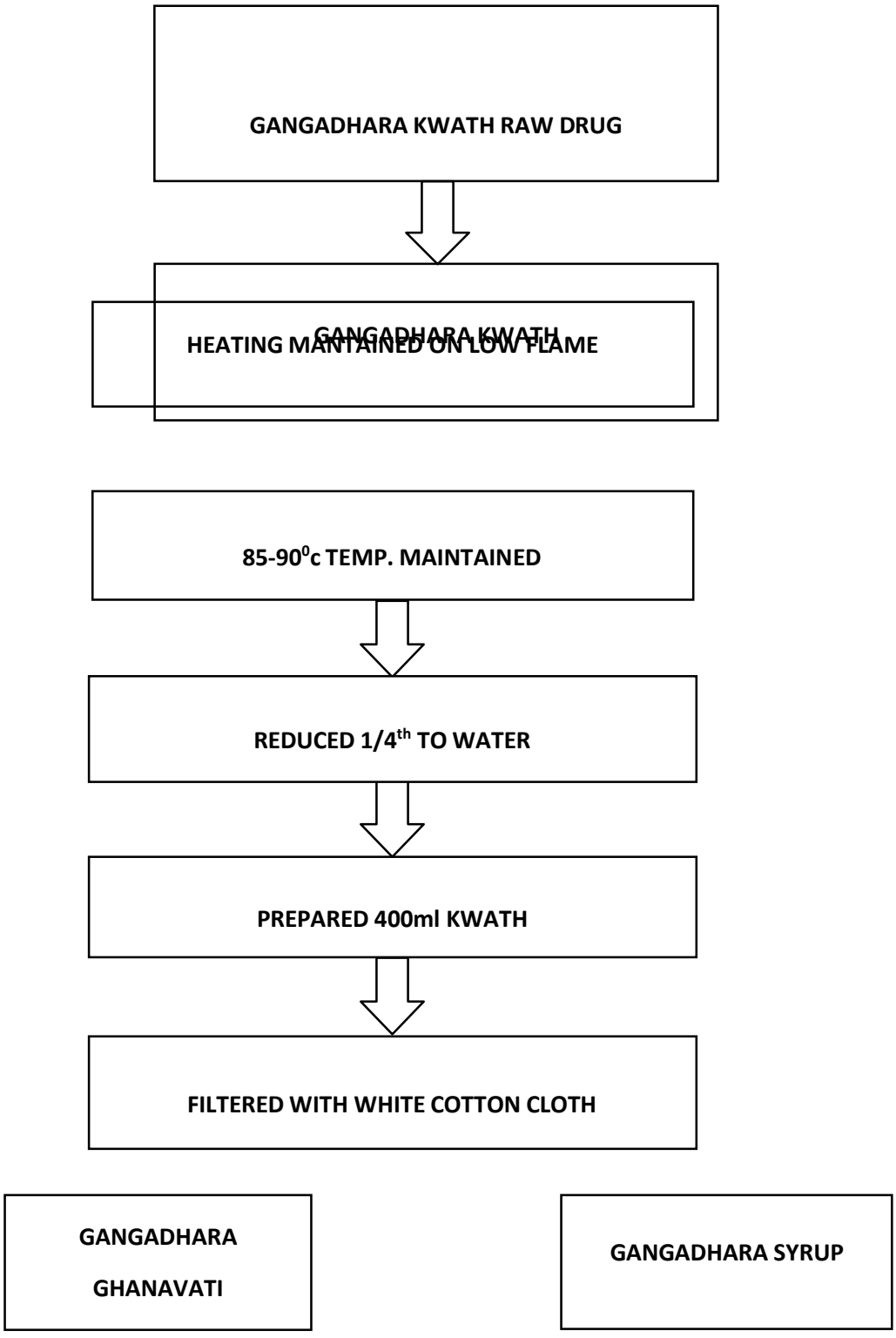

GANGADHARA KWATH

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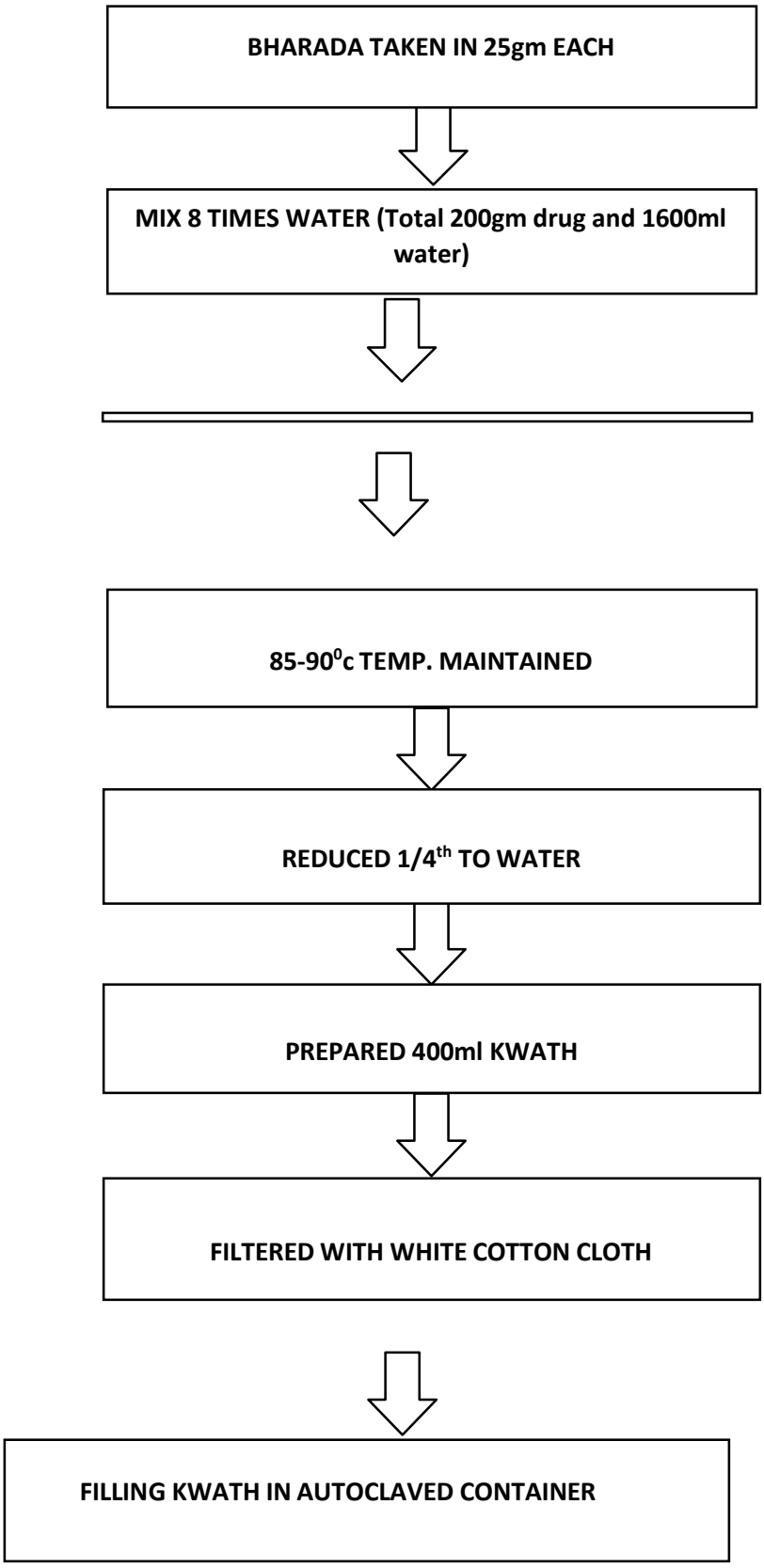

