

# Standardization and quality control parameters of *Dashanga Kwatha* ghana tablet: An Ayurvedic formulation

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## ABSTRACT

Herbal medicines have a long therapeutic history and are still serving many of the health needs of a large population of the world. However, the quality control and quality assurance still remains a challenge because of the high variability of chemical components involved. Herbal drugs, singularly and in combinations, contain numerous compounds in complex matrices in which no single active constituent is responsible for the overall efficacy. This creates a challenge in establishing quality control standards and standardization of finished herbal drugs. Many preparations have been mentioned in Ayurvedic text books for the treatment of Urdhwaga Amlapitta (non-ulcer dyspepsia). *Dashanga Kwatha* is one such known formulation. In this study, *Dashanga Kwatha* was converted into tablet form to increase the shelf life, make it easy to dispense, for dose fixation, etc. The *Dashanga Kwatha* Ghana tablet was subjected to organoleptic analysis, phytochemical analysis, and qualitative analysis to detect the presence of various functional groups, and to high performance thin layer chromatography (HPTLC) examination by optimizing the solvent systems. The investigation revealed the presence of tannins, mucilage, ascorbic acid, alkaloids, saponins, glycosides, flavonoids and carbohydrates mainly.

**Key words:** *Dashanga Kwatha*, decoction, quality control, standardization, tablet

## INTRODUCTION

Ancient Indian literature comprises a remarkably broad definition of medicinal plants and considers all plant parts to be potential sources of medicinal substances.<sup>[1]</sup> However, a key obstacle which has hindered the acceptance of the alternative medicines in the developed countries is the lack of documentation and rigorous quality control. There

is a need for documentation of research work carried out on traditional medicines. With this backdrop, it becomes extremely important to make an effort toward standardization of the plant-based medicines.

Administration of drug in various dosage forms provides an opportunity to the physician to choose better options. Various dosage forms have been described in the *Ayurvedic* texts. One among them is *Kwatha Kalpana*, i.e. decoction.

*Kwatha* preparations are one among the *Panchavidha Kashaya Kalpana*<sup>[2]</sup> which are highly effective, but they are to be used when freshly prepared and they are often overlooked due to the preparation method and palatability.

In the present study, *Dashanga Kwatha*,<sup>[3]</sup> a known formulation used in *Urdhwaga Amlapitta* (non-ulcer dyspepsia), was converted into tablet form by *Rasakriya*<sup>[4]</sup> method to increase the shelf life, make it palatable, easy to dispense, for dose fixation, etc.

With the intention of standardization and quality control of the plant-based drugs, *Dashanga Kwatha Ghana* was converted into tablet form and analyzed by various analytical parameters.

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## MATERIALS AND METHODS

### Procurement and preparation of plant material

The crude drugs mentioned in *Chakradutta* in *Amlapitta Rogadhikara*<sup>[5]</sup> for the preparation of *Dashanga Kwatha* were taken from the pharmacy of IPGT and RA, Gujarat Ayurved University, Jamnagar, after proper authentication by the Department of Pharmacognosy of the Institute. Then, the physical impurities were removed and the drugs were washed with water, sorted and sun dried below 45°C. Dried drugs were stored in tightly closed containers. The crude drugs used in *Dashanga Kwatha* with their botanical identities and parts used are given in Table 1.

### Preparation of *Dashanga Kwatha Ghana* tablet

The authenticated crude drugs were crushed to a coarse powder separately and then mixed thoroughly with 8 parts of water in a stainless steel container and then continuous mild heat was applied until it was reduced to one-fourth of its initial quantity. During the heating process, continuous stirring was done to facilitate the evaporation and avoid any deterioration due to burning of materials. After a desirable reduction in volume was achieved, the *Kwatha* was filtered through single folded cotton cloth and collected in a separate vessel.

Then, the *Kwatha* was boiled again over slow fire on a gas stove, maintaining the temperature between 90°C and 95°C till a semisolid consistency is obtained. As the water evaporates, the viscosity of the extract increases, resulting in *Ghana*<sup>[6]</sup> form. Then, the *Ghana* was mixed with the *Churna* of *Dashanga* (up to 10% of extract) further forming a solid mass.

The solid mass (*Ghana*) was forced through a no. 16 sieve and granules were prepared and then dried at 50°C in a hot air oven for 10 hours. The dried granules were passed again through a no. 20 sieve. The formulation was then compressed in a single-punch tablet press with a target weight of 250 mg.

*Dashanga Kwatha* and *Dashanga Kwatha Ghana* tablet were

subjected to various analytical parameters as follows.

