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Original Article

Traditional Manufacturing Procedure of *Guduchi Satwa*; Sedimental Water Insoluble Starchy Extract of *Tinospora cordifolia* willd. Miers & its Process Validation

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ABSTRACT

The sedimental starchy aqueous extract of *Tinospora cordifolia* Willd. Miers known as *Guduchi satwa* or *Amrita sarkara* etc in Sanskrit language or *Giloe satwa* in Hindi. It has been abundantly used in Ayurvedic practices as a versatile medicine. Three batches of *Guduchi satwa* were prepared in accordance to the traditional reference and the SOP was maintained throughout the process. Total preparation procedure was carried out through 5 steps such as *Kuttana* (pounding), *Nimajana* (dipping/soaking), *Manthana* (churning or rubbing), *Nistarana* (decantation) & *Sosana* (drying). Findings of the manufacturing procedure & observations were systematically recorded and compared with the verse of ancient literatures. Collection time & size of the stem, colour of satwa, total preparation time and total water used etc are vividly discussed. To maintain the quality control further subjected to analysis for organoleptic characters and physical constants. After gathering the data the manufacturing process was validated by taking its average.

Key words: *Guduchi satwa*, *Tinospora cordifolia*, Manufacturing process, Validation.

1. INTRODUCTION

To enhancing or to decrease the utility (pharmacodynamic action) of a relatively small quantity/quality or large quantity/quality of a substance are possible by *Samyoga* (combination), *Vishlesha* (disunion), *Kala* (time factor), *Samskara* (various pharmaceutical operations) and *Yukti* (intelligent planning) [1]. The *Samskara* is considered to be a change or sequence of changes, occurring/induced

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may in form of physical, chemical or both which accelerates the final product with improve therapeutic qualities, stability and acceptability. These are to be ensured at the level of manufacturing operations or Pharmaceutical process. Thus, it is necessity to study/observe the preparation of a drug with utmost care, comprehend the principles underlying, document the findings for further comparison, corroborate the document with therapeutic efficacy and then formulate the resolutions.

Giloy or *Guduchi* and their product like *Giloy satwa* have huge market in Indian health pharma. The Indian *Giloy* and *Giloy satwa* market is mostly takeover by Dabur India Pvt. Ltd., Patanjali, Baidyanath and Unjha Ayurved pharmacy etc. With this competitive market segment, many companies are emphasizing on its acceptability by compromising with its quality and efficacy. And their Organoleptic characters are varies also. Apart from the number of factors like impact of regional, seasonal or climatic variations, manufacturing process variation influences the availability of active principles and secondary metabolites in the final product also. Non availability of standard references and lacks of Standard Manufacturing Procedures (SMPs) are the prime cause for non-uniformity of the production. Standardization implies, application of suitable methods and process by which optimal conditions are ensured for obtaining predictable results and product which conforms a certain set of standards in terms of quality, purity, stability and safety. Hence to maintain the uniformity production at market label, the study was undertaken to validate the technical manufacturing process in compliant to traditional principles. *Satwa* is the essence of the material or drug. In relation to the *Satwa* of an herbal drug is water extractable solid substance. Plants with medicinal value present in starchy part are subjected to a special method to extract the same. It is an important *Kalpana* (*preparation*) among the other pharmaceutical process used in general practice of Ayurveda. *Nimajjana* (sinking/dipping), *Manthana* (churning or rubbing) and *Sosana* (drying) are the *Samskaras*, in which *Toya & Agni sarnikarsa* (water & heat treatment) are the specific method of pharmaceutical process or techniques that modify the natural product turns into potent dosage form which is easily absorbable in the biological system [2]. *Satwa kalpana* can be considered as an *Upakalpa* of *Hima kalpana* in Ayurved because a part of pharmaceutical process is involved in it.

The solid starchy extract of *Tinospora cordifolia* Willd. Miers known as *Guduchi satwa* is very commonly prescribed in Ayurvedic practice. Various *Tinospora* species are commonly used for extracting the starch. The term *Guduchi satum*, *Gilo ka sat* or *Palo* is commonly used in Ayurveda. Literature reveals its synonym as, *Amrita satwa*, *Tantri satwa*, *Chhinna satwa*, *Dhara satwa*, *Kundali satwa*, *Souma satwa*, *Amrita sarkara* etc., *Seenthil Sarkarai* in Sidha system of medicine and *Sat Giloy* in Unani system of medicine [3-9]. The drug is most useful in *Vatarakta* (gout),