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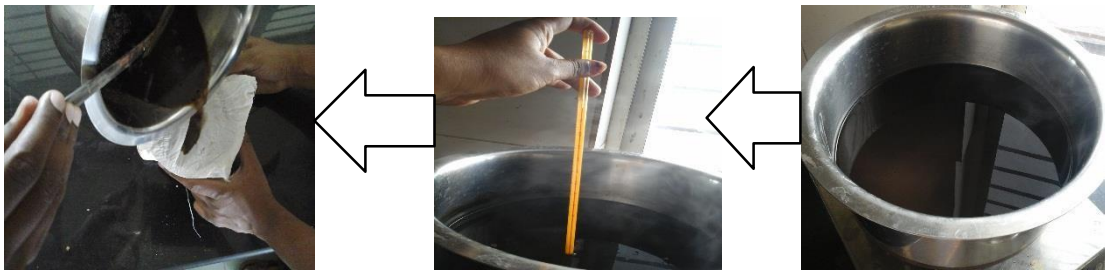
KWATH PREPARATION

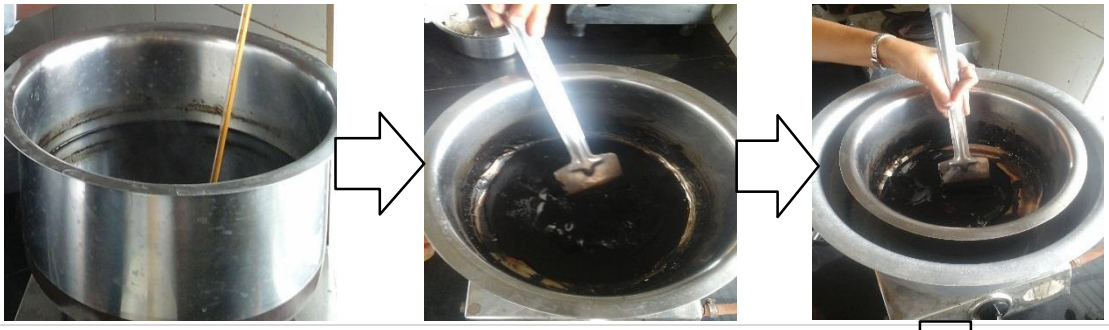
DRUGS IN VESSEL **WATER ADDED HEATINGPROCESS**

