

## VALIDATION OF STANDARD MANUFACTURING PROCEDURE OF GUDUCHI GHANA [DRIED AQUEOUS EXTRACT OF *Tinospora cordifolia* (Willd.) Miers] AND ITS TABLETS

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### Abstract

There has been a dramatic surge in popularity of Ayurvedic herbal extracts over the past thirty years. Vast work is needed yet to develop globally accepted standards in the manufacturing process. Guduchi is one of the most versatile rejuvenating herbs, possessing numerous therapeutic attributes. Though there is rising continuous demand for its dried aqueous extract called Ghana in international market, its well developed and Standard Manufacturing Procedure (SMP) up to its final tableting are lacking. Considering this, the present study was aimed to develop SMP for preparation of Guduchi Ghana and its tablet dosage form. Fifteen batches of Guduchi Ghana were prepared by following classical guidelines and compressed into tablets. Tablets were further subjected to relevant analysis to develop physicochemical profile. The average percentage of dried Ghana obtained was 5 %. Optimum hardness, weight of tablets, disintegration time and friability of Guduchi Ghana tablets were found complying the official standards. Glycosides, Alkaloids, Tannin, Phenols, Carbohydrates, Starch and Sterols were found present in Guduchi Ghana tablets. The data obtained in present study may prove a torch bearer for future studies.

**Key words:** Guduchi; Ghana; Standard Manufacturing Procedure; Tablets.

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## INTRODUCTION

Since ancient era, people have used herbs in raw form or their various preparations for healing, preventive, curative, rejuvenative and immuno-modulating properties. Among them, *Tinospora cordifolia* (Willd.) Miers locally known as Guduchi, Amrita or Giloy is of great interest for several researchers. In spite of the great advancements observed in modern medicine in recent decades, herbal preparations still make an important contribution to health care.<sup>[1]</sup> The use of phyto-therapy according to the efficacy and safety criteria is not sufficient to guarantee the quality of both the herbal medicine and its use. Moreover, processes like heating or boiling may alter the dissolution rate, chemical constituents level or even creates perplexity in pharmacological activity of its organic constituents. Therefore, quality products of standard manufacturing procedure with batch uniformity are needed to maintain quality assurance, which allow the patient to make safe use of them.

Ghana is a concentrated dosage form, which is a modification of Kwatha (decoction) Kalpana (pharmaceutical processing). It is prepared by boiling the Kwatha upto semisolid consistency and then drying it to solid state.<sup>[2]</sup> The Ghana was compressed into Vati, considering the growing popularity and advantages like accuracy of dosage, stability, patient acceptance and easy transportation. Therefore, it was preferred to prepare tablets of finally prepared Guduchi Ghana.

Considering all these points in view, present work has been planned to establish SMP of Guduchi Ghana and its tablets.

## MATERIAL AND METHODS

### Material collection and authentication

The whole pharmaceutical procedure was arranged in following three unit processes i.e.

preparation of Guduchi Kwatha, Guduchi Ghana and then its tablets. Total 15 batches of Guduchi Ghana were prepared so as to ensure the standard operative procedure. Guduchi Kwatha<sup>[3]</sup> and Ghana<sup>[4]</sup> were prepared by adopting classical methods.

Fresh Guduchi stem spreading over Nimba (*Azadirachta indica*) tree was procured from the campus of Gujarat Ayurved University, Jamnagar in the month of April-May 2012 and authenticated at Pharmacognosy laboratory of the institute.

Necessary equipments like SS (Stainless steel) vessel, SS ladle, cotton cloth, measuring jar, SS spoon, gas stove, L.P.G. cylinder, thermometer, hot air oven, mixer etc. were arranged prior to begin the process.

### Preparation of Guduchi Kwatha

The physical impurities and papery bark of Guduchi were removed and washed thoroughly with water. Stem was made into pieces of 1-2 inches having 1.6-2.1 cm diameter and crushed thoroughly, added with four times of potable water in a SS vessel and kept for soaking overnight (12 hrs). Next morning the contents were subjected to heat with continuous stirring. Water was evaporated slowly till its reduction to 1/4<sup>th</sup> and galenical was filtered through four fold cotton cloth to obtain Guduchi Kwatha.