Pandu (anemia), *Tibra jwara* (acute fever), *Vamana* (vomiting/eructation), *Jirna jwara* (chronic fever), *Kamala* (jaundice), *Prameha* (excessive out flow of urine) especially *Pittaja meha*, *Aruchi* (anorexia), *Swasa* (dyspnea), *Kasa* (cough), *Hikka* (hiccough), *Arsa* (piles), *Kshaya* (tuberculosis), *Daha* (burning sensation), *Mutrakrichhra* (painful voiding of urine), *Pradara* (leucorrhea), *Soma roga* (excessive white/watery discharge from vagina/urethra) and due to its throughout use in the disease fever, it is known as 'Indian Quinine'[10,11].

Apart from the various secondary metabolites of *Tinospora cordifolia*, the three major groups i.e protoberberine alkaloid, terpenoids and **polysaccharides (substantial constituent of Satwa)** have been reported to be responsible for applauded therapeutics activity [12,13]. The study on physical characteristic and chemical composition of the starch (*Satwa*) obtained from *Guduchi satwa* (extract) reveals that, polysaccharide was found to consist chiefly of 1-4 linked glucan with occasionally branched points [14].

2. MATERIALS AND METHODS

Selection of Raw Material

The fresh stem of the *Tinospora cordifolia* Willd. Miers was collected from two different sources and areas of CAMC, Rajnandgaon, C.G state. As a first sources, fresh and healthy stem of *Guduchi* which creped over the *Neem* (*Azadirachata indica*) tree and for second sources, which creped over general trees (other than the tree of *Neem*) were collected in the month of May – Jun (Fig. 1,2,3 & 4). The size of the stem (Fig. 5 & 6) was in between 1.5 to 2.5cm in diameter (*Angustha pramana*). The identity of the drug was confirmed by Prof. Dr.B.N.Mahapatra MD (Ayu) in *Dravyaguna*, PhD (Ayu), Former Principal, Govt. Ayurvedic College, Balangir, Odisha, India. The crude drug was confirmed by compared with voucher specimen.

Study Design

Three batches of *Guduchi satwa* were prepared by employing classical method [9, 15]. The whole preparation was carried out at Rasayanshala (Mini pharmacy), Dept. of R.S & B.K, CAMC, Rajnandgaon, C.G state, India. During the preparation, pharmaceutical findings and observations were systematically recorded & analyzed.

Analytical Study

Organoleptic characters of fresh *Gu uci* stem and dried *Sattva* were noted and subjected for testing with pharmacopeal standard on Physical constants [16] at BIO-Lab, Bhubaneswar, Odisha, India

Method of Preparation

After carefully examine of raw materials, foreign matter like sand, soil, adulterants and outer loose pelt etc were removed from the drugs & washed thoroughly with tap water (Figure 1-6). 10 k.g stems were cut into pieces (excluded the nodes of the stem) and crushed in iron mortar into coarse form. The coarse part of the drug was placed in wide mouthed aluminum vessel with 08 time potable water and kept for

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soaking overnight. Next morning this mass was macerated gently and repeatedly in same water inside the vessel for about one hour. When the drug has lost its mucilaginous properties almost, the coarse and fibrous part of the drug was repeatedly squeezed and placed in another vessel. The entire maceration process was again repeated with the addition of 04 time potable water. Then the total remained water was kept undisturbed for about 4 hour to allow the particles of starchy materials to settle down. The supernatant liquid was carefully siphoned off and decanted without disturbing the sediment material. The starchy material is then collected, again washed in potable water and allowed to settling down. For a careful washing process, 04 time water was used. Heavy starchy sediment, which was settled at bottom of the vessel was collected in a tray, dried on sun rays and stored as *Guduchi satwa* in air tight jars (Fig.7 to 14).



Fig 1: Guduchi



Fig 2: Neem guduchi



Fig 3: Stem of guduchi



Fig 4: Stem of neem guduchi



Fig 5: Diameter of guduchi stem



Fig 6: Diameter of neem guduchi stem



Fig 7: Collected stem of guduchi



Fig 8: Cutting of guduchi setm



Fig 9: Uniform size of stem pieces



Fig 10: Pounded coarse slimy mass



Fig 11: Maceration



Fig 12: Satwa during decantation process



Fig 13: Collection of white sediment



Fig 14: Sundried guduchi satwa

Observation

The colour of the mixture was green along with stem. Less mucilaginous was felt during the process of maceration of the pounded stem with water. The colour of the filtrate was mild greenish brown. During filtration, white coloured with impurities sedimentation along with fibrous material at the bottom of the container was observed. After washing, it becomes whiter. The colour of the final collected product is greenish white. After dried on sun rays the colour of the product is clear and pure white (*Sankhabha*).