FILTERATION **MAINTAING TEMP.** **BOILING**



PREPARATION OF GHANAVATI

KWATH HEATING **REDUCING WATER** **WATER BATH PROCESS**



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GHANAVATI **PREPARING GHANA**

PREPARATION OF SYRUPKWATH

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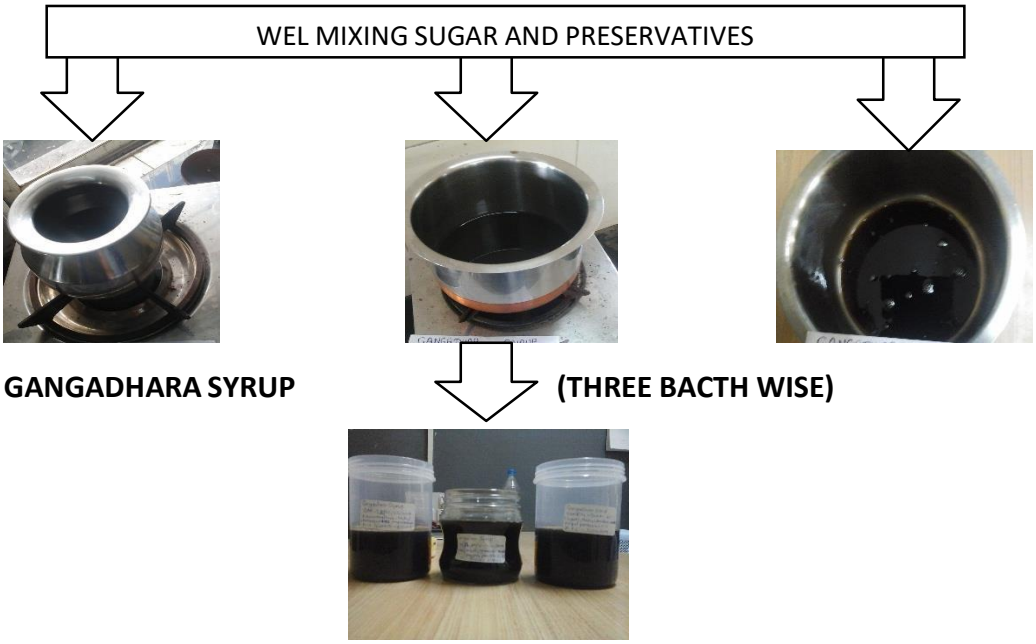

OBSERVATIONS AND RESULTSOBSERVATIONS:

TABLE NO. 1: GANGADHARA KWATH

Sr.No.	Observation of parameters		For sample Kwath	Kwath for Ghanavati	Kwath for syrup
1.	Kwath evaporation during process	Start	62^0c	62-65^0c	62-65^0c
		End	92^0c	90-95^0c	90-95^0c
2.	Total time taken for preparation for Kwath		3.30 hrs.	4 hrs.	6 hrs.

TABLE NO. 2: GANGADHARA GHANAVATI

Sr.no.	Observation parameters		Observation values
1.	Quantity of Kwath		2 lit.
2.	Maximum Temperature during process		92^0c
3.	consistency of	Starting	Liquid

	Kwath	After 1 hrs.	Thickened
		After 2 hrs.	Sticky
		After 3 hrs.	Semi solid
4.	Final quantity of Ghana obtainedbefore drying (g)		142g.
5.	Total time for drying (days) in shade		12-13days
6.	Final quantity of dried Ghanavati obtained (g)		124g.
7.	Percentage yield of dried Ghanavati		12.4%

TABLE NO. 3: GANGADHARA SYRUP

Sr.No.	Observation parameters		Syrup batch I	Syrup batch II	Syrup batch III
1.	Quantity of Kwath (ml)	-	200ml	200ml	200ml
2.	Temperature during process	-	80-85^{0}c	80-85^{0}c	80-85^{0}c
3.	Batch wise sugar %	-	60%	65%	70%
4.	Batch wise preservatives (mg.)	methyl-p hydroxyl benzoate	0.80	0.83	0.85
		propyl-4 hydroxyl benzoate	0.12	0.13	0.14
5.	Temperature during sugar added	-	80-85^{0}c	80-85^{0}c	80-85^{0}c
6.	Temperature during preservatives added	-	62-65^{0}c	62-65^{0}c	62-65^{0}c

7.	Final quantity of syrup	-	320ml	330ml	340ml

Organoleptic characters:

TABLE NO. 4: Gangadhara kwath, Ghanavati and syrup

S.NO.	Parameters	KWATH	GHANAVATI	SYRUP
1.	Shabda	**-**	Dull sound on shaking.	**-**
2.	Sparsha	Liquid	Hard	Sticky
3.	Roopa	Greenish brown	Black	Greenish brown
4.	Rasa	Tikta	Tikta	Madhur
5.	Gandha	Specific	Specific	Sweet

RESULTS-

Analytical parameters:

Analysis of raw material-

1) Raw materials collected from GMP certified pharmacy and Botanical garden.

2) Raw materials authenticated from botanist.

