



**Research Article**

**COMPARATIVE ANALYSIS OF SAMSAMANI VATI/GUDUCHIGHANA VATI OF COMPETITIVE AYURVEDA PHARMACEUTICALS OF INDIA**

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**ABSTRACT**  
*Guduchi/Giloy (Tinospora cordifolia)* is declared a national herb of India due to its multiple medicinal properties. *Samsamani Vati* is also known as *Guduchi ghanavati* (a concentrated form of decoction of *Guduchi* stem) the secondary *Kalpala* (formulation) derived from the primary *Kwatha Kalpana* (decoction). *Samsamani Vati* is freely distributed by the Ministry of AYUSH in all states and union territories of India as prophylaxis for COVID-19. The molecular docking of Tinocordicide - a constituent of *Guduchi (Tinospora cordifolia)* showed significant interruption of the viral RBD and host ACE2 interactions. *T. cordifolia*, *T. crispa*, *T. sinensis*, *T. smilacina*, *T. bakis*, and *T. sagittata* are different species of *Guduchi*, whereas *Tinospora crispa* and *T.sinensis* are hepatotoxic. General people are aware of the use of *Samsamani vati/Guduchi Ghana vati/Giloy* and purchase from leading Ayurveda medicine manufacturers in India. Tinosporaside is an immune-modulatory active compound as well as a cholinergic inhibitor. It is an attempt for compare analysis of *Samsamani Vati/Guduchi Ghana vati* used in the population for the prevention of COVID-19 of government supply and lead Pharmaceutical Company of India. The *Samsamani Vati/Guduchi Ghana vati* of lead Ayurveda Pharmaceutical and Government Supply. (Dabur, Zandu, Patanjali, Himalaya, Baidyanath and IMPCL) were purchased from the local market and put forth for analysis. Tinosporide is significantly detected in Patanjali, Zandu and IMPCL-manufactured *Samsamani Vati*, whereas a trace amount of bioactive compound in Dabur and not detected in Baidyanath. The analysis showed that no uniformity of *Samsamani Vati/Guduchi Ghana Vati* of the competitive brand of India. It is recommended to maintain uniformity of bioactive molecules not only for desired efficacy but also for safety.

**INTRODUCTION**

Ayurveda formulations will be the future preventive and curative medicine for many chronic diseases even COVID-19<sup>[1,2]</sup>. *Giloy*, (*Tinospora cordifolia*) also known as *Guduchi* and 'Amrita' in the classical texts of Ayurveda literally means the plant who protects from many diseases and the root of immortality<sup>[3]</sup>. *Samsamani Vati (Guduchi/Giloya ghana vati)* is a classical formulation of *Siddhayoga samgraha*

indicated in different types of *Jvara* (fever). *Samsamani Vati/Giloy Ghana Vati* is proved as a biological response modifier by macrophage activation and increased interleukin production. The molecular docking of Tinocordicide constituent of *Guduchi (Tinospora cordifolia)* showed significant interruption of the viral RBD and host ACE2 interactions<sup>[3,4]</sup>. The Ministry of AYUSH launched a campaign to distribute of *Samsamani Vati* to large population as prophylaxis medicine for COVID-19 under its series of activities under the 'Azadi Ka Amrit Mahotsav'. *Samsamani Vati* is otherwise known as *Guduchi ghanavati* (a concentrated form of decoction of *Guduchi* stem) the secondary *Kalpala* (formulation) derived from the primary *Kwatha Kalpana* (decoction). Two types of *Guduchi* are described in Ayurveda which are botanically identified as *Tinospora cordifolia* and *Tinospora sinensis* or *Tinospora malabaria*. But *T.*

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*cordifolia*, *T. crispa*, *T. sinensis*, *T. smilacina*, *T. bakis*, and *T. sagittata* have been reported to possess significant immunomodulatory effects. *Guduchi* or *Amruta* is declared as National herb by Government of India. The important bioactive molecules are terpenoids, alkaloids, lignans, bitter steroids, glycosides, and sesquiterpenoids, aliphatic compounds, essential oils, fatty acids, and polysaccharides. The aerial parts, mainly stems of *T. cordifolia*, various constituents including phenyl propanoid glycosides like cordifolioside A and B, syringin with diterpenoids tinosporaside, tinosporin, tinosporidine, tinocordifolioside, and alkaloids columbin, isocolumbin, berberine, magnoflorine have been reported.

