Standardization of *Triphalaguduchyadi Vati*- A Herbal Formulation For Childhood Obesity

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Abstract:

Childhood obesity is a condition where excess body fat negatively affects a child's health or well-being. Due to the rising prevalence of obesity in children and its many adverse health effects it is being recognized as a serious public health concern. *Triphalaguduchyadi Vati* is an Ayurvedic polyherbal preparation comprising of comprising of *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia bellirica* Roxb.), *Amalaki* (*Emblica officinalis* Gaertn.), *Musta* (*Cyperus rotundus* Linn.), and *Guduchi* (*Tinospora cordifolia* Thunb.). They together have *Kapha-Medhohara* properties along with *Lekhaniya* and *dipaneeya* actions thus helps in fat metabolism and weight reduction. **Methods**: Physico-chemical analysis of *Triphalaguduchyadi Vati* were performed as per standard methodology such as Hardness test, Water-soluble extract, Alcohol soluble extract, pH Value, Ash value, Loss on drying, Disintegration time, HPTLC etc. **Results**: The Pharmaceutical analysis of *Triphalaguduchyadi Vati* has showed Hardness of *Vati* 5.1 Kg./Cm.^{2}, 29.2 % of Water-soluble extract, 21 % of Alcohol soluble extract, pH 5.5, Ash value 10.55 %, Loss on drying 7.6 %, HPTLC showed 9 & 11 spots at 254nm and 366nm respectively. **Conclusions**: The quality indicating tests for *Triphalaguduchyadi Vati* reported from this study can be used as routine quality check parameter for this polyherbal preparation.

Keywords: Childhood obesity, *Triphalaguduchyadi Vati*, Pharmaceutical analysis, HPTLC

Introduction:

Childhood obesity is a known pioneer to obesity and other non-communicable diseases (NCDs) in adulthood. However, the extent of the problem among children and adolescents in India is unclear due to scarcity of well-conducted nationwide studies and lack of homogeneity in the cut-points used to define childhood overweight and obesity. According to the recent report of National Family Health Survey (NFHS-4, 2015-16), prevalence of obesity in India was 18.6% and 20.7% among men and women aged 15–49 years respectively. Particularly in Gujarat, the percentage of female and male who are overweight or obese is 23.7 and 19.7 respectively.[1]The most frightening aspect of obesity is that shorten the lifespan. Apart from that Childhood obesity is a forerunner of metabolic syndrome, poor physical health, mental disorders, respiratory problems and glucose intolerance, all of which can track into adulthood.[2] Obesity is caused by number of factor including more intake of food, sedentary lifestyle, less physical and mental work and sometimes heredity.

Obesity has been described by the term *Sthoulya* and *Medoroga* in Ayurvedic texts. Also *Atisthoulya* is included in *Asta Nindita Purusha*. *Acharya* Charak mentioned *Atisthoulya* as disease of *Kapha Dosha* so, *Kapha dosha*, *Agni dushti* and vitiated *Medo dhatus* are leading factor in pathogenesis of *Atisthoulya*. [3] *Triphalaguduchyadi Vati* is an Ayurvedic polyherbal preparation comprising of comprising of *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia bellirica* Roxb.), *Amalaki* (*Emblica officinalis* Gaertn.), *Musta* (*Cyperus rotundus* Linn.), and *Guduchi* (*Tinospora cordifolia* Thunb.)[4] As per the *Rasapanchaka* of the ingredients of the *Triphalaguduchyadi Vati* have *Tikta-Katu Rasa, Ruksha-Laghu Guna, Ushna Veerya, Katu/Madhur Vipaka* hence they together have *Kapha-Medhohara* properties along with *Lekhaniya* and *dipaneeya* action.[5]So, this polyherbal formulation improve fat metabolism in an obese individual and thus helps in maintaining the weight.

Material and methods:

Drug Material

Raw drug materials were collected from the pharmacy store of Gujarat Ayurved University. The ingredients and the part used are given in the table 1.