- Organoleptic parameters: *Rupa* (color), *Rasa* (taste), *Gandha* (odor) and *Sparsha* (touch)
- Physico-chemical parameters: pH of 5% aqueous soln.<sup>[7]</sup>, loss on drying at 110°C<sup>[8]</sup>, ash value<sup>[9]</sup>, acid insoluble ash<sup>[10]</sup>, water soluble extractive<sup>[11]</sup>, methanol soluble extractive<sup>[12]</sup>
- Quantitative tests for tablet: Weight variation test<sup>[13]</sup>, tablet hardness test<sup>[14]</sup>, tablet disintegration time<sup>[15]</sup>, friability<sup>[16]</sup>
- Qualitative tests for various functional groups:<sup>[17,18]</sup> Tannins, mucilages, sterols/terpenoids, ascorbic acid, alkaloids, saponins, starch, flavonoids, glycosides and carbohydrates
- Chromatographic analysis: High Performance Thin Layer Chromatographic (HPTLC)<sup>[19]</sup>
- Test solution: Methanol extract of *Dashanga Kwatha Ghana* tablets.
- Stationary phase: Silica gel GF<sub>254</sub>  
Toluene:ethyl acetate (8:1.5 v/v) was selected as the solvent system through trial and error method. The developed plate was visualized under visible day light, short UV (254 nm), long UV (366 nm). The Rf values were recorded.
- Toxicological: Heavy metal analysis<sup>[20]</sup>, pesticide residue value<sup>[21]</sup>
- Microbial overload<sup>[22]</sup>: Bacterial and fungal growth study was carried out
- Reagents and chemicals: All the reagents and chemicals used for the study were of analytical grade.

## RESULTS

Comparative organoleptic characters were the following: *Rupa* (color) was dark brown, *Rasa* (taste) was bitter, *Gandha* (odor) was characteristic due to the specific properties of the various ingredients and *Sparsha* (consistency/texture) of *Dashanga Kwatha* was liquid and *Dashanga Kwatha Ghana* Tablet was smooth as given in Table 2.

pH of the *Kwatha* was 4.53 ± 0.03 and that of tablet was 4.21

**Table 1: Crude drugs of *Dashanga Kwatha***

Drug name	Hindi name	Botanical name	Family	Part used
Vasa	Adusa	<i>Adhatoda Vasica</i> Nees	Acanthaceae	Dried leaf
Guduchi	Giloy	<i>Tinospora cordifolia</i> (Willd.) Miers.	Menispermaceae	Stem
Parpata	Pittapapada	<i>Fumaria parvijflora</i> Lam.	Fumaraceae	Whole plant
Nimba	Neem	<i>Azadirachta indica</i> A. Juss.	Meliaceae	Stem bark
Bhunimba	Chirayata	<i>Swertia chirata</i> Buch. Ham	Gentianaceae	Whole plant
Bhringaraja	Bhangara	<i>Eclipta alba</i> Hassk.	Asteraceae	Whole plant
Haritaki	Harad	<i>Terminalia chebula</i> Retz.	Combrataceae	Dried fruit without seed
Bibhitaki	Behara	<i>Terminalia belerica</i> Roxb.	Combrataceae	Dried fruit without seed
Amalaki	Amla	<i>Phyllanthus emblica</i> Linn.	Euphorbiaceae	Dried fruit without seed
Patola	Parwal	<i>Trichosanthes dioica</i> Roxb	Cucurbitaceae	Dried leaf

**Table 2: Organoleptic parameters of *Dashanga Kwatha* and tablet**

Parameters	<i>Kwatha</i>	Tablet
Color	Dark brown	Dark brown
Taste	Bitter	Bitter
Odor	Characteristic	Characteristic
Form	Liquid	Solid (smooth)

**Table 4: Quantitative parameters of *Dashanga Kwatha Ghana* tablet**

Parameters	Result
Weight variation test	Avg. wt.: 251.23 mg Min. wt.: 248.86 mg Max. wt.: 253.20 mg
Tablet hardness test	2.74 ± 0.079
Tablet disintegration time	33 min
Friability	0.92%

± 0.02, loss on drying in *Kwatha* was 3.4 ± 0.20% w/w and in tablet was 0.09 ± 0.01% w/w as given in Table 3.

The average weight of the tablet was 251.23 mg, hardness of tablet was 2.74 ± 0.079 and disintegration time was 33 min and friability was 0.92% as given in Table 4.

Qualitative analysis reveals the presence of tannins, mucilage, ascorbic acid, alkaloids, saponins, glycosides, flavonoids and carbohydrates in the formulation, whereas sterols/terpenoids and starch were absent as given in Table 5.