### Preparation of Guduchi Ghana

The Guduchi Kwatha was subjected to heat with constant stirring till the entire mass converted into semi solid state. The mass was shifted into a glass tray and placed in oven at 45°C - 50°C for complete drying. After complete drying it was collected, made into fine powder through mixer grinder, passed through 80 no. sieve and packed in air tight container. By following similar process, 14 more batches were prepared to ensure SMP.

## General observations

In the Kwatha preparation, during the onset of boiling, the liquid was light brownish green in colour and bitter in taste. Later the colour turned to dark green. Evaporation process started at 70°C, which was aggravated on stirring. Maximum temperature found in the liquid was in between 95°C-100°C. After 2 hours of boiling whitish froth was observed on liquid. After 3 hours, the liquid was found to be of viscous nature. After 4 hours of boiling increase in glueyness of the liquid was observed. After complete drying by dry oven method, the semisolid, sticky and greenish brown mass of Ghana turned to blackish brown. Fine powdered Ghana was dark brown in colour. Unit process of Guduchi Ghana preparation is placed in Figure 1.

## Preparation of tablets of Guduchi Ghana

Tablets were prepared as per pharmacopeal specifications by following the principle of direct compression.<sup>[5]</sup> Ghana was passed through sieve 20 to obtain the granules and dried in oven at 50°C till it is completely dried. Next day it was mixed with 1 % binding agent (Gum acacia). Granules were passed through tablet punching machine to prepare tablets of 500 mg. A 16 station single rotary tableting machine was used for tableting. The tablets were collected, weighed and stored in air-tight sterile glass container along with small piece of cotton in it.

## Analytical study

Organoleptic characters of fresh Guduchi Stem, Kwatha, wet Ghana and powdered Ghana were noted. The tablets obtained were subjected for testing with pharmacopoeial standard parameters like hardness,<sup>[6]</sup> weight uniformity,<sup>[7]</sup> disintegration time,<sup>[8]</sup> friability<sup>[9]</sup> etc. Qualitative analysis for various functional groups were also done.<sup>[10][11]</sup>

## RESULTS AND DISCUSSION

Raw drug was collected in April-May months, as more extraction of Ghana is observed in this season.<sup>[12]</sup> Fresh Guduchi was taken in present study as per classical guideline - Sadaiva ardra prayojyeta (always use in fresh state).<sup>[13]</sup> Guduchi growing on Nimba is believed to be superior in therapeutics,<sup>[14]</sup> therefore it was preferred for pharmaceutical processing. To develop SMP, 15 batches of each of the trial drugs were prepared. (Table 1 and 2) Before the preparation of Kwatha, separation of physical impurities and outer skin was done for quality maintenance, specific size reduction up to a certain extent to facilitate proper extraction of water-soluble constituents.

First postharvest processing includes primary cutting or comminuting. 'Angustha pramana' (thumb size or medium size) stems<sup>[15]</sup> having diameter 1.6-2.1 cm were selected for study.<sup>[16]</sup> The diameter of the stem, size of the pieces, soaking time, temperature, were maintained uniformly in all batches. Guduchi stems were crushed and made into coarse slimy mass in Ulukhala Yantra (pounding apparatus). Particle size reduction provides a large surface area for drug to interact with water for adequate transfer of active constituents for better extraction. The amount of water was taken as per w/v concept i.e. for each 5 kg of Green Guduchi stem, 20 L water was taken by volume. Further, overnight soaking was done for proper penetration of the menstruum into the cells of the drug and later subjected to mild heat to avoid destruction of the component sensitive to higher temperature.

In the beginning, crushed Guduchi stem was floating over liquid. Overnight soaking (12 hrs) was done before application of heat to allow micellae take up the liquid film and the tissues swell. Swelling also results from distension and bursting of thin walled cells that have taken up the liquid by osmosis. As a result, Guduchi stem was floating.

**Figure 1: Unit process of Guduchi Ghana preparation**



It is suggested to decide the duration of soaking according to the climate, as in pilot study it was observed that excess duration of soaking (more than 12 hours) in hot season has lead to unwanted microbial growth in it.

The solubility of compound in a solvent increases with increasing temperature and higher temperature facilitate penetration of the solvent into the cellular structure of the organism to be extracted. Heating was done maintaining temperature at 90°C-95°C along with continuous stirring. It was applied for proper extraction and reducing the chances of degradation of some of the active constituents.