8. TABLE NO. 1: Analysis of raw drugs

S. NO.	PARA-METER	UNIT	CHAULAI	DADIMA	JAMBOO	SHRUNGATAKA
1.	pH (5% solution)	_	6.40	04.89	05.04	05.35
2.	Loss on drying at 105^0c	%	10.38	09.43	09.78	10.33
3.	Total Ash	%	18.73	05.25	05.06	12.10
4.	Acid Insoluble Ash	%	0.81	0.71	01.15	02.30

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5.	Water Soluble Extract	%	16.80	27.02	10.93	09.82
6.	**Heavy Metals**					
i.	Cadmium	ppm	BDL	BDL	BDL	BDL
ii.	Mercury	ppm	BDL	BDL	BDL	BDL
iii.	Arsenic	ppm	BDL	BDL	BDL	BDL
iv.	Lead	ppm	BDL	BDL	BDL	BDL
7.	**Microbial Assay**					
i.	Total viable aerobic count	Cfu	$26x10^3$	$15x10^3$	$42x10^3$	$92x10^3$
ii.	Total fungal count	Cfu	$5x10^3$	$4x10^3$	$4x10^3$	$9x10^3$
iii.	Entero-Bacteria-cea	Cfu	$110x10^1$	$8x10^1$	$11x10^1$	$70x10^1$

BDL- Below Detectable level.

TABLE NO. 2: Analysis of raw drugs

S. NO.	PARA-METER	UNIT	BILWA	BAHRISTHAM	MUSTA	SHUNTHI
1.	pH (5% solution)	_	04.78	05.24	5.40	03.37
2.	Loss on drying at 105^0c	%	11.25	08.98	09.92	09.23
3.	Total Ash	%	03.51	08.76	08.98	04.37
4.	Acid Insolubl e Ash	%	0.71	01.80	02.56	0.75
5.	Water Soluble Extract	%	46.89	03.57	10.92	10.25
6.	**Heavy Metals**					

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i.	Cadmium	ppm	BDL	BDL	BDL	BDL
ii.	Mercury	ppm	BDL	BDL	BDL	BDL
iii.	Arsenic	ppm	BDL	BDL	BDL	BDL
iv.	Lead	ppm	BDL	BDL	BDL	BDL
7.	**Microbial Assay**					
i.	Total viable aerobic count	Cfu	$4x10^3$	$43x10^3$	$74x10^3$	$2x10^3$
ii.	Total fungal count	Cfu	$6x10^3$	$20x10^3$	$8x10^3$	$1x10^3$
iii.	Entero-Bacteria-cea	Cfu	Absent	$14x10^1$	$4x10^1$	$2x10^1$

BDL- Below Detectable level.

GANGADHARA KWATH

TABLE NO. 3: Analysis of Gangadhara kwatha

Sr.No.	PARAMETERS	UNIT	VALUE
1.	pH	-	04.89
2.	Specific Gravity	-	01.03
3.	Total Ash	%	0.77
4.	Total Solid	%	6.80
5.	Water Soluble Substance	%	5.49
Antimicrobial activity			
Sr.No.	**Test Organisms**	**Concentrated of sample**	**Diameter of Inhibition Zone in (mm)**
1.	Escherichia coli	100%	0

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2.	Staphylococcus aureus	100%	0
3.	Bacillus cereus	100%	0

GANGADHARA GHANAVATI-

TABLE NO. 3: Analysis of Gangadhara Ghanavati

Sr.no.	Parameter	Unit	Value
1.	pH	-	4.55
2.	Loss on drying at 105^0	%	10.79
3.	Friability test	%	passes
4.	Uniformity of weight	%	-2.6
5.	Disintegration time	-	Dose not disintegrate completely
6.	Total ash	%	9.47
7.	Acid insoluble ash	%	0.098
8.	Hardness	%	3.0
	Microbial study		
1.	E. coli	mm	24
2.	Staphylococcus aureus	mm	-
3.	Bacillus cereus	mm	-

GANGADHARA SYRUP

TABLE NO. 4: Analysis of Gangadhara syrup batch I(0 month)

Sr.No.	PARAMETERS	UNITS	SYRUP BATCH I VALUE (0 month)

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			A1	B1	C1
1.	pH	_	4.41	4.40	4.50
2.	Specific Gravity	_	1.2284	1.2426	1.2617
3.	Total Sugar	%	41.79	43.64	46.7
4.	Non Reducing	%	39.70	41.45	44.36
5.	Reducing Sugar	%	02.20	2.32	1.75
6.	Colour	_	Brown	Brown	Brown
7.	Concentration	%	53.53	57.37	58.4
8.	Viscocity	cSt	02.47	02.09	05.21
	Microbial Study				
1.	E.coli	mm	19	0	17
2.	Staphylococcus aureus	mm	0	0	0
3.	Bacillus cereus	mm	14	13	0

TABLE NO. 5: Analysis of Gangadhara syrup batch II (6 month)

Sr.No.	**PARAMETERS**	**UNITS**	**SYRUP BATCH II VALUE (6 month)**		
			A2	B2	C2
1.	pH	_	4.22	4.26	4.34
2.	Specific Gravity	_	1.2087	1.2715	1.2427
3.	Total Sugar	%	40.25	50.27	46.12
4.	Non Reducing	%	38.23	47.75	43.81

