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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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
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 Sesana (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 Ayurveda because a part of pharmaceutical process is involved in it.

The solid starchy extract of Tinospora cordifolia Wild. 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, Chhinnma satwa, Dhara satwa, Kundali satwa, Souma satwa, Amrita sarkara etc., Seenthil Sarkarai in Siddha system of medicine and Sat Giloy in Unani system of medicine [3-9]. The drug is most useful in Vataarakta (gout), Pandu (anemia), Tibra jwara (acute fever), Yamana (vomiting/eructation), Jirra jwara (chronic fever), Kamula (jaundice), Prameha (excessive out flow of urine) especially Pittaja meha, Aruchi (anorexia), Swasa (dysponea), Kasa (cough), Hikka (hicough), Arsa (piles), Kshaya (tuberculosis), Daha (burning sensation), Mutrakrichhra (painful voiding of urine), Pradara (leucorrea), 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 Wild. 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 (Azadirachta 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 between1.5 to 2.5cm in diameter (Angutha 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
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).
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).

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                              | 1.3 - 2.3                   | 1 - 2                    | 160 (80 + 40 + 40)                                           | 177                                 | 1.77            | 21                                      |

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

| Sample | Kuttana | Vimajana | Mantana + Shhirikarana (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 | Sample Guduchi Stem II | Sample 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 | Sample GS - II | Sample 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 |
|------|------------------------------------|--------|
| 1    | Alkaloid                           | -      |
| 2    | Quinone                            | -      |
| 3    | Tannin                             | -      |
| 4    | Naponin                            | -      |
| 5    | Steroid                            | +      |
| 6    | Phenol                             | -      |
| 7    | Flavonoid                          | -      |
| 8    | Sugar                              | -      |

GS - I | GS - II | GS - III | GS - I | GS - II | GS - III | GS - I | GS - II | GS - III | GS - I | GS - II | GS - III | GS - I | GS - II | GS - III | GS - I | GS - II | GS - III | GS - I | GS - II | GS - III |
**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 contains 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 (offical 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) & Niragnaya (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 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 *Nimajjana* soon after *Kuttaana* 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 *Nimajjana & 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.

Nistaran: The supernatant liquid was carefully siphoned off and decanted carefully without disturbing the sediment material. A few quantity of starchy product was collected. The decantation process was repeated until the collection of white starchy product with the help of 4 time potable water. By this process of samskara, physical impurities along with remaining fibrous parts were alsoofer from settled starchy material. The total water used for the process of Nimajmana, Munthana & Nistaran was 16 times of Guduchi kalka which can be correlated with the statement in hindi 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 Nistaran process [9, 30].

Sosana: 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 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 Sankhaniibha (like as conch shell) and Subhra kanda (white piece) as depicted in Y.R and R.Y.S respectively [9, 30, 33].

The above five processes of Samskaras concludes that, at the level of Pancababhutas, Prithvi is adhara for all the process and Akasa is providing space for the same. Remaining three Mahabhutas, namely Jala, Agni and Vayu are responsible for transformations or changes taking place in a substance. Therefore in any Pancabhautika 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, Courmarine, 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 starchy 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 Grisha 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 bhesa Ratnakar, B.P; Bhavprakash, D.G.V; Dravyaguna Vijñana, 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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