The important pharmacological properties are immune-modulatory, antipyretic, anti-inflammatory, hepato protective, anti-stress, anti-histaminic activities. *Guduchi* has good clinical outcome in asymptomatic case of Covid-19 infections<sup>[5]</sup>. In the recent past some *Guduchi*-induced liver injuries has also reported<sup>[6,7]</sup>. It may due to the *Tinospora crispa* and *T. sinensis* which are known hepato-toxicity and Borapetosides and Tinoseneside are two diterpenoids responsible for liver injury<sup>[8,9]</sup>. This news spread in electronic and press media. It was a strong counter publication by eminent scholar<sup>[10]</sup> but no sufficient data to defend it. Marker-based standardization is one of the important methods of characterization of botanical drugs. Standardization also aids in defining the amount of constituents that are attributable to biological activity. The Ministry of AYUSH has been creating awareness of the use of *Samsamani Vati* for the prevention of COVID-19. Due to the mass distribution of *Samsamani vati* in large population and the increased risk of self-medication of *Samsasamai Vati*. The chemical analysis and characterization of bioactive molecules and contaminants are highly necessary for uniform quality. In this aspect, standardization of *Samsamani Vati/Giloy Ghana vati* is an important aspect for assuring quality, safety, and efficacy. Tinosporaside is an immune-modulatory active compound as well as a cholinergic inhibitor<sup>[11,12]</sup>. General people are aware of the use of *Samsamani vati/ Guduchi Ghana vati/Giloy* for prevention of various diseases and purchased from a leading manufacturer in India.

Therefore, it is an attempt for compare analysis of *Samsamani Vati/Guduchi Ghana vati* used in the population for the prevention of COVID-19 of government supply and lead Pharmaceutical Company of India. Among the complex mixture of biologically active compounds in the *Guduchi* plant, tinosporaside can be used as an analytical marker to determine the quality of plant material of different sources<sup>[13]</sup>.

**Objective:** The primary objective of the study to check the quality of *Samsamani/Guduchi Ghana Vati* of various lead Pharmaceutical companies and Government supply. The secondary objective is to quantify the bioactive molecules like- Tinosporide, bitters from various samples.

## MATERIALS AND METHODS

### Apparatus

Water bath, sonicator (Trans-O-Sonic, Mumbai, India), and weighing balance (Sartorius, Göttingen, Germany) were used for general experiments. CAMAG (Muttentz, Switzerland) Linomat 5-sample applicator, CAMAG TLC Scanner 4, and CAMAG Photo-document were used for HPTLC analysis.

### Reagents, Materials and Standards

Milli-Q water, Solvents namely Toluene, ethyl acetate, formic acid, methanol and pre-coated aluminium silica gel 60 F<sub>254</sub> TLC plates were procured from Merck Specialties Private Limited (Karnataka, India). Tinosporide standard was isolated in-house and characterized by different chromatographic techniques.

### Test Material

Marketed formulation of *Samsamani Vati/ Guduchi Ghana Vati* was collected from local market.

### Sample preparation for Tinosporide by HPTLC

The *Samsamani vati/Guduchi Ghana vati* of lead Pharmaceutical and government Supply. (Dabur, Zandu, Patanjali, Himalaya, Baidyanath and IMPCL) were purchased from local market and batch mark were noted. 10 tablets of each sample pulverized using mortar pestle. Around 2.0gm of each sample was taken into a 50ml volumetric flask and 20ml of methanol was added and sonicated for 10 minutes followed by heating on a water bath for another 10 minutes. The resulting solution was filtered through Whatman no. 1 filter paper in a 25ml volumetric flask and the volume was made up with methanol. The resulting solution was used as test solution after filtration through 0.2µm syringe filter. The analytical method validation studies were performed as per International Conference on Harmonization-Quality (ICH-Q2 (R1)) guidelines.

### HPTLC Conditions

The chromatographic estimation was performed by spotting standards and sample of *Samsamani Vati/Giloy Ghana Vati* on pre-coated aluminium TLC plates of silica gel 60 F<sub>254</sub> (20cm × 10cm, E. Merck) using a CAMAG Linomat V sample applicator and a 100mL syringe. The samples, in the form of bands of length 8 mm, were spotted at a constant application rate of 80nL s<sup>-1</sup> using nitrogen aspirator. The plates were developed using the mobile phase Toluene: Ethyl acetate: Formic Acid: Methanol [15:15:4:1; v/v/v/v]. Linear ascending development

