



Formulation and Comparative Standardization of Polyherbal Swadisht Virechan Churna

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ABSTRACT

Standardization of herbal formulation is essential in order to check quality, purity, safety and efficacy of drug. “Swadisht Virechan” churna play an important role in constipation and detoxification due to safety and efficacy in it. Hence churna has been formulated by standard procedure and evaluated by organoleptic study, physical characteristics and physicochemical screening. One marketed formulation and one lab scale formulation were subjected to comparative standardization. The churna was standardized by determination of organoleptic characters, pH, loss on drying, ash value, extractive value, physical characteristics such as bulk density; tap density, angle of repose to determine flowability, determination of particle size, microbial content. The result of various parameters obtained from study showed that marketed formulation and lab scale formulation have comparable physical values. The flowability of formulation was found to be poor in both formulations. These studies showed that there is no uniformity in preparation of formulation which is may be due to varied geographical locations where there plants grow. The present paper reports the investigation and standardization of swadisht virechan churna an Ayurvedic formulation. The physical parameter evaluated confirms the standard of the formulated churna.

Keywords: “Swadisht Virechan” churna, Ayurvedic formulation, Standardization.

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INTRODUCTION

Ayurveda is regarded as ancient science of life and is based on principle of “maintaining the health of healthy person and relieving the patients from the diseased condition”. The object of Ayurveda is to counteract the imbalance of three essential elements vatta, pitta and kapha (air, bile and phlegm respectively)^[1].

Swadisht virechan churna is one of the Ayurvedic medicine use for constipation and detoxification .They are formulated at lab scale and evaluated with standard (Marketed preparation).In recent days, churna is formulated into tablets in order to fix the dose easily. These forms of medicament are prescribed general, because of their particle size. Smaller the particle size greater is the absorption rate from GIT and hence the greater is the bioavailability. Due to lack of modern Pharmacopeial standards laid down and followed for processing of swadisht virechan churna using traditional methods, the medicine may not have the desired quality and batch to batch consistency. Thus WHO has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and by applying suitable standards and parameters .India is having a rich heritage of traditional medicine constituting with its different components like Ayurveda, Siddha and Unani. Botanical constituents are the major part of these traditional medicines. The development of these traditional systems of medicine with the perspectives of safety, efficacy, and quality will help not only to preserve the traditional heritage but also to rationalize the use of natural products in healthcare. Along with this, the growing need for a safer drug, where attention has been drawn to the quality, efficacy, and standard of Ayurvedic formulations. Churna is one such Ayurvedic formulation that is defined as a fine powder of drug or drugs in Ayurvedic system of medicine. The churna is free flowing and retains its potency for one year, if preserved in an air tight container. They are similar to powder formulations in Allopathic system of medicine^[2].

Standardization of herbal formulation is essential in order to assess the quality of drugs for therapeutic value as it is a plant-derived material containing raw ingredients. According to (W.H.O) most of the developing countries rely on traditional medicines. Hence, it has given a detailed protocol in 1999 for the standardization of herbal drugs^[3].

The present project reports the investigation and standardization of Swadisht virechan churna an Ayurvedic formulation. One marketed formulation sample and In house preparation were subjected to organoleptic study, physical characteristics and physiochemical screening. Swadisht virechan churna is a compound as it consists of more than one ingredient. The principle of using churna is due to the fact that therapeutic value of most of the substance greatly increases when

they are reduced to a very fine state of subdivision. They are also easily administrable especially in the cases of children where they cannot swallow pills, tablets or capsules. The result of various parameters obtained from study showed that marketed formulation & in house have comparable physical values. The flowability of formulation was found to be poor in all formulation. There is no uniformity in preparation of formulation and these results could be utilized as a reference for setting limits for the reference standards for the quality control and quality assurance of these drugs [3].