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5.	Reducing Sugar	%	2.86	3.08	2.58
6.	Colour	_	Brown	Brown	Brown
7.	Concentration	%	52.54	59.81	56.91
	Microbial Study				
1.	E.coli	mm	20	22	0
2.	Staphylococcus aureus	mm	27	35	30
3.	Bacillus cereus	mm	0	0	0

TABLE NO. 6: Analysis of Gangadhara syrup batch III(9 month)

Sr.No.	PARAMETERS	UNITS	SYRUP BATCH III VALUE (9 month)		
			A3	B3	C3
1.	pH	_	04.83	04.73	04.92
2.	Specific Gravity	_	1.2196	1.2632	1.2486
3.	Total Sugar	%	48.30	59.58	50.10
4.	Non Reducing	%	35.70	46.11	37.67
5.	Reducing Sugar	%	12.60	13.46	12.43
6.	Colour	_	Dark Brown	Dark Brown	Dark Brown
7.	Concentration	%	53.64	62.33	58.77
8.	Viscocity	cSt	01.51	02.86	02.69
	Microbial Study				
1.	E.coli	mm	16	15	0
2.	Staphylococcus aureus	mm	21	18	0
3.	Bacillus cereus	mm	16	16	0

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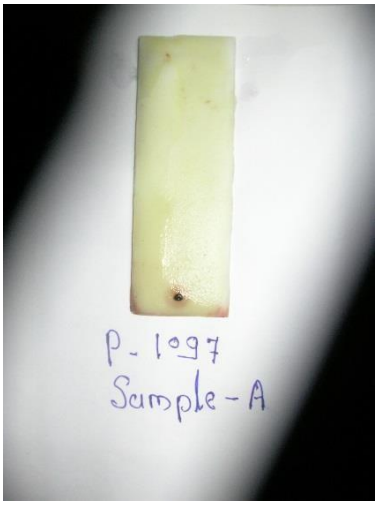
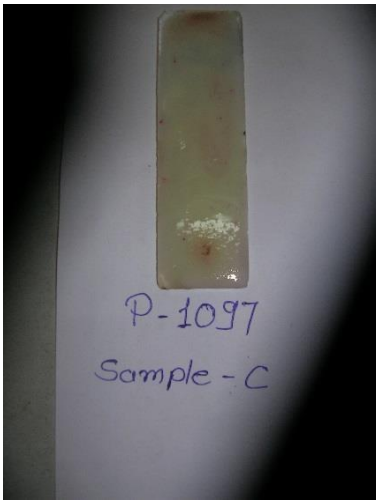
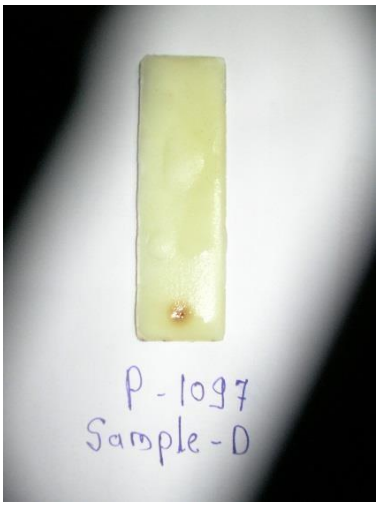
TLC OF RAW DRUGS