Findings of the analysis of HPTLC, heavy metals, pesticide residual value, microbial count and pathogens of *Dashanga Kwatha Ghana* tablet are shown in Tables 6–10, respectively.

## DISCUSSION

*Ghana Kalpana*, a second derivative preparation of *Kwatha Kalpana*, is one of the extraction methods in which water soluble material is extracted by *Kwatha* method and reheated till it is converted into concentrated solid form.

The procedure adopted to convert *Dashanga Kwatha Ghana* into tablet form was wet granulation method of tablet preparation. Gum acacia was added as the binding agent (1%) of the derived *Ghana*, i.e. 70 g in powder form along with the 10% powder of *Dashanga Kwatha*. Its addition imparts cohesiveness and ensures that the tablet remains intact after compression as well as imparts desired hardness and size.<sup>[23]</sup> However, it has the disadvantage of being variable in its composition based on its natural origin, and it is usually fairly contaminated with bacteria. This material has the advantage of being a low-cost adhesive. Drying of granules in hot air oven was carried out at 45–50°C for 6 hours to reduce microbial

**Table 3: Physico-chemical parameters of *Dashanga Kwatha* and tablet**

Parameters	<i>Kwatha</i>	Tablet
pH at 5% aqueous soln.	4.53 ± 0.03 (3)	4.21 ± 0.02 (3)
Loss on drying at 110°C (%w/w)	3.4 ± 0.20 (3)	0.09 ± 0.01 (3)
Specific gravity	1.01 ± 0.01 (3)	-
Total solid content (%w/w)	6.2 ± 0.03 (3)	-
Ash value (%w/w)	-	12.0 ± 0.30 (3)
Acid insoluble ash (%w/w)	-	1.03 ± 0.02 (3)
Water soluble extractive (%w/v)	-	49.8 ± 0.2 (3)
Methanol soluble extractive (%w/v)	-	42.5 ± 2.5 (3)

The numbers in parentheses indicate the numbers of samples/determinations carried out

**Table 5: Qualitative parameters of *Dashanga Kwatha* and *Dashanga Kwatha Ghana* tablet**

Parameters	<i>Kwatha</i>	Tablet
Tannin	+	+
Mucilage	+	+
Sterols/terpenoids	-	-
Ascorbic acid (vitamin C)	+	+
Alkaloids	+	+
Saponins	+	+
Starch	-	-
Flavonoids	+	+
Glycosides	+	+

+ Present, - absent

proliferation. Granules were prepared by passing through sieve no. 16. In the present study, 1% talc was used as the lubricant. Since lubrication is basically a coating process, the finer the particle size of the lubricant, the more effective the lubricant is likely to be. With the help of tablet punching machine, these granules were compressed into tablets with a target weight of 250 mg.

The organoleptic parameters form the basic criteria for selecting a raw drug and also to confirm the finished product. Texture of tablets was smooth indicating the surface uniformity without cracks. This is the primary character to assess the quality of tablets. Color was brownish, taste was bitter and odor was characteristic due to the specific properties of the various ingredients [Table 2].

The pH conventionally represents the acidity and alkalinity; pH of the *Kwatha* and tablet showed to be weak acidic in nature.

Loss on drying indicates the moisture content; in the present sample, it was 0.1%.

Ash value depends upon the inorganic substances present in the particular drug; this parameter has importance in quality control and standardization of drugs. The higher the inorganic substances present in drugs, more will be the ash value.

**Table 6: Rf values of HPTLC analysis of methanolic extract at long UV (366 nm)**

Peak	Rf	Height	Area
1	0.02	63.7	426.0
2	0.04	245.8	2784.0
3	0.13	161.1	6355.1
4	0.16	151.4	3263.9
5	0.21	140.2	5481.0
6	0.24	128.1	2989.7
7	0.30	131.7	3629.2
8	0.33	148.9	3646.1
9	0.39	157.4	4401.8
10	0.43	315.4	10,040.3
11	0.51	725.0	17,936.6
12	0.60	406.0	14,288.0
13	0.64	61.4	1906.4
14	0.75	65.5	2632.2
15	0.90	101.6	3908.1
16	0.97	23.0	823.7

**Table 8: Heavy metal analysis**

Heavy Metal	Wave length	Limit	Results mg/kg (ppm)
Arsenic (As)	193.696	3 ppm	Not detected
Lead (Pb)	220.353	10 ppm	Not detected
Mercury (Hg)	253.652	1 ppm	Not detected
Cadmium (Cd)	228.802	0.3 ppm	Not detected

**Table 10: Total microbial count and pathogens**

Test parameters	Result	Limit
Total microbial count	40 CFU per g	
Total bacterial count	30 CFU per g	100 CFU per g
Total fungal count	10 CFU per g	
Pathogens		
<i>Escherichia coli</i>	Absent	Should be absent per
<i>Salmonella</i> spp.	Absent	10 g
<i>Pseudomonas aeruginosa</i>	Absent	
<i>S.aureus</i>	Absent	

Here, the ash value was  $12.0 \pm 0.30\%$  which may be due to the extensive heating process involved in preparation of this formulation [Table 3].