In that the, research article show the formulation process of the powder drug in the lab scale and comparative study of formulated powder drug in lab scale with pharmaceutical marketed herbal preparation. In that describe the, process of the formulation and other parameter, like-moisture content of the powder drug, bulk density, tab density, angle of repose, pH of the powder drug, Ash value, Extraction value (Acid soluble extraction value, Alcohol soluble extraction value) with respect to the crude fiber containing value,& microscopy with the help of stander optical microscope.

Pharmacological Action [4]

- The pharmacological action of swadisht virechan churn depends on the Senna leaves which content sennoside alkaloid, sennoside irritate bowel lining, stimulate the bowl muscles & induce laxation.
- All other ingredients in swadisht virechan churn are to reduce side effect of Senna leaves.
- Liquorice soothes the lining of the alimentary canal and reduces after effect of the Senna.
- Funnel reduce cramps induces by Senna leaves.
- Purified sulfur also has laxative action and assists to manage the constipation.

Medicinal Properties [4]

Swadisht virechan churn has following medicinal property; Laxative, Blood purifier, Antibacterial & antimicrobial, Antipyretic

MATERIALS AND METHOD

Procurement of Churna

One marketed preparation of swadisht virechan churn was purchase form the Ayush pharmacy, Ayurvedic medical store in Malkapur. Second in lab preparation was made base on the Ayurvedic parameter such as color, odor taste, shape, size i.e. gandha, ruchi, aakruti, Varna, parimana.

Preparation of Churna (In-house preparation) [7]

The entire procured and authenticated individual drug was dried in shade and cleans by hand

sorting. The individual drug was then crush using grinder and pass through #60. The individual drug weigh as per quantity required. The drug ware mix using mortar and pestle, the mixed formulation was unloaded, weight and packed in label glass bottles

Table 1 Ingredients ^[4]

Sr.no	Herbs	Botanical name	Family	Parts used
1.	Saunf	Foeniculam vulgare	Umbelliferae	Fruits
2.	Liquorice	Glycyrrhiza glabra	Glycyrrhizae	Roots
3.	Senna	Cassia angustifaulia	Leguminosae	Leaf
4.	Mishri	Saccharum officinarum	-	-

Table 2 Composition

Sr.no	Ingredients	Qty. given
1.	Shuddha Gandhak (pure Sulphur)	10%
2.	Mulethi(Liquorice)	10%
3.	Saunf(fennel seeds)	10%
4.	Senna (cassia angustifaulia)	30%
5.	Mishri(saccharum officinarum)	40%

Evaluation Parameter

Organoleptic Characteristics

Color:

Churna was taken into watch glass and placed against white background in white tube light .It was observed for their color by naked eye.

Odor:

2 gram churna was smelled and odour was noted.

Taste:

A Pinch of churna was taken and examined for its taste buds of the tongue.

Physicochemical parameters

Determination of P^H:

Placed accurately weighed 1 gm. of churna in a 100 ml volumetric flask and made up the volume up to 100 ml with distilled water. The solution was sonicated for about 10 minutes. PH was measured with the help of digital P^H meter.

Determination of Loss on Drying ^[1, 8, 9]:

Loss on drying was determined by weighing about 2 gm. of the powdered material in previously weighed dried Petridish (tarred evaporating dish) and dried in an oven at 105-110°C, till two consecutive weights, which do not differ by more than 5mg. The weight after drying was noted and loss on drying was calculated. The percentage was expressed as % w/w with reference to air dried Sample.

Determination of Ash value ^[1, 8, 9]:**Total Ash Value**

It is designated to measure the total amount of material remained after ignition. This include both physiological ash i.e. residue from plant tissue itself and non-physiological ash i.e. residue obtained from extraneous matter i.e. sand and soil adhering to plant 2 gm. of churna was weighed accurately in a previously ignited and tarred silica crucible. The material was then ignited by gradually increasing the heat to 500-600°C until it appeared white indicating absence of carbon. It is then cooled in a desiccator and total ash in mg per gm. of air dried material is calculated.