Table 1 Composition of *Triphalguduchyadi Vati*

Sr. No.	Ingredient[4]	Botanical /English Name	Part Used	Ratio
1.	*HARITAKI*	*Terminalia chebula* Retz.	Dried Fruit	1 parts
2.	*BIBHITAKI*	*Terminalia bellirica* Roxb.	Dried Fruit	1 parts
3.	*AMALAKI*	*Emblica officinalis* Gaertn.	Dried Fruit	1 parts
4.	*MUSTA*	*Cyperus rotundus* Linn.	Dried Rhizome	1 parts
5.	*GUDUCHI*	*Tinospora cordifolia* Thunb.	Dried Stem	1 parts

Method of Preparation of the *Triphalguduchyadi Vati*:

Haritaki, Bibhitaki, Amalaki, Musta, Guduchi were taken in given proportion and made into fine powder and sieved in mesh no. 80. The powders were mixed well in mass mixing machine until a homogenous mixture was obtained. Out of total amount of drugs, 10% of the crude drugs were used for the preparation of decoction. Thereafter, the above-mentioned powders were mixed with decoction and *Vati* of 500 mg each was prepared.

Physico-Chemical Parameters:

Following Physico-chemical studies were carried out as per WHO guidelines [6], Ayurvedic Pharmacopoeia [7], and Indian Pharmacopoeia [8] for Standardization of *Triphalaguduchyadi Vati*.

1. Variation in weight; 2. Hardness test; 3. Water-soluble extract; 4. Alcohol soluble extract; 5. pH Value; 6. Ash value; 7. Loss on drying; 8. Disintegration time; 9. HPTLC

High-Performance Thin Layer Chromatography (HPTLC)

HPTLC (High-Performance Thin Layer Chromatography) is the most beneficial tools for herbal fingerprinting in today's Era. It is most sophisticated and highly precise for the results. This is based on the principle of TLC (Thin layer chromatography). It is a higher version of TLC. It is very suitable Instrument for the herbal standardization with the help of its marker compound we can easily identify the compound present in plant and quantity is also measure if with the help of Quantitative analysis. Basically, the important process in HPTLC is Preparation of samples, loading the samples through sample applicator and at last scanner will help us to read the samples in multi wavelengths.

The principle of HPTLC

The principle remains the same as of TLC i.e. adsorption. One or more compounds are spotted on a thin layer of adsorbent coated on a chromatographic plate. The mobile phase solvent flows through because of capillary action (against gravitational force). The component with more affinity towards stationary phase travels faster. Thus, the

components are separated by a thin layer chromatographic plate based on the affinity of the components towards the stationary phase.

Steps involved in HPTLC:

1. Selection of chromatographic layer; 2. Sample and standard preparation; 3. Layer pre-washing, 4. Layer pre-conditioning; 5. Application of sample and standard; 6. Chromatographic development; 7. Detection of spots; 8. Scanning; 9. Documentation of chromatic plate

Chromatographic conditions:

Application mode: CAMAG Linomat V Hamilton Syringe ; Development chamber: CAMAG Twin trough chamber (20 x 10 cm^2) ;Plates: Pre coated silica gel GF254 plates ;Chamber saturation: 30 min ;Development distance: 10 cm ;Development time: 30 min ;Scanner: CAMAG TLC Scanner III ;Scanning mode: Linear at wavelength 254 nm and 366 nm ;Detection: Deuterium lamp, Mercury lamp ;Photo documentation: CAMAG reprostar ;Data system: CATS software (Ver. 3.17) ;Drying device: Oven ;U.V. Spectrum: 200 nm to 700 nm

Solvent System HPTLC studies

Solvent system: Toluene: Ethyl acetate (8.0:2.0)

Results and Discussion:

Table 2: Results of standardization tests for *Triphalaguduchyadi Vati*

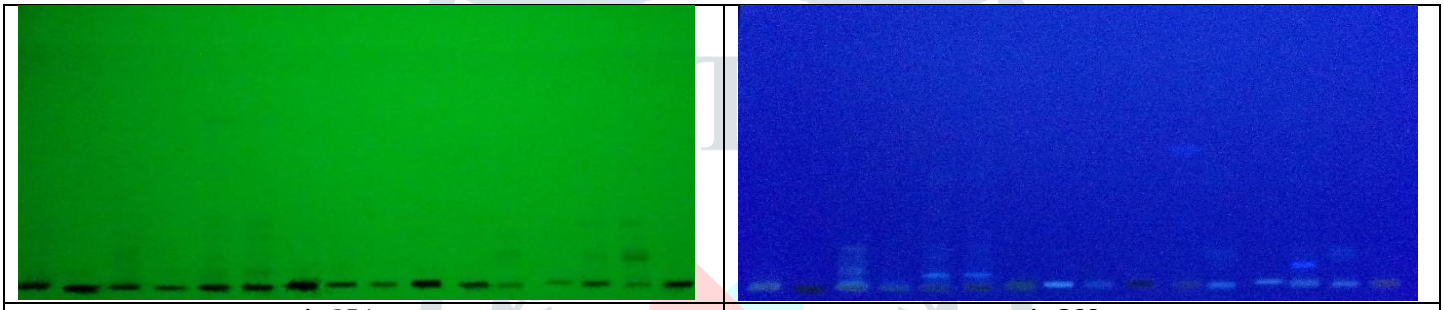
Parameters	**Results**
Color	Brownish Gray
Odour	Pungent
Taste	Sour astringent
pH	5.5
Average wt.	512.4 Mg.
Weight variation of lowest wt.	11.91%
Weight variation of highest wt.	7.03%
Hardness	5.1 Kg./Cm.
Loss on drying	7.6%
Ash value	10.55%
Disintegration time	>1 hr.
% Water solubility extractive	29.2%
% Alcohol soluble extractive	21%

Fig. 1 *Triphalaguduchyadi Vati*

Fig. 2 Powder of *Triphalaguduchyadi Vati*

Standardization tests performed for *Triphalaguduchyadi Vati* were as per AYUSH testing protocol for *Vati* (Table 2, Figure 1 & 2). *Triphalaguduchyadi Vati* is found to be brownish gray in color with characteristic pungent odour and bitter astringent taste. pH of *Triphalaguduchyadi Vati* was found to be 5.5, that is in the acidic range. Most drugs are either weak acids or weak bases. Weak electrolytes, in addition to lipid solubility, depend upon its degree of ionization which is influenced by pH of the area. Weak acids become less ionized (charged) in an acidic medium and weak bases become less ionized in an alkaline medium. Basic drug will absorb more from intestine because it becomes unionized in basic medium. In acidic medium basic drug will become more ionized and thus no absorption will takes place. As *Triphalaguduchyadi Vati* is lightly acidic it will be absorbed properly. Variation in the weight was found to be within normal limit. Weight is mainly affected by factors such as tooling of the compression machine, head pressure, machine speed and flow properties of the powder. Inconsistent powder or granulate density and particle size distribution are common sources of weight variation during compression. Variation between *Vati* with respect to dose and weight must be reduced to a minimum. Uniformity of weight is an in process test parameter which ensures consistency of dosage units during compression. The *Triphalaguduchyadi Vati* is found to be hard until 5.1 kg/cm^2 which is also well within the normal limit. The testing of a *Vati's* hardness (or more correctly breaking force) plays a vital role in both product development and subsequent quality control. High hardness values may indicate increased disintegration times and reduced dissolution values. On the other hand, if hardness is too low then friability and hence % defective may well be too high. By exploiting the correlation between hardness, disintegration, dissolution, friability, percentage defective and weight variation, the various parameters can be manipulated to produce a dosage form with optimum characteristics. The *Triphalaguduchyadi Vati's* disintegration time is >60 min. which is also a good property of a tablet for easy dissemination of active constituents. An orally administered drug must disintegrate to attain good absorption of its active substance. The first step toward dissolution is usually the break-up of the tablet; a process described as disintegration. The disintegration test results in a time necessary to disintegrate a group of tablets into small particles under standard conditions. The disintegration test is a valuable tool in quality control environments. However, it is not a bioavailability indicator. The uniformity of active ingredient and

content will make sure the dosage supplied to the patients is correct and preventing from overdose cases and so on. Photo documentation of ethanolic extract of *Triphalaguduchyadi Vati* showed 9 and 11 spots under 254 and 366 respectively (Table 3 & 4, Figure 4-7). Densitometric scan at 254 nm revealed 9 peaks corresponding to 9 different compounds in the ethanol extract, compounds with Rf 0.02 (75.27%), 0.21 (4.89%), 0.34 (4.79%) and 0.42 (3.85%) were the major peaks (Table 3, Figure 4). At 366 nm there were 11 peaks, one with Rf 0.02 (85.78%), 0.42 (1.71%), 0.50 (1.71%) being the major peaks detected (Table 3, Figure 6). HPTLC is an important tool in standardization and quality control of polyherbal formulations. As there are more than one ingredient qualitative HPTLC fingerprinting can be used for development of quality standards for polyherbal formulations [9, 10]. These physico-chemical constants like pH, variation in weight, hardness, disintegration time, results of TLC photo documentation, the unique Rf values and densitogram obtained at different wavelengths can be used as fingerprint to check quality of *Triphalaguduchyadi Vati*.