3. RESULTS

Table 1: Details of Pharmaceutical process of G.S in Quantification

Sample	Quantity of Guduchi Stem in K.G	Diameter of the Stem in cm	Size of the Stem in inch	Quantity of water in Lit. (soaking + maceration + decantation)	Final quantity of Dried Satwa in gm	% of Dried Satwa	Total time taken for Preparation in hour
GS - I	10	1.2 – 2.3	1 - 2	160 (80 + 40 + 40)	194	1.94	20.10
GS - II	10	1.2 - 2.2	1 - 2	160 (80 + 40 + 40)	189.6	1.89	21.3
GS- III	10	1.5 - 2.3	1 - 2	160 (80 + 40 + 40)	177	1.77	21

Table 2: Total Time Taken for the Preparation of G.S

Sample	Time Duration				
	Kuttana	Nimajana	Manthana + Sthirikarana (Maceration + Sedimentation)	Nistarana	Sosana
GS - I	1.25 hour	9.10 hour	1.15 hour + 4 hour	2 hour	2.2 hour
GS - II	1.3 hour	10 hour	1 hour + 4.3 hour	2 hour	2.3 hour
GS - III	1.3 hour	10 hour	1 hour + 4 hour	2 hour	2.3 hour

Table 3: Organoleptic character of Guduchi stem

Sl.No	Parameter	Sample		
		Guduchi Stem - I	Guduchi Stem - II	Guduchi Stem - III
1	Rupa (colour)	Greenish brown	Creamish brown	Creamish brown
2	Rasa (Taste)	Bitter	Bitter	Bitter
3	Gandha (smell/odour)	Non specific (Characteristic smell after removing outer loose skin)	Non specific (Characteristic smell after removing outer loose skin)	Non specific (Characteristic smell after removing outer loose skin)
4	Sparsa (Touch)	Soft, rough	Soft, rough	Soft, rough

Table 4: Organoleptic character of Guduchi satwa

Sl. No	Parameter	Sample		
		GS - I	GS - II	GS - III
1	Colour	Creamish white	whitish	whitish
2	Appearance	Solid	Solid	Solid
3	Smell/odour	Non specific	Non specific	Non specific
4	Touch	Soft ++	Soft ++	Soft ++
5	Taste	Tasteless	Tasteless	Tasteless

Table 5: Qualitative Phytochemical screening of Guduchi satwa

S.No.	Components present in Guduchi satwa	Sample		
		GS - I	GS - II	GS - III
1	Alkaloid	-	-	-
2	Quinone	-	-	-
3	Tannin	-	-	-
4	Saponin	-	-	-
5	Steroid	+	+	-
6	Phenol	-	-	+
7	Flavonoid	-	-	-
8	Sugar	-	-	-

Process Validation

Table 6: Process Validation for Guduchi satwa

Parameters	Observation (Table :1 &2) (average of G.S - I, G.S - II & G.S -III)
Amt. of Green stem (kg) – 1 part	10 kg
Quantity of Water (L) – 16	80 lit + 40 + 40 lit.(used during soaking + Maceration + decantation)
Total time taken	21.15 hour
Total yield	183.3 gm
% of Yield	1.83

4. DISCUSSION

The drug selected and authenticated as *Tinospora cordifolia* as *Guduchi*. Both *Valli* (*Tinospora cordifolia*) and *Kanda/Padma Guduchi* (*Tinospora malabarica*) is better to use or to prepare the *Satwa*. But starch from *Valli Guduchi* is both quantitatively qualitatively more efficacious in comparison to *T. malabarica*, because former contents more carbohydrates, tannins than latter [17]. It is also reported that male variety of *Tc* yields much quantity and better quality of *Satwa* than female [18]. Under the contemplation of gender instability phenomenon, the stem was collected in the month May – Jun [19]. The literature of modern era reveals to collect the stem in *Grishma ritu* also (summer season) [20-22]. Henceforth the recommendation of traditional practitioners to collect the *Satwa* in *Grishma ritu* makes the consequence analogous with scientific evidence of gender instability phenomenon of *Tc*.