Thus, occasional mechanical stirring is needed to facilitate the natural circulation evaporation. Initially, liquid of Guduchi Kwatha was brownish green in colour and bitter in taste and this may be due to extraction of bitter principle from the material. Evaporation was started at 70°C, which was aggravated on stirring. After 2 hours of boiling, white coloured layers were observed on liquid. After 3 hours of boiling, mild sticky nature of liquid was observed.

Stem started to settle down after 2-3 hours of heating, because in the beginning swelling continues until the pressure caused by the liquid layers is equal to the cohesive forces

between the micellae. When air was replaced by water in certain amount by heating, the pressure was increased and the material breaks the liquid boundary. Then the material was settled down. Continuous stirring of Kwatha was done to protect the material from burning. Residual Kwatha was filtered in hot condition, through four folded cotton cloth to maintain quality of obtained product. All the batches of Guduchi Kwatha were prepared by following the same procedure. (Table 1)

In preparation of Ghana from Kwatha, mild heating was done with peak temperature 70°C-75°C by continuous stirring to maintain proper extraction and reducing the chances of burning. After 3 hours of heating, liquid became concentrated and stickier. It may be due to the presence of starch in the material. Starch is insoluble in cold water but on boiling, it forms a colloidal solution about 15 times its weight of water and the solution forming jelly on cooling. Protracted boiling also results in gelatinization of the starch material.<sup>[17]</sup>

During final stages, mild heat should be given and continuous stirring should be done to avoid its adhesiveness to the vessel and to avoid chances of burning of active constituents. To protect the material from direct heating and to remove the water content, material was transferred into a glass tray and was dried in oven between 45-50°C temperatures. After complete drying it was collected and made into fine powder through mixer grinder. The average percentage of dried Ghana obtained was 5.00 %. (Table 2)

Organoleptic characters were documented for fresh Guduchi Stem, Kwatha, wet Ghana and dried Ghana). (Table 3) The differences were insignificant. Details of tableting with their Organoleptic characters are placed in Table 4 and Table 5.

Shape of Guduchi Ghana tablet was circular with flat facets. Hardness of the tablets was

found to be 1.66 kg/cm<sup>2</sup>. The average weight of Ghana tablet was found to be 502.50 mg. The Disintegration time for Guduchi Ghana tablets was found to be 2.48 minutes. Friability was 0.82 % w/w for Ghana tablet. Physical analysis of Guduchi Ghana tablets are given in Table 6. Equipments and their specifications used in Kwatha, Ghana and tablet preparation are placed in Tables 7, Table 8 and Table 9.

As Guduchi Ghana has much hygroscopic nature, it rapidly gains moisture in short time, if kept exposed to environment. Therefore, it is suggested to keep it in dry, sterile and airtight container as soon as it is prepared. A small piece of cotton was kept with tablets in container to avoid regaining of moisture and lumping of tablets.

Earlier, studies have been made on Guduchi Ghana by using 4 times and 8 times water and the mean percentage of Ghana obtained was 3.2 – 3.68%, 4.04 – 5.56%, 5.0 – 5.50% and 8.42% respectively.<sup>[18][19][20][21]</sup> However, in these particular study, Kwatha was filtered through single folded cotton cloth. Whereas, in present study four folded cotton cloth was used for filtering.

Ghana is absolute water soluble aqueous extract and the other un-dissolved particles are not desired in it, which may hamper the quality and therapeutic attributes of the final product. Therefore four folded cloth was used. Though, the final percentage of Ghana obtained was not much by this four folded filtering, but it proved to be much therapeutically effective in a trial on 100 patients of Type-2 Diabetes Mellitus which showed 27.27% marked improvement and 47.72% moderate improvement statistically.<sup>22</sup> Comparatively, in another work of Guduchi Ghana on same disease, which used 8 times water for extraction with only single layer cloth filtering showed no marked improvement and 14.58% moderate improvement.<sup>[23]</sup>