At 254 nm | At 366 nm

Fig. 3: HPTLC photo documentation of Alcohol extract of *Triphalaguduchyadi Vati* Track 10; Solvent system: Toluene: Ethyl acetate (8.0:2.0)

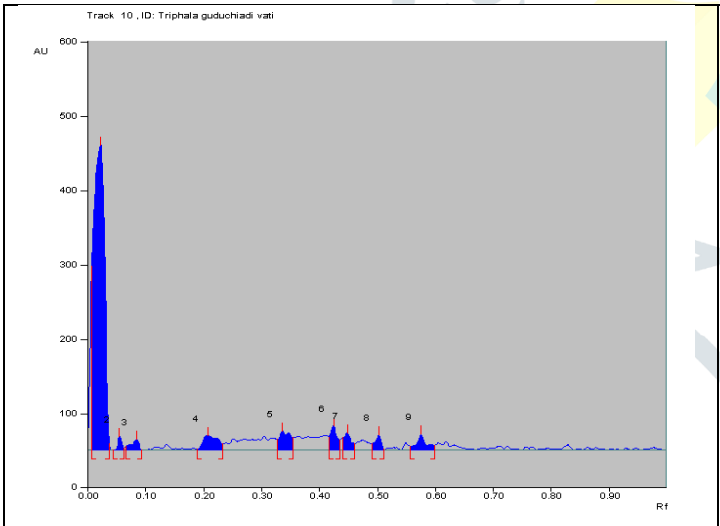


Fig. 4: Peak display at 254nm

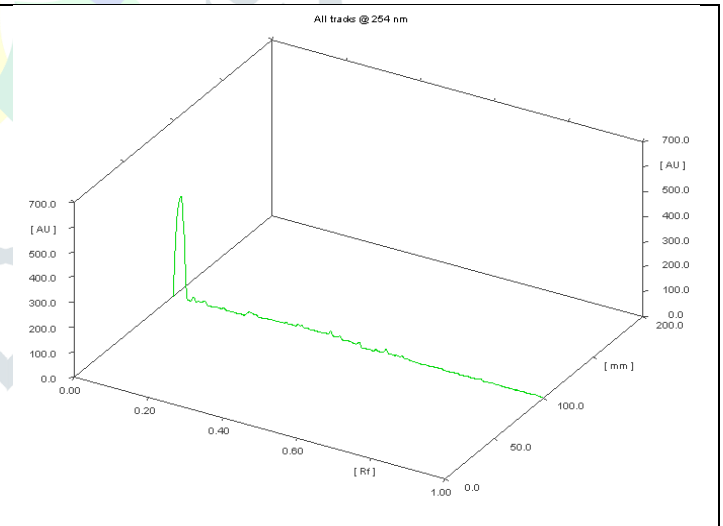


Fig. 5: 3D view at 254nm

Table 3: Densitometric scan at 254nm

Peak	Strat Rf	Start Height	Max Rf	Max Height	Height %	End Rf	End Height	Area	Area %
1	0.01	246.9	0.02	410.1	70.19	0.04	8.6	6303.3	75.27
2	0.04	0.1	0.05	17.7	3.04	0.06	1.9	92.0	1.10
3	0.07	4.7	0.08	14.0	2.40	0.09	0.0	152.9	1.83
4	0.19	1.2	0.21	19.7	3.38	0.23	8.5	409.7	4.89
5	0.33	14.6	0.34	25.1	4.30	0.35	16.3	401.3	4.79
6	0.42	17.2	0.42	32.6	5.58	0.44	13.6	322.2	3.85
7	0.44	16.4	0.45	22.4	3.84	0.46	8.9	237.6	2.84
8	0.49	8.4	0.50	20.5	3.51	0.51	0.7	176.8	2.11
9	0.56	5.2	0.58	22.0	3.77	0.60	6.1	278.3	3.32