Acid Insoluble Ash Value

To the crucible containing total ash, 25 ml of HCl was added and boiled gently for 5 minutes, and then about 5 ml of hot water was added and transferred into crucible. The insoluble matter was collected on an ash less filter paper. This was then washed with hot water until filtrate is neutral and the filter paper along with the insoluble matter was transferred into crucible and ignited to constant weight. The residue was then allowed to cool and then weighed.

Determination of Extractive values:**Water Soluble Extractive Value** ^[1, 8, 9]

5 gm. of churna was accurately weighed and placed inside a glass stoppered conical flask. It is then macerated with 100 ml of chloroform water for 18 hours. It was then filtered and about 25ml of filtrate was transferred into a china dish and was evaporated to dryness on a water bath. It was then dried to 105° C for 6 hours, cooled and finally weight.

Alcohol Soluble Extractive Values ^[1, 8, 9]

Ethanol was used as solvent in place of chloroform water and remaining procedure was the same as that of water soluble extractive value

Determination of Crude Fiber Content ^[9]:

2 grams of churna accurately weighed was placed in a round bottom flask and then 100ml of 0.128M Sulphuric acid was added and refluxed for 1 hour ,then filtered through ashless filter paper and the residue was washed with water until filtrate becomes neutral.

The residue was then weighed (a) ignited to ash and finally the weight of ash (b) was determined. The difference between a and b represented the crude fiber content and was calculated on dry weight basis.

Evaluation of Physical Characteristic**Bulk Density** ^[10, 11]:

Bulk or fluff density is the ratio of given mass of powder and its bulk volume. It is determined by transferring an accurately weighed amount of powder sample to the graduated cylinder with the aid of a funnel. The initial volume was noted as untapped or poured volume. The ratio of weight of the volume it occupied was calculated.

$$\text{Bulk density} = \text{mass of powder/Bulk volume of powder (g/ml)}$$

Tapped Density ^[10, 11]:

It is measured by transferring a known quantity (25 gm.) of powder into a graduated cylinder and tapping it for a specific number of times. The initial volume was noted. The graduated cylinder was tapped continuously for a period of 10-15 min. The density can be determined as the ratio of mass of the powder to the tapped volume (Apparatus use Electro Lab Tab Density Tester ETD-1020 USP)

$$\text{Tapped Density} = \text{mass of powder/Tapped volume of powder}$$

Angle of Repose ^[10, 11]:

The internal angle between the surface of pile of powder and the horizontal surface is known as Angle of repose. The angle of repose was determined by Fix Funnel Method. Angle of repose has been used as indirect methods of quantifying powder flowability because of its relationship with inter particle cohesion. Angle of repose is related to density, surface area and shape of the particles, and the coefficient of friction of the material.

$$\text{Angle of Repose} = \tan^{-1}(h/r)$$

Where,

h =Height of pile

r =Radius of pile

Table 3 Angle of repose I.P limits

Sr.no	Angle of repose	Powder flow
1.	<25	Excellent
2.	25-30	Good
3.	30-40	Passable
4.	>40	Very poor

Hausner's Ratio ^[7]:

It is related to inter particle friction and as such can be used to predict the powder flow properties. Powders with low interparticle friction such as coarse spheres have a ratio of approximately 1.2, whereas more cohesive, less flowable powders such as flakes have a Hausner's ratio greater than 1.6

$$\text{Hausner's ratio} = \text{DF} / \text{Do}$$

Where,

DF = Tapped density

Do = Bulk density

Table 4 Hausner's Ratio I.P Limits

Sr.no.	Hausner's Ratio	I.P Limits Value
1.	Excellent	1.00-1.11
2.	Good	1.1-1.18
3.	Fair	1.19-1.25
4.	Possible	1.26-1.34
5.	Very Poor	1.35-1.45
6.	Very Very Poor	>1.60

Carr's Index ^[7]:

Another indirect method of measuring the powder flow from bulk density is Carr's index.

$$\text{Carr's index} = \% \text{ compressibility} = (\text{DF}-\text{Do}/\text{Do}) \times 100$$

Where,

DF = Tapped density

Do = Bulk density

Table 5 Carr's Index I.P Limits

Sr.no.	Carr's Index	I.P Limits value
1.	Excellent	<10
2.	Good	11-15
3.	Fair	16-20
4.	Possible	21-25
5.	Poor	26-31
6.	Very poor	32-37

Determination of Particle Size ^[10, 11]

This was done by Optical Microscopy Method.