Various components have their solubility in particular media. In this study, soluble principles of the samples were seen in water and methanol; in water, it was 49.6% and in methanol, it was 40%. In both the media, solubility of sample was more as the sample itself which was used to prepare the tablet was derived from water extractive. In the solubility test, increase in water soluble extractive was found, which depicts its more bioavailability in water medium [Table 3].

**Table 7: Rf values of HPTLC analysis of methanolic extract at short UV (254 nm)**

Peak	Rf	Height	Area
1	0.11	173.7	2141.2
2	0.17	28.8	464.3
3	0.25	36.3	847.9
4	0.31	26.5	420.2
5	0.35	14.1	263.0
6	0.43	17.7	375.1
7	0.58	77.8	3336.5
8	0.76	49.9	2495.2
9	0.98	200.8	6047.3

**Table 9: Pesticide residual value**

Organophosphorous pesticide	Limit (mg/kg)	% Area
Dichlorovos	1.0	Not detected
Diazinon	0.5	Not detected
Methyl parathion	0.2	Not detected
Parathion	0.5	Not detected
Phorate	0.05	Not detected
Phorate sulfoxide	0.05	Not detected
Azinphos-methyl	0.0025	Not detected

Average hardness was 2.75 kg/cm<sup>2</sup>. Disintegration time was 33 min and friability was not more than 0.92% on an average [Table 4]. Physico-chemical analysis of *Dashanga Kwatha Ghana* tablet was done for the quality control purpose. Qualitative tests are used to detect the presence of functional groups, which play a very important role in the expression of biological activity. The present study reveals the presence of tannins, mucilage, ascorbic acid, alkaloids, saponins, glycosides, flavonoids and carbohydrates in the formulation, whereas sterols/terpenoids and starch were found to be absent [Table 5].

Preliminary HPTLC profile of *Dashanga Kwatha Ghana* tablet has been developed [Figures 1–3]. This can be considered as the reference standard for validating this formulation in future [Tables 6 and 7].

Heavy metals were not detected [Table 8], thus showing the purity of the raw drugs and also the finished product. This also indicates quality control maintenance during pharmaceutical preparation.

Medicinal plant materials are liable to be affected by pesticide residues which accumulate from agricultural practices of spraying, treating soils during cultivation and through the administration of fumigants during storage. Organophosphorous pesticides were found below the detection limit, which is a clear indication of quality land practices and safe storage of raw drugs [Table 9].

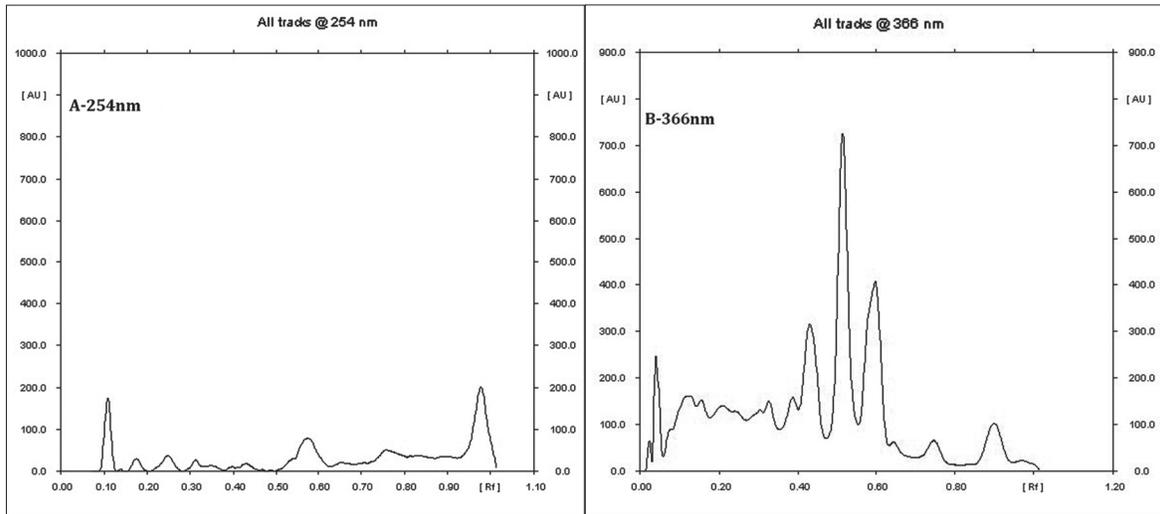


Figure 1: Densitogram of *Dashanga Kwatha Ghana* tablets (A – 254 nm, B – 366 nm)