Like other plant *Tc* also contains various chemical constituents as by product. Out of which starch is an insoluble carbohydrate occurring as a reserve food in form of starch grain. They occur in almost all part of plant but especially it is abundant in stem (officinal part) of *Guduchi*. For the preparation of G.S, fresh stem was used as accosted in the text *Br.P & A.C* [23, 24]. No such reference was found regarding size of the stem in ancient literature. However the text *S.Y.S & B.B.R* advocates ‘*Angustha’ pramana* (as size of the middle finger) and ‘*tamangusthaparva matram*’ (as size of the upper part of thumb finger) of stem to be taken for the preparation of *Guduchi ghana vati* and *Guduchi kalpa* respectively [25,26]. The size of the stem may affect on the percentage of yield of *Guduchi satwa*. It is reported that the yield of G.S is more in medium size (1.6 to 2 cm) stem [27]. This report is consonance with the acclaimed literatures.

Two types of method of preparation for *Satwa* were traced in ancient literatures. The involved processes of methods are *Agneya* (endothermic) & *Niragneya* (exothermic). In endothermic process heat is required for transformation of qualities from raw material to finished product e.g - Preparation of *Bibhitaka Tulasi* satwa [28]. And preparation of *Guduchi satwa* is exothermic process concluded under 5 steps called as *Samskaras* viz *Kuttana* (pounding), *Nimajana* (dipping/soaking), *Manthana* (churning or rubbing), *Nistarana* (decantation) & *Sosana* (drying).

Kuttana: The stems were cut into pieces and crushed in iron mortar into coarse form. By pounding the drug, *Agni mahabhuta* (heat) is liberated (exothermic heat) which softens the molecular bonding of chemical constituents through *Akasha* (*Ether*) and *Vayu mahabhuta* (*air*) as well as it causes transformation of *Guna* (natural qualities) to desired part (*Satwa*).

Nimajana: The coarse part of the drug was added with 08 time potable water and kept for soaking overnight. *D.G.V* and in commentary of *B.P*, 04 time water for soaking have been mentioned, whereas, in the annotation of *R.Y.S & A.F.I* advocates 16 times and 21 times water respectively [22,29-31].

This process can be told as *Toya sannikarsa samskara*. Here, *Jala Mahabhuta* (water) is required to soften the hardness present in *Parthiva dravyas* (hard substances). As the drug has heavy mucilaginous properties 8 time portable water was taken for the study to make easy for further process as well as to avoid the ceramic colour in finished product. The direct references pertaining to soaking for overnight was not detected in any text of ancient literatures except *Sha.N* [32]. The evidences concerning to macerations, it is mentioned in *A.C, S.Y.S & D.G.V* that the process of *Manthana & Galana* (filtration) to be performed along with *Nimajana* soon after *Kuttana* process and thereafter the filtered saturated liquid to be kept undisturbed for one day or one night (both can be taken as 12 hrs). And this is only sedimentation time has been described. However in *Sha.N*, the author advised to keep the mixture of *Guduchi kalka* and water for soaking for 2days. Reference recommends *Guduchi* will be collected and the *Satwa* will be prepared in *Grishma ritu* (summer season). So that, if *Guduchi kalka* will be soaked in water for two days, then there may be the chances of highly contamination and stinking smell in finished product. Because in this season the involvement of microbial organisms may accelerates for quick decomposition/fermentation in process. With the view of *Panchabhautik* theory (principle of five basic elements as Akash, vayu, agni, jala & prithivi), the process was slightly changed to get the more starchy product or *Satwa*. So that the mucilaginous mass (coarse part of *Guduchi* stem) with portable water kept overnight for 10 hrs [9, 25, 29].

Manthana: Next morning this mass was macerated gently and repeatedly in same water inside the vessel for about one hour. When the drug has lost its mucilaginous properties almost, the coarse and fibrous part of the drug was repeatedly squeezed without changing the water and removed the fibrous part. Afresh, the entire process was repeated once more with 4 time potable water to obtain the residual starchy material present in fibrous part. Then all the remaining water was mixed and filtered with two fold of cloth. Then the filtered water was kept undisturbed for about 4 hour to allow the particles of starchy materials to settle down. The total water used in the process of *Nimajana & Manthana* was 12 times of *Guduchi kalka* (Table 1).

This process is called *Toyagni-sannikarsa samskara* where exothermic heat is liberated and with help of *Jala mahabhuta*, *Samyoga-vibhaga* occurred inside the material i.e *Satwa* is exodus as *Akasha mahabhuta* which is providing space to receive good attributes/therapeutic efficacy.