Table 6 Marketed preparation

Sr.no	Size range	Size midpoint	Frequency	% Frequency	Cumulative Frequency (%)
1	0-10	05	06	6.06	6.06
2	12-20	15	07	7.07	13.13
3	23-30	25	08	8.08	21.21
4	30-40	35	11	12.12	33.33
5	40-50	45	12	11.11	44.44
6	50-60	55	09	9.09	53.53
7	60-70	65	16	16.16	69.69
8	70-80	75	14	14.14	83.83
9	80-90	85	07	7.07	90.90
10	90-100	95	09	9.09	99.99

Table 7 In-house Preparation

Sr.no	Size range	Size Midpoint	Frequency	%Frequency	Cumulative Frequency%
1	0-10	5	11	11.22	11.22
2	10-20	15	08	8.16	19.38
3	20-30	25	15	15.30	34.68
4	30-40	35	10	10.20	44.88
5	40-50	45	07	7.14	52.02
6	50-60	55	13	13.26	65.28
7	60-70	65	09	9.18	74.46
8	70-80	75	08	8.16	82.62
9	80-90	85	12	15.24	94.86
10	90-100	95	05	5.10	99.96

Limit Test

Limit Test for Iron ^[8, 12]:

Limit test was performed in Nessler's cylinder. 2ml of test and standard solutions (20ppm) were taken in separate cylinders and then 2ml of 20% solution of citric acid and 0.1 ml thioglycollic acid were added. The solution was then mixed and made alkaline with iron free ammonia, dilute to 50ml with distilled water. It was then allowed to stand for 5 minutes and colour obtained in sample was compared with that of standard colour. If the colour produced in test is more when compared to that of standard solution then the sample was said to fail the limit test and said to pass the test if vice versa occurs.

Limit Test for Chlorides ^[8, 12]:

1 ml of 0.05845% w/v solution of sodium chloride in Nessler's cylinder [A] and add 1ml of dilnitric acid, make up the volume to 50 ml with water, add 1 ml of silver nitrate solution, stir with glass rod and set aside for 5 minutes.

Specified weight of the substance is dissolved in water and transferred to Nessler's cylinder [B]. To the solution 1 ml of nitric acid is added and the volume made up to 50 ml with the water. Then 1 ml of silver nitrate solution is added and the solution is stirred. If the opalescence from the sample has been less than the standard opalescence, the sample will pass the limit test.

Limit Test for Sulphate ^[8, 12]:

Dissolve the specified quantity of the substance in distilled water, transfer to a Nessler's cylinder, and the preparation of the solution. Dilute to 45 ml with distilled water, add 5 ml barium sulphate reagent, stir immediately with a glass rod, and allow standing for 5 minutes. The turbidity is not greater than the standard turbidity, when viewed transversely.

Limit Test for Lead ^[12]:

Limit test was performed in Nessler's cylinder. 1ml of standard lead solution and test solution were taken in separate cylinders and were diluted to 25ml using distilled water and then pH was adjusted to value 3-4 by adding dilute acetic acid or dilute ammonia solution and then diluted to 35ml using distilled water. To both the solutions 10ml freshly prepared hydrogen sulphate solution was added, mixed and diluted with water to 50ml. It was then allowed to stand for 5 minutes and viewed downwards over white surface. The color produced in test solution should not be more intense than that of standard solution, if so then the sample is said to pass the limit test for lead

Limit Test for Mercury ^[7]:

To 10 drops of test solution 6M HCl was added to get a white precipitate. The precipitate was then treated with 6M ammonia solution. If the color of precipitate changes to grey or black color then it indicates the presence of mercury.