was carried out in 20cm × 10cm twin-trough glass chamber (CAMAG) saturated with the mobile phase. The optimized chamber saturation time for the mobile phase was 15 minutes at room temperature. The length of the mobile phase run was 60mm. Approximately 20ml of the mobile phase was used for development. After the development, TLC plate the plates were derivatized by dipping in anisaldehyde - sulphuric acid [ASA] reagent and subsequent heating at 105°C for 5 min in hot-air oven (Figure: 1-6). The slit dimension settings of 6.00 × 0.45mm in length and a scanning rate of 20mm s<sup>-1</sup> were employed. The monochromator bandwidth was set at 20nm. Densitometric scanning was performed on a CAMAG TLC Scanner 4 in absorbance mode at 560nm and

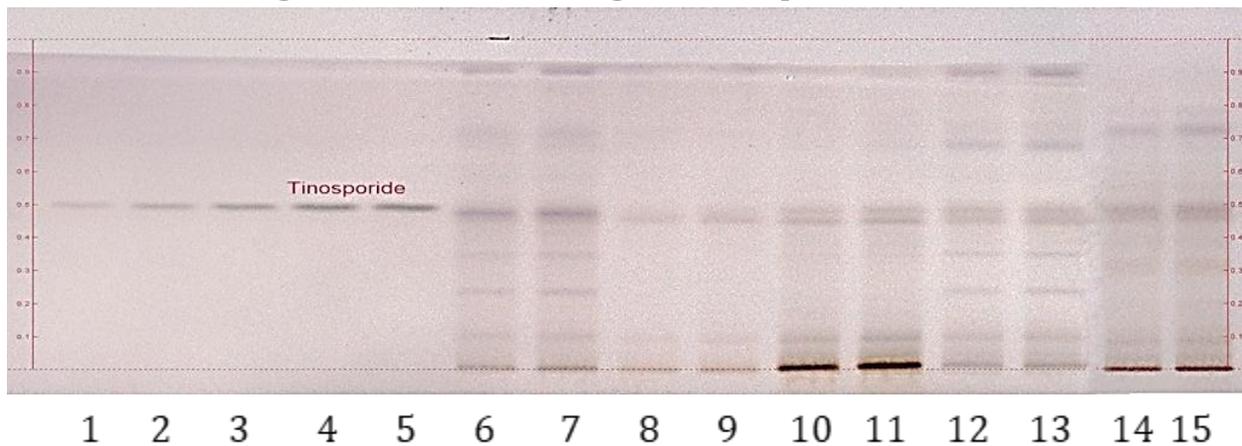
operated by winCATS planar chromatography version 1.4.9 (CAMAG).

The physico-chemical parameters of Competitive Brand Samples was analyzed as per Ayurvedic Pharmacopoeia of India<sup>[14]</sup>.

**Results**

Tinosporide is significantly detected in Patanjali, Zandu and IMPCL products whereas trace amount in Dabur and not detected in Baidyanath sample as shown in Figure-1. The bitter principle was more in Zandu and Baidyanath Product. The heavy metal (Lead and Mercury) is more than permissible limit in IMPCL products (Table no-1). None of the studied products contain Arsenic and cadmium. All products are free from pathogen and Aflatoxins. The results are incorporated in Table-1.

**Figure 1: HPTLC Chromatogram of Competitive Brands**



**Track Details**

- Track 1-5:** Tinosporide Std.
- Track 6-7:** Baidyanath Giloy Ghan Bati
- Track 8-9:** Dabur Samshamani Vati Giloy Ki Ghanvati
- Track 10-11:** Zandu Giloy Ghanvati
- Track 12-13:** Impcl Samsamani Vati
- Track 14-15:** Patanjali GiloyGhanvati