Nistarana: The supernatant liquid was carefully siphoned off and decanted carefully without disturbing the sediment material. A few quantity of starch product was collected. The decantation process was repeated until the collection of white starch product with the help of 4 time potable water. By this process of *samskara*, physical impurities along with remaining fibrous parts were aloof from settled starch material. The total water used for the process of *Nimmajana*, *Manthana* & *Nistarana* was 16 times of *Guduchi kalka* which can be correlated with the statement in hindu annotation of *R.Y.S* regarding drug and water ratio (Table 2). As portrait in *A.C* & *R.Y.S*, the appearance of G.S was found like *Pindakriti* or *Ghanibhuta* (a mucilaginous mass) respectively in the last stage of *Nistarana* process [9, 30].

Sosana: Heavy starch sediment, which was settled at bottom of the vessel was collected in a tray, dried on sun rays and stored as *Guduchi satwa* in air tight plastic Jars. The literature *A.C* suggested that the process of *Sosana* should be done under deep sun rays; however *R.Y.S* recommended for air dry. To avoid any microbial load and also to get the pure white colour in finished product, the drying process of G.S was carried out under sun rays. This process can be included under *Agni-sannikarsa samskara*. The colour of the finished product i.e. G.S samples were found in consonance with the term *Sankhanibha* (like as conch shell) and *Subhra khanda* (white piece) as depicted in *Y.R* and *R.Y.S* respectively [9, 30, 33].

The above five process of *Samskaras* concludes that, at the level of *Pancamahabutas*, *Prithvi* is *adhara* for all the process and *Akasa* is providing space for the same. Remaining three *Mahabutas*, namely *Jala*, *Agni* and *Vayu* are responsible for transformations or changes taking place in a substance. Therefore in any *Pancabhattika* substance, continuous changes or transformations are taking place due to presence of *Agni mahabhuta*. But the rate of transformation may differ according to quantity or strength of *Agni mahabhuta* present in it along with other supportive materials also.

The studies of physical characteristics were performed at two stages of production i.e. at raw drug and at finished products. The physical or organoleptic characteristics (*Rupa*, *Rasa*, *Gandha*, *Sparsa*) revealed that all the samples of raw drug (green *Guruchi* stem) and finished products were approximately same (Table: 3 & 4).

The qualitative analysis or the micro chemical test of all samples revealed the only presence of Steroids in Chloroform extraction of G.S. (Table:5). However the presence of Alkaloid, Phenol, Quinone, Sugar, Cournarine, Furan and Triterpene in Methanolic extraction has been reported also [34].

The recorded total percentage of yield of G.S was 1.83. Though it is differ from reports of other studies but this can help to fix the range for the % of the yield. Because this study was carried out by following the ancient references in each steps that facilitate to develop a standard operative procedure for preparation of this versatile herbal medicine. The differentiation of % of yield may vary from person to person due to different or improper preparation method or slapdash preparation or any geographic conditions (% of yield varies from 1.5 to 4.5) [35-37].

4. CONCLUSION

Guduchi satwa is sedimental aqueous starch extract of *T.Cordifolia*. It is first ever appeared in the literature *Rasendra Mangalm*. The preparation process of *Guduchi satwa* can be included under secondary derivative of five basic *klapana* of Ayurveda as *Hima kalpana*. The best method of preparation of *Guduchi satwa* can be referred from the text *Abhinav chintamani*. The literature of modern era reveals to collect the stem in *Grishma ritu* (May-June). The yield of G.S is more in medium size (1.6 to 2 cm) stem. Total 16 parts of water and 21 to 22 hour is required to complete the preparation process of G.S (Table 6). The organoleptic characters of G.S were found in accordance with classical statements of references. The investigated methods and parameters may be utilized as recognized methods for authentication of *Guduchi satwa* preparation.

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List of Abbreviations

A.F.I; Ayurvedic Formulary of India, A.C; Abhinav chintamani, Br.P; Brihat pakavali, B.B.R; Bharat bhesaj Ratnakar, B.P; Bhavprakash, D.G.V; Dravyaguna Vijnana, G.S; Guduchi satwa, R.Y.S; Rasayog Sagar, S.B.M; Siddha Bhesaja Manjusa, S.Y.S; Siddhayoga Samgrah, Sha.N; Shaligram nighantu, Tc; Tinospora cordifolia, Y.R; Yogratnakar.

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