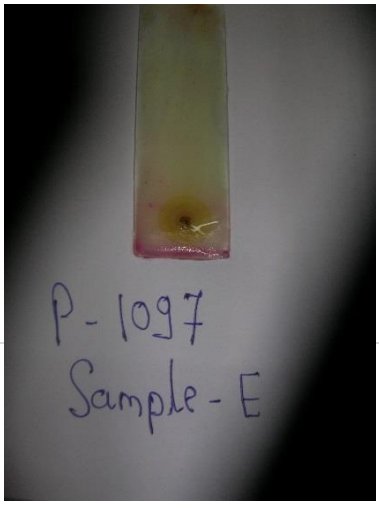
MUSTA

CHAULI





TLC OF RAW DRUGS



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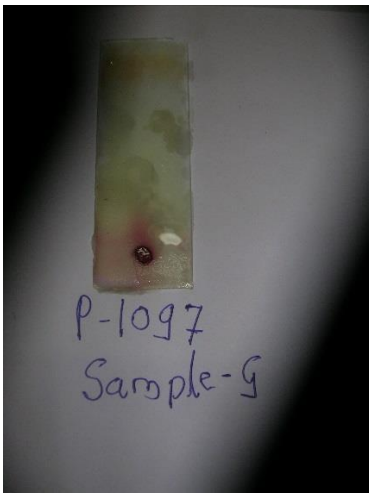
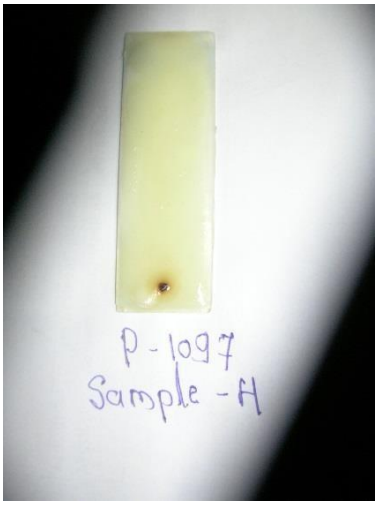
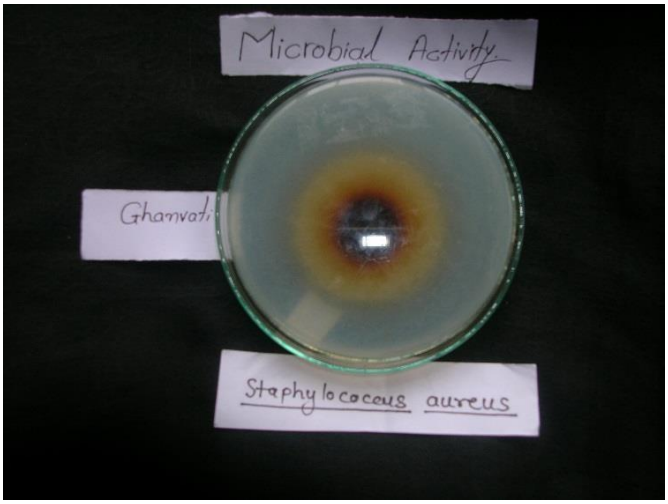
DADIM **BAHRISTHAM**

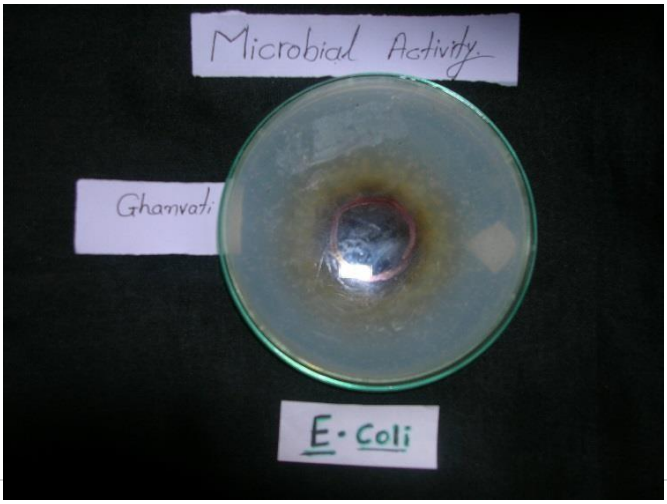




BILWA **SHRUNGATAKA**

ANTI-BACTERIAL ACTIVITY OF GHANA VATI





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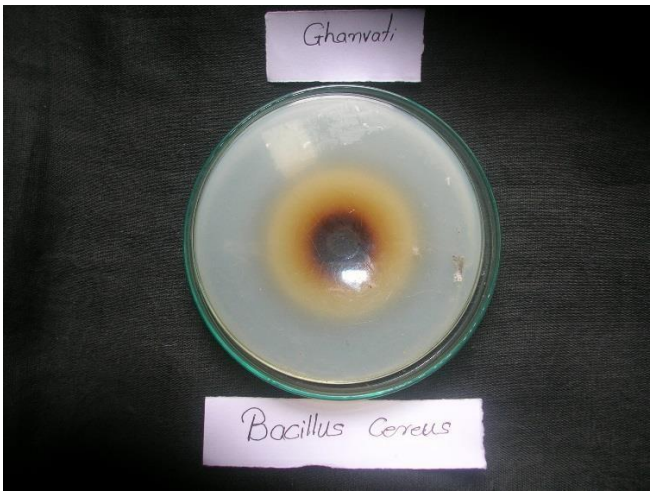