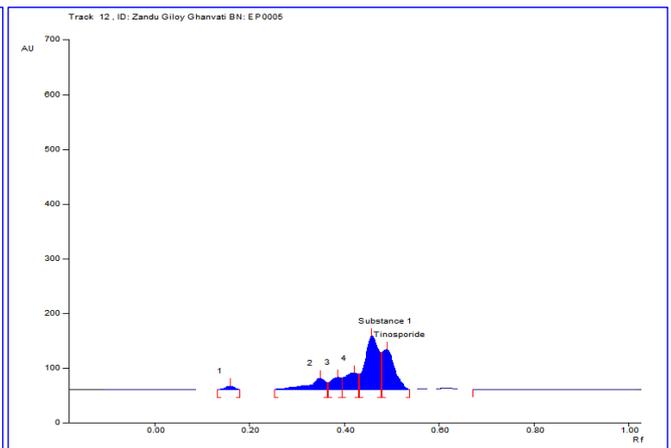
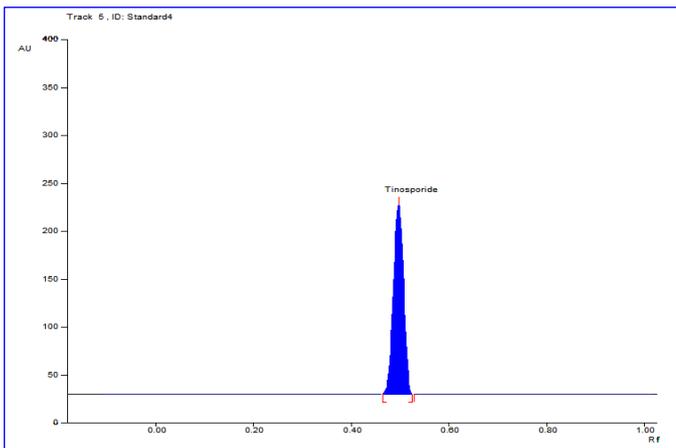


Figure-2: HPTLC Chromatogram of Tinosporide std.

Figure-3: HPTLC Chromatogram of Zandu Giloy Ghanvati

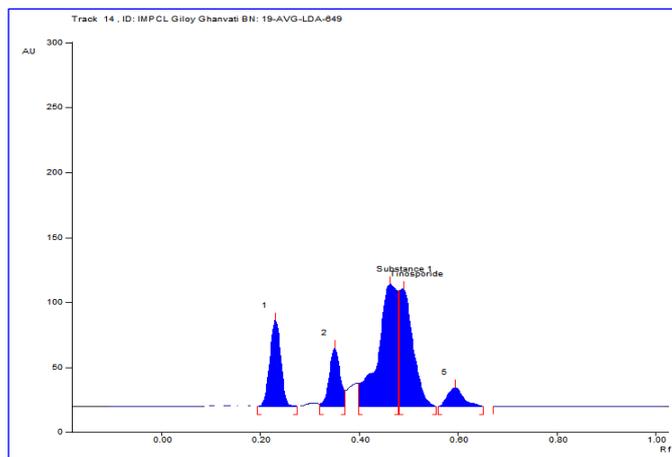


Figure-4: HPTLC Chromatogram of IMPCL *Samsamani Vati*

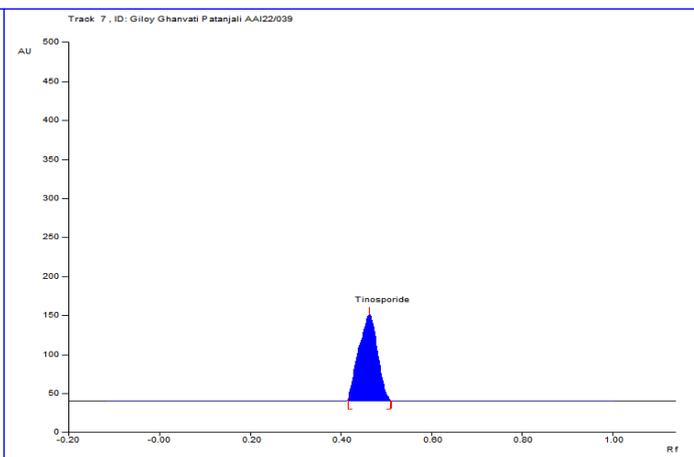


Figure-5: HPTLC Chromatogram of *Patanjali Guduchi/Giloy ghanvati*

Figure 6: Overlaid reflectance spectra of Peak at similar R<sub>f</sub> in Patanjali, Zandu & IMPCL samples