Determination of Microbial Content ^[13]

1gm of churna was dissolved in nutrient agar culture and volume adjusted to 100ml with the same medium. About 10ml of sample was transferred into 100ml of nutrient agar culture broth and incubated for 18-24 hours at 43-45°C. A subculture was prepared on a plate with nutrient agar culture and incubated at 43-45°C for 18-24 hours. The growth of red, generally non-mucoid colonies of gram negative rods appearing as reddish zones indicates the presence of E.coli if not then it indicates the absence of E.coli.

OBSERVATIONS, RESULTS AND DISCUSSION

The results of the organoleptic character was given in Table No.8 and physical parameter evaluation such as pH, loss on drying, ash value, extractive value, and crude fiber content were given in Table No.9. Determination of physical parameter such as bulk density, tapped density, angle of repose, Hausner's ratio, Carr's index were shown in Table No.10. Particle size was determined in Table No.11. The detection of heavy metals such as iron, chloride, lead, mercury, sulphate were tabulated in Table No.12 and detection of microbial content was shown in table-13

Table 8 Organoleptic Characters

Sr.no.	Formulation	Appearance	Color	Odor	Taste
1.	Marketed formulation	Fine powder with smooth texture	Greenish yellow	Pleasant	Sweet
2.	In house formulation	Fine powder with smooth texture	Greenish yellow	Pleasant	Sweet

Table 9 Physicochemical Parameters

Sr.no	Physicochemical parameters	Marketed	In House
1	P ^H	6.6	6.6
2	Loss on drying	3%w/w	2.53%w/w
3	Total ash value	24.53gm	26.07gm
4	Acid insoluble ash value	0.01gm	0.02gm
5	Water soluble extractive value	0.50gm	0.59gm
6	Alcohol soluble extractive value	0.15gm	0.16gm
7	Crude fiber content	0.01gm	0.10gm

Table 10 Physical parameters

Sr.no	Physical parameters	Marketed	In house
1	Bulk density	0.23g/ml	0.30g/ml
2	Tapped density	0.39g/ml	0.42g/ml
3	Angle of repose	34.99 ⁰ c	45 ⁰ c
4	Hausner's ratio	1.69	1.40
5	Carr's index	41.02	28.57

Table 11 :Particle Size- Marketed Formulation

Mean size um (d)	No. of particle In each size(n)	n×d	n×d ²	n×d ³	Percent n×d ³ (%)	Cumulative Frequency.
5	06	30	150	750	0.4002443	0.002
15	07	105	1575	23625	0.092	0.094
25	08	200	5000	125000	0.4905	0.584
35	12	420	14700	514500	2.019	2.60
45	11	495	22275	1002375	3.934	6.53
55	09	495	27225	1497375	5.876	12.41
65	16	1040	67600	4394000	17.224	29.65
75	14	1050	78750	5906250	23.180	52.83
85	07	595	50575	4298875	16.872	69.71
95	09	855	81225	7716375	30.28	99.99
Total	£99	£528	£3490	£25479125	£99.99	
		5	75			

$$\text{Surface Length mean} = \frac{\sum nd^2}{\sum nd} = \frac{349075}{5285} = 66.05$$

$$\text{Volume Surface mean} = \frac{\sum nd^3}{\sum nd^2} = \frac{25479125}{349075} = 72.99$$

$$\text{Surface number mean, } d_{sn} = \frac{\sqrt{\sum nd^2}}{\sqrt{\sum nd}} = \frac{349075}{5285} = 66.05$$

$$\text{Length number mean, } d_{ln} = \frac{\sum nd}{\sum n} = \frac{5285}{99} = 53.3$$

Particle Size- In house Formulation

Mean size Um (d)	No. of particle In each size(n)	n×d	n×d ²	n×d ³	Percent n×d ³ (%)	Cumulative Frequency.
5	11	55	275	1375	0.006	0.006
15	8	120	1800	27800	0.128	0.13
25	15	375	9375	234375	1.116	1.25