**Table 1: Details of Guduchi Kwatha in different batches**

Batches	Initial qty. of Guduchi (kg)	Diameter of stem (cm)	Size of the pieces (inch)	Temperature (after 1 hour)	Obtained Kwatha (L)	Residue (kg)	Total time taken for Kwatha (h)
1	5	2.1-2.6	1.0-2.0	90°C -95°C	5.01	5.2	8
2	5	1.5-2.0	1.0-2.0	90°C -95°C	5.04	4.9	8
3	5	1.5-2.0	1.0-2.0	90°C -95°C	5.02	5.1	8
4	5	1.6-2.0	1.0-2.0	90°C -95°C	5.06	5.4	8
5	5	1.5-1.9	1.0-2.0	90°C -95°C	5.0	5.3	8
6	5	1.6-2.1	1.0-2.0	90°C -95°C	5.1	5.1	8
7	5	1.7-2.1	1.0-2.0	90°C -95°C	5.05	4.8	8
8	5	1.5-2.0	1.0-2.0	90°C -95°C	5.11	5.2	8
9	5	1.6-2.2	1.0-2.0	90°C -95°C	5.09	5.1	8
10	5	1.4-2.0	1.0-2.0	90°C -95°C	5.06	5.0	8
11	5	1.5-2.2	1.0-2.0	90°C -95°C	5.08	5.2	8
12	5	1.6-2.1	1.0-2.0	90°C -95°C	5.0	5.3	8
13	5	1.5-2.1	1.0-2.0	90°C -95°C	5.02	5.2	8
14	5	1.6-2.2	1.0-2.0	90°C -95°C	5.01	4.6	8
15	5	1.6-1.9	1.0-2.0	90°C -95°C	5.03	5.0	8
<b>Avg</b>	<b>5</b>	<b>1.6-2.1</b>	<b>1.0-2.0</b>	<b>90°C -95°C</b>	<b>5.04</b>	<b>5.1</b>	<b>8</b>

**Table 2: Details of Guduchi Ghana in different batches**

Batch	Total duration for Ghana preparation (h)	Final qty of semisolid Ghana (g)	Percentage of semisolid Ghana obtained (%)	Qty. of dried Ghana before grinding (g)	Qty. of dried Ghana after grinding (g)	Loss (g)	Time for drying (hrs)	Percentage of dried Ghana obtained (%)
1	5.30	520.0	10.4	276.4	243.8	32.6	26	4.87
2	7.00	618.2	12.3	294.6	279.4	35.2	25	5.58
3	6.30	696.2	13.9	300.4	283.8	16.6	27	5.67
4	6.30	619.8	12.4	293.4	280.6	12.8	25	5.61
5	6.30	683.9	13.6	300.1	285.6	14.5	26	5.71
6	6.30	690.0	13.8	295.0	279.0	16.0	27	5.58
7	6.30	681.2	13.6	305.1	291.0	14.1	25	5.82
8	5.30	715.3	14.3	308.0	295.2	12.8	25	5.90
9	6.30	858.1	17.1	318.5	302.9	15.6	26	6.0
10	7.00	873.0	17.4	312.0	299.1	12.9	26	5.91
11	5.30	590.1	11.8	222.2	210.1	12.2	27	4.20
12	6.30	371.0	7.4	160.0	149.0	11.0	25	2.98
13	7.00	344.8	6.9	162.0	154.8	7.2	25	3.10
14	6.30	451.2	9.0	202.2	189.2	13.0	27	3.81
15	6.30	476.0	9.5	231.4	215.0	16.4	25	4.32
<b>Avg</b>	<b>6.24</b>	<b>612.5</b>	<b>12.22</b>	<b>265.4</b>	<b>250.3</b>	<b>15.1</b>	<b>25.8</b>	<b>5.0</b>

**Table 3: Organoleptic characters of fresh Guduchi stem, Kwatha, wet Ghana and powdered Ghana**

Sr. No.	Parameter	Guduchi stem	Intermediate product		Finished product
			Kwatha	Wet Ghana	Powdered Ghana
1	Rupa (Colour)	Creamish brown	Brownish green	Greenish brown	Dark brown
2	Sparsa (Touch)	Soft	Liquid, Sticky	Soft, Slimy	Smooth
3	Gandha (Odour)	No specific	Characteristic	No specific	Aromatic (chocolaty)
4	Rasa (Taste)	Bitter	Bitter	Bitter	Bitter