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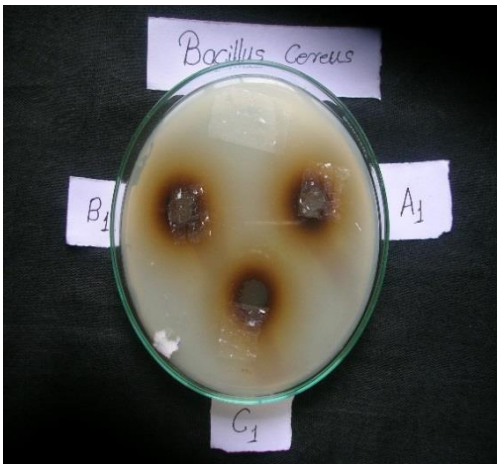
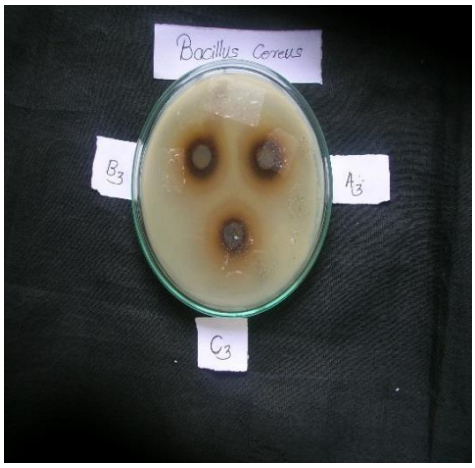
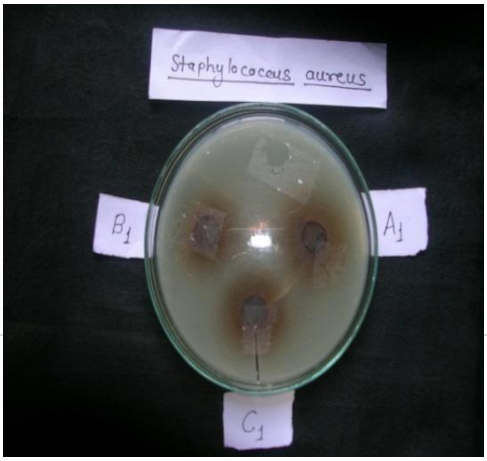
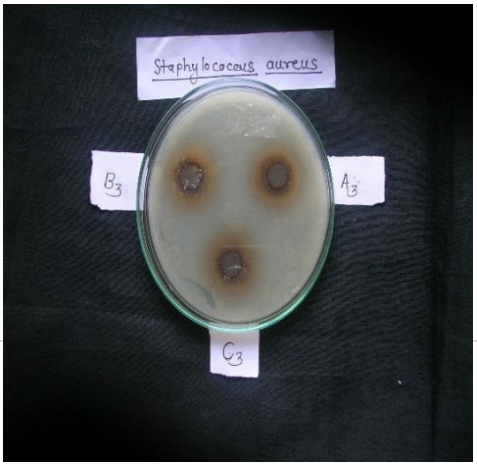


'9' MONTH



BACILLUS CEREUS





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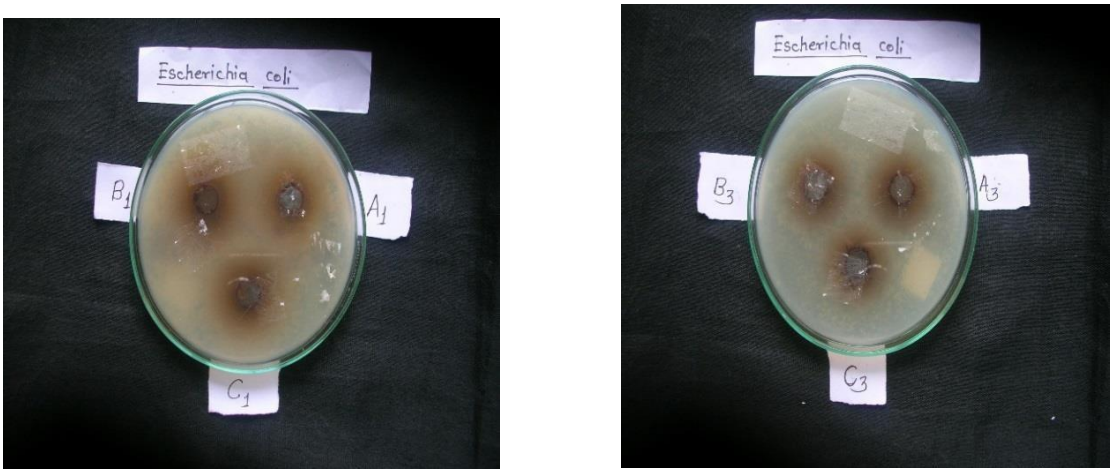
STAPHYLOCOCUS AUREUS

0' MONTH **'9' MONTH**



ESCHERICHIA COLI

A1, A2, A3 - 60% concentrated sugar syrup

B1, B2, B3 - 65% concentrated sugar syrup

C1, C2, C3 - 70% concentrated sugar syrup

S.G. - Specific Gravity

T.S. – Total Sugar

N.R.S. – Non-reducing Sugar

R.S. – Reducing Sugar

Con. – concentration

VIS. - viscosity

DISCUSSION

LITERARY-

- Syrup are the modified form of preparation mentioned in the morden pharmaceutics. In Ayurveda, basic kalpana like Swarasa, Kwath etc. are mentioned. But due to drawbacks like shelf life and palatability, secondary kalpana like churna, vati were introduced.
- It is easier to administer Ghanavati instead of Kwath i.e. easy dispensing,

better palatability and lower dose and syrups can be easily administered in children & elderly so preparation of Ghanvati and syrup of same covers the entire age group.

KWATH-

- In kwath preparation, temperature is an important factor because there are chances that it can decompose some of the thermo labile active constituents. Therefore, during the preparation of Kwath temperature was maintained between90-95^{0}c.
- Stirring was done during the preparation of Kwath. It was applied for proper extraction and reducing the chances of degradation of some of the active constituents.

GHANAVATI-

- For Ghana preparation continuous stirring was done carefully to avoid burning of the reduced drug material, afterwards it was rolled into pills immediately, as delay may cause more hardness of the Ghana.
- Ghanavati was allowed to dry completely in shed as moisture may cause fungal growth and hence deterioration of the qualityof the product.
- Autoclave glass containers were used for storage to avoid microbial contamination.