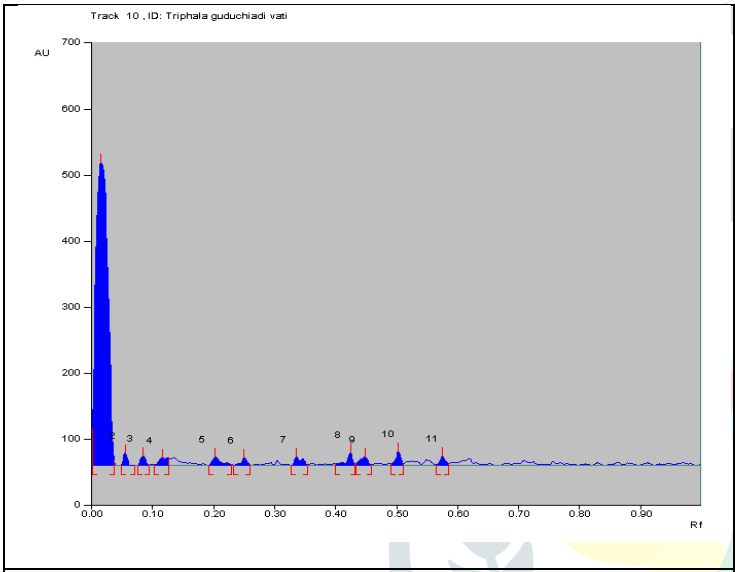


Fig. 6: Peak display at 366nm

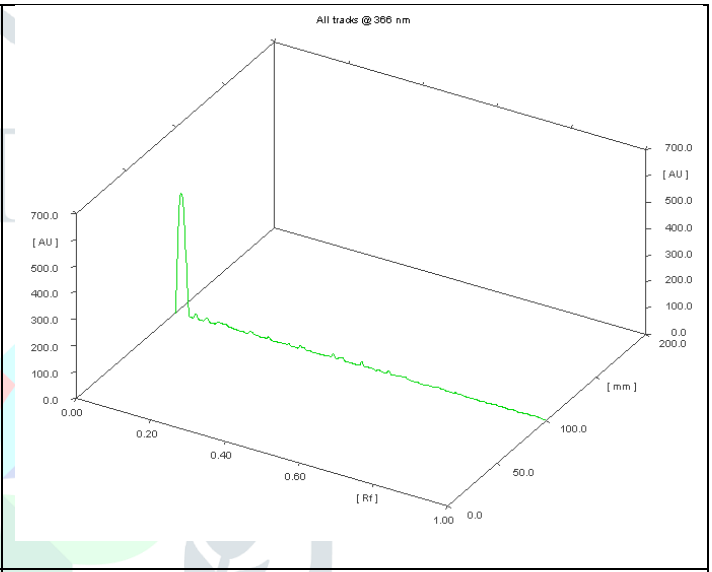


Fig. 7: 3D view at 366nm

Table 4: Densitometric scan at 366nm

Peak	Start Rf	Start Height	Max Rf	Max Height	Height %	End Rf	End Height	Area	Area %
1	0.00	54.4	0.02	458.0	75.72	0.04	6.3	7273.4	85.78
2	0.05	0.5	0.06	17.8	2.94	0.07	0.1	94.8	1.12
3	0.08	0.4	0.08	13.8	2.28	0.09	0.6	92.0	1.09
4	0.10	1.1	0.12	11.7	1.93	0.13	10.3	139.3	1.64
5	0.19	0.0	0.20	12.5	2.07	0.23	0.9	139.8	1.65
6	0.23	0.5	0.25	11.1	1.84	0.26	1.1	88.2	1.04
7	0.33	0.0	0.34	12.7	2.09	0.35	0.9	120.6	1.42
8	0.40	2.3	0.42	19.2	3.18	0.43	2.9	144.7	1.71
9	0.43	3.0	0.45	13.0	2.15	0.46	1.3	137.3	1.62
10	0.49	2.5	0.50	20.5	3.40	0.51	2.7	144.6	1.71
11	0.56	1.0	0.58	14.5	2.41	0.59	3.1	104.1	1.23

Conclusion:

The present physico-chemical analysis of *Triphalaguduchyadi Vati* confirmed the purity and genuinety of the drug. The quality indicating tests for *Triphalaguduchyadi Vati* reported from this study can be used as routine quality check parameter for this polyherbal preparation.

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Conflicts of Interest: Nil

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