**Table 4: Process validation for tableting of Guduchi Ghana**

Ingredients	Guduchi Ghana
Weight of product before tableting (g)	1000
Quantity of binding agent (g)	Gum Acacia (1%) 10
Total time taken for Tablet preparation(h)	3
Total weight of tablet obtained (g)	928
Yield (%)	92.90
Weight of residue (g)	76.2

**Table 5: Organoleptic parameters of Guduchi Ghana Tablets**

Parameters	Tablet
Color	Dark brown
Taste	Bitter
Odour	Characteristic (a bit chocolaty)
Touch	Smooth

**Table 6: Physical analysis of Guduchi Ghana Tablets**

Sr. no.	Parameters	Guduchi Ghana Tablets (Avg. values)
1.	Shape	Round
		Max.
		12.44
2.	Diameter	Min.
		12.12
		Avg.
3.	Width	Max.
		4.61
		Min.
4.	Hardness (kg/cm <sup>2</sup> )	3.80
		Avg.
		3.91
5.	Weight of Tablet	1.66
		Max. (mg)
		506.24
6.	Disintegration time (min)	Min. (mg)
		497.08
		Avg. (mg)
7.	Friability (% w/w)	502.50
		2.48
		0.82

**Table 7: Equipments and their specifications used in Kwatha preparation**

Sr. no.	Instrument	Parameter	Specification
1.	Stainless steel vessel	Depth	9.5 inch
		Diameter	18 inches
		Circumference	56 inches
2.	Stainless steel ladle	Capacity	40 L
		Length	21.5 inches
3.	Gas stove (Jumbo burner)	Diameter	04 inches
		Circumference	12 inches
4.	L.P.G. cylinder	Capacity	14.5 kg
		Temperature range	360°C
5.	Thermometer	Maximum Capacity	2.2 kg
		Minimum Capacity	10 g
6.	Weighing balance	Error	200 mg
		Maximum Capacity	2.0 L
7.	Measuring jar	Length	1 x 1 meter
8.	Cotton cloth		

**Table 8: Equipments and their specifications used in Ghana preparation**

Sr. no.	Instrument	Parameter	Specification
1.	Stainless steel vessel	Depth	5.5 inch
		Diameter	11.8 inches
		Circumference	31 inches
2.	Stainless steel ladle	Capacity	8.0 L
		Length	14.5 x 2.5 inches
3.	Gas stove (Big burner)	Diameter	03 inches
		Circumference	10 inches
4.	L.P.G. cylinder, Thermometer and Weighing balance	Capacity/ Temp range	same as in Kwatha preparation
		Inner chamber	SS
5.	Hot air oven	Size of Chamber	12× 12× 12 inches
		Temp. range	up to 300°C
		Accuracy	±10°C
		Temp. control	Thermostatic
		Wattage / Voltage / Hz /	750W / 230V A.C. / 50Hz /
6.	Mixer	Rating	30min
		R.P.M. [No load / Full load]	20,000 / 10,500
		Speed	3 speeds
		Blade fixed	3 blades

**Table 9: Equipments and their specifications used in Vati (Tablets) preparation**

Sr. no.	Instrument	Parameter	Specification
1.	Stainless steel tray	Length	8.0 inch
		Breadth	8.0 inches
2.	Stainless steel sieve	Diameter	5.5 inches
		Number	20
3.	Tablet punching machine	Punching type	16 station rotary tableting
		Maximum capacity	up to 15 mm
		Speed	variable
4.	Hot air oven and Weighing balance	Capacity	same as in <i>Ghana</i> preparation
		Model	200-D
5.	Weighing balance (For tablet): Analytical balance	Range	200 g

The final yield of Ghana has shown different findings in each of few previous works. The reason behind it could be dissimilarities in terms of ecological and climatic conditions, seasonal differences in drug collection, ratio of water used for Kwatha extraction and the method of filtration of final obtained Kwatha. The effects of regional or seasonal variations are reported on number of medicinal plants.<sup>[24]</sup> Season also has its impact on availability of active principles<sup>[25]</sup> and secondary metabolites<sup>[26]</sup> in medicinal plants.

## CONCLUSION

The Average percentage of Guduchi Ghana obtained is 5.00%. The organoleptic characters found in accordance with classical statements were almost similar in all batches. The tablets exhibited optimum disintegration time, weight uniformity, and hardness. The findings of present study ensure the uniformity in the operative procedures.



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