SYRUP-

- Kwath was taken base for syrup.
- Syrups were made in 3 batches according to the percentage ofsugar (60%, 65% and 70%) to assess the stability of the preparation.
- Syrup were also kept in sterile container to avoid microbial contamination.

ANALYTICAL STUDY-

pH-

If drug pH reduces than in acidic form they are not stable. Gangadhara Kwath, Ghanavati and syrup were showed with in some range so that are stable for at 9 months.

TOTAL ASH-

The total ash is particularly in the evaluation of purity of drugs i.e. the presence or absence of foreign organic matter such asmetallic salt and / or silica and which is show concentration of

drugs. So the Gangadhara Kwath total ash is 0.77% and total ash of Ghanavati is 9.47% which is show concentration of drug.

LOSS ON DRYING-

Loss on drying is a criteria of shelf life. Presence of moisture in any preparation causes degradation of product. High content of water may favour the growth of micro-organism which isshowed the stability of drug.

DISINTEGRATION TIME-

Disintegration of Ghanavati is useful as a quality assurance toolfor conventional dosage forms and also show the agitation of the gastric contents. But as Gangadhar Ghanavati does not disintegrate complete because Ghanavati drug may be closely & tightly binding due to heat and its concentration is more.

FRIABILITY-

Tablets must be able to withstand mechanical stresses during their manufacturing, distribution and handling by the end-user. So the friability and hardness of Ghanadhara Ghanavati is mechanical integrity. Which was passed during friability analysis.

ANTIBACTERIAL ACTIVITY-

Gangadhara Kwath not showed significant inhibition zone for Escherichia coli, Staphylococcus aureus and Bacillus cereus. But Gangadhara Ghanavati showed only E.coli inhibition zone and batchs of Gangadhara syrup showed significant inhibition zone in E.coli, Staphylococcus aureus and Bacillus cereus in different manner. 60% concentrated sugar of 0 month shows in E.coli and Bacillus cereus inhibition zone, 6 month inhibitionzone shows in E.coli and Staphylococcus aureus and 9 month inhibition zone shows in E.coli, Staphylococcus aureus and Bacillus cereus. 65% concentrated sugar of 0 month shows only in Bacillus cereus, 6 month inhibition zone shows in E.coli and Staphylococcus aureus and 9 month inhibition zone shows in E.coli, Staphylococcus aureus and Bacillus cereus.70% concentrated sugar of 0 month shows only in E.coli, 6 month inhibition zone shows in only Staphylococcus aureus and 9 month shows no inhibition zone. Which is show anti-diarrhoeal drug activity according to activity of bacteria. Bacterial inhibition zones of Gangadhara syrups are greater than Kwathand Ghanavati because used sugar and preservatives in syrup which was increased its stability.

SUMMARY

Dissertation starts with introduction, which includes importance of Ayurveda, about Bhava Prakasha.

No any work was done before on the preparation of Gangadhara Kwath and also on Gangadhara Ghanavati and Gangadhara syrup. Comparative antibacterial activity not done before for Bacillus cereus,E.coil and Staphylococcus aureus.

The aim of present study was to convert Gangadhara Kwath into Gangadhara Ghanavati and Gangadhara syrup. Then to evaluate shelflife of Gangadhara syrup and compare the antibacterial activity of Kwath and that of Ghanavati and syrup.

Reference of present study topic was reviewed first. Literary review for Kwath kalpana, Ghanavati, and syrup preparation were done. Drugs were reviewed with their information regarding Rasa, Guna, Virya, Vipaka, Doshaghnata, Prabhava, Karma and Chemical constituents. Disease review done with both Ayurvedic and modern aspect. Introduction and pathogenesis of Streptococcus aureus, E. coli and Bacillus cereus reviewed.

Coarsely powdered drugs added in 8 parts of water. Mixture kept for boiling and reduced to $1/4^{th}$ part called as 'Kwath.' Then Kwath boiled till the water part get evaporated and thicker mass obtained i.e. 'Ghana.' After cooling, vati were rolled out manually and added sugar 60%, 65% and 70% in prepared Kwath and made Syrup properly.

Gangadhara Kwath, Gangadhara Ghanavati and Gangadhara syrup showed analytical reports.

Gangadhara Kwath did not show antimicrobial activity. Antimicrobial activity of Gangadhara Ghanavati seen by Agar well method on E.coli. Bacterial inhibition zones of Gangadhara syrups are greater than Kwath and Ghanavati because used sugar and preservatives in syrupwhich was increased its stability.

CONCLUSION

- 12.4% of Gangadhara Ghanavati can be obtained from Gangadhara Kwath.
- Shelf life of Gangadhara Ghanvati and syrup are 9 months whereas of Gangadhara Kwath is only one day.
- Bacterial inhibition zones of Gangadhara syrups are greater than Kwath and Ghanavati because used sugar and preservatives in syrup which was increased its stability in 9 month study.

LIMITATIONS-

Due to time limitation could no longer sheif life studies. Thisstudy duration is 9

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month.

FURTHER SCOPE-

For preclinical and clinical study.

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