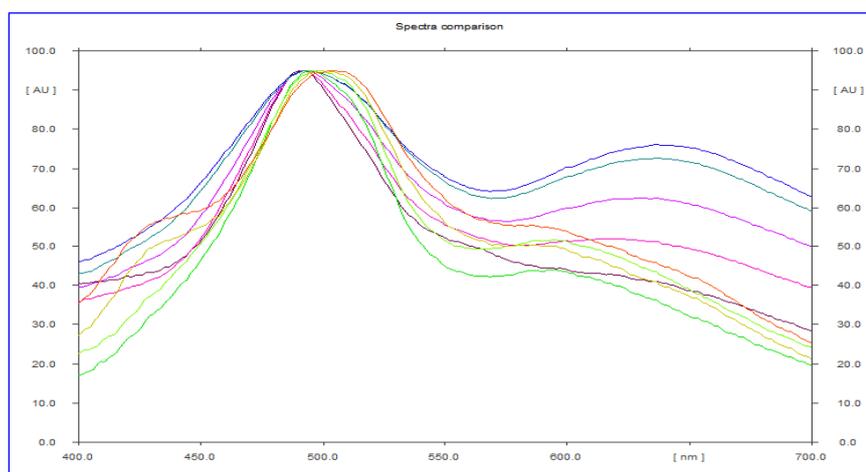


Table 1: Comparative analysis report of *Samsamani Vati/Giloy Ghana Vati*

Parameter	Result				
	Zandu	Dabur	Baidyanath	IMPCL	Patanjali
1. Total Ash (%w/w)	5.86	1.74	8.37	9.26	4.50
2. Acid Insoluble Ash (%w/w)	1.45	0.19	1.16	4.47	2.31
3. LOD (%w/w)	7.51	7.83	7.07	6.84	9.95
4. Alcohol Soluble Extractive (%w/w)	38.04	10.25	14.71	16.77	5.83
5. Water Soluble Extractive (%w/w)	64.69	57.55	67.55	43.88	79.62
6. pH (1% w/v suspension)	5.24	5.73	5.51	6.55	4.85
7. Assay					
a. as Total Bitters (%w/w)	a.1.55	a. 0.89	a. 1.44	a. 1.23	a. 1.68
b. Tinosporide (%w/w)	b. 0.040	b. Traces	b. ND*	b. 0.055	b. 0.10
8. Microbial Analysis (cfu/g)					
a. Total Plate Count	a. 103	a. 3775	a. TNTC	a. TNTC	a. 975
b. Total Yeast and Mould	b. <10	b. <10	b. <10	b. 150	b. 65
C. Pathogens (in 10 g)					
i. <i>E.coli</i>	c. All absent				
ii. <i>Salmonella sp.</i>	c. All absent				
iii. <i>P.aeruginosa</i>	c. All absent				

iv. <i>S.aureus</i>					
9. Heavy Metals (ppm)					
a. Lead	a. 5.63	a. ND	a. 1.39	a. 30.12	a. 0.43
b. Arsenic	b. 0.04	b. ND	b. ND	b. ND	b. ND
c. Cadmium	c. 0.02	c. ND	c. ND	c. ND	c. 0.059
d. Mercury	d. ND	d. ND	d. 7.02	d. 32.37	d. ND
10. Aflatoxin	Not detected				

\*ND-Not Detected

## DISCUSSION

General people aware of the use of *Samsamani vati/ Guduchi Ghana vati/Giloy* and purchase from leading Ayurveda manufacturers of India. The comparative analysis suggested the difference in physico-chemical parameters (like, total ash, acid insoluble ash, extractives values) as well as assay parameters though HPTLC<sup>[15]</sup>. Bioactive compound are secondary metabolites of plant or microbes express bio active properties without adding nutritional benefit to human. The uniformity of bio active molecules is a big challenges due diverse types of raw materials, soil condition and extraction methods<sup>[16]</sup>. The high amount of mercury and lead in IMPCL tested samples may be due to contamination of soil or in preparation. But heavy metals in Ayurveda medicine is a big issues should be address properly with strong regulation. Similar study of marked sample of Ayurveda medicine also showed divergent types of HPTLC fingerprinting<sup>[17,18]</sup>. The determination of Borapetosides and Tinoseneside is beyond this paper whereas Borapetosides is also not hepatotoxic as reported<sup>[19]</sup>. *Tinospora cordifolia* is also hepato toxic as claimed<sup>[20]</sup>. It may be due to pre-existing liver diseases and other contaminants in crude herb. Any western medicine contains just one active molecule, synthetically, whereas *Samsamani Vati* has mixture of over dozen chemicals that act synergistically. Every Ayurveda medicine should have complete chemical profiling with advanced technology and phytochemical screening is very necessary to maintain bioactivities and safety<sup>[21]</sup>.

## CONCLUSION

There is no uniformity of *Samsamani Vati/ Guduchi Ghana vati* of competitive brand of India. It is recommended to maintain uniformity in all Ayurveda pharmaceuticals of bioactive molecules not only for desired efficacy but also for safety.

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