35	10	350	12250	428750	2.042	3.29
45	07	315	14175	637875	3.038	6.33
55	13	715	39325	2162875	10.301	16.63
65	09	585	38025	2471625	11.770	28.40
75	08	600	45000	3375000	16.075	44.47
85	12	1020	86700	7369500	35.10	79.57
95	05	475	45125	4286875	20.41	99.98
Total	£98	£4610	£292050	£20995250	£99.98	

$$\text{Surface Length mean} = \frac{\sum nd^2}{\sum nd} = \frac{292050}{4610} = 63.63$$

$$\text{Volume Surface mean} = \frac{\sum nd^3}{\sum nd^2} = \frac{20995250}{292050} = 71.88$$

$$\text{Surface number mean, } d_{sn} = \frac{\sqrt{\sum nd^2}}{\sum nd} = \frac{292050}{4610} = 43.82$$

$$\text{Length number mean, } d_{ln} = \frac{\sum nd}{\sum n} = \frac{4610}{98} = 47$$

Table 12 Limit Test

Sr. no.	Heavy metals	Values
1	Chlorides	Within the limit
2	Iron	Within the limit
3	Lead	Within the limit
4	Mercury	Absent
5	Sulphate	Within the limit

Table 13 Microbial content

Sr.no	Microorganism	Present / Absent
1	Escherichia coli	Absent

The churna consisting of fine powder of herbs in appropriate ratio was subjected to standardization by means of various physical and chemical methods. The organoleptic characters were comparable, however adversity in taste was observed. The p^H value obtained was found to be within standard. The loss on drying was determined to find out any increase in weight caused by moisture absorption. The value obtained was found to be within limit of standard. The total ash value is an indicative of total amount of inorganic material after complete incineration and the acid insoluble ash value obtained is an indicative of silicate impurities, which might have arisen due to improper washing of crude drugs. Both the total ash value and acid insoluble value obtained were found to be within standard limits. Increase in ash value indicates contamination, substitution and adulteration. The extractive values namely water soluble and alcohol soluble indicates the amount of active constituents in a given amount of plant material when extracted with respective solvent, a lower value compared to standard value indicates presence of exhausted material. In the present study both the extractive values were found to be more than the standard values. The determination

of crude fiber content is an indicative of fiber content in formulation and was found to comply with standard value.

The flowability of the formulation was found to be poor in both marketed formulation and in lab formulation, by determining the bulk density, tapped density and angle of repose. Tapped density gives information on consolidation of a powder. Smaller the value of angle of repose, Hausner's ratio and Carr's index the better the flow properties. All the formulations had their different physical characteristics values but all were over the acceptable range, which could not be practically considered as per standards.

Heavy metals if present in formulation will have deteriorious effect on different organs of body in particular kidneys and leads to renal toxicity. Hence evaluation of heavy metals is an important role. Heavy metals include iron, lead, mercury, chloride and sulphate. In the present study iron, lead, chloride and sulphate was evaluated by means of limit test where the allowed maximum limit were 20 ppm respectively and were found to be within limits. The presence of mercury was determined qualitatively and found to be absent. The formulated churna was finally subjected to microbiological evaluation namely for E.coli and was found to be absent hence the formulated churna complied with the WHO requirements.

CONCLUSION

The physical parameter evaluated confirms the standard of the formulated churna. The result of present study was clearly indicate to determine quality ,purity ,integrity of swadisht virechan churna with due aid of comparative analysis of laboratory and marketed product .It is concluded that there is no uniformity in preparation of formulation which is may be due to varied geographical locations where there plants grow .physicochemical parameter such as the water soluble, alcohol soluble and moisture content, bulk density, tapped density, Carr's index, Hausner's ratio, P^H , water soluble ash, acid insoluble ash and organoleptic characteristics can be efficiently used for standardization of Polyherbal formulations. The result obtained from the study could be utilized as a reference for setting limits for the reference standard for quality control & quality assurance of these drugs.

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