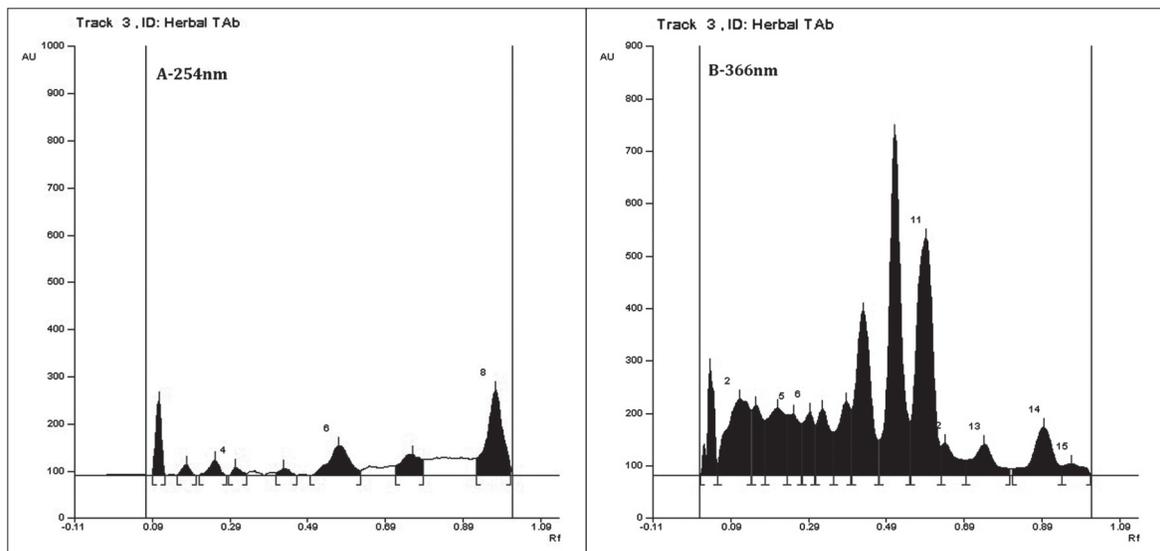


Figure 2: HPTLC profile of *Dashanga Kwatha Ghana* tablets (A – 254 nm, B – 366 nm)

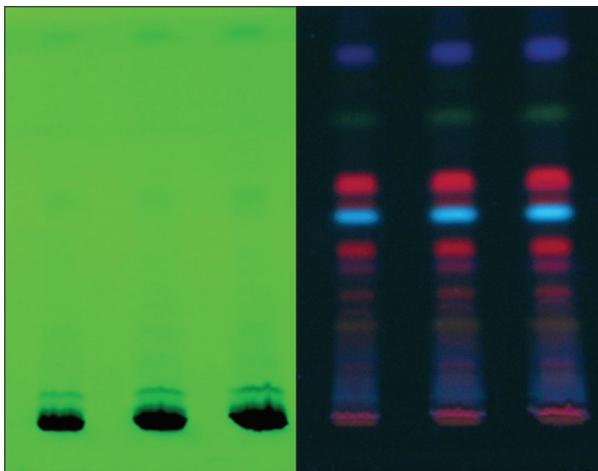


Figure 3: Photograph chromplate (A – 254 nm, B – 366 nm)

Medicinal plant matters normally carry bacteria and moulds often originating in soil in high numbers. In the present formulation, the microbial count was within permissible limits<sup>[24]</sup> [Table 10], which indicates the proper hygiene norms followed during the preparation of formulation and packing.

## CONCLUSIONS

The study reveals that sufficient quality control parameters were followed during the preparation of formulation. Organoleptic parameters, physicochemical analysis, heavy metal analysis, pesticide residue and microbial overload analysis were carried out as per the norms of WHO guidelines and the absence of heavy metals, pesticides in raw material and microbes in the finished product indicates the genuineness of final product.

HPTLC profile generated in this particular study can be considered as a preliminary tool ascertaining the authenticity of *Dashanga Kwatha Ghanavati* in the tablet form.

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