



## STANDARDIZATION OF IN HOUSE PREPARED POLYHERBAL FORMULATION NIRMALAYA CHURNA

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**ABSTRACT**

Standardization of herbal formulation is essential in order to assess the quality of drugs for therapeutic value. According to an estimate of World Health Organization (W.H.O) nearly 80% of populations of developing countries rely on traditional medicines. The World Health Organization (WHO) in 1999 has given a detail protocol for the standardization of herbal drugs comprising of a single content, but very little literature is available for the standardization of poly-herbal formulation. We have developed a simple scheme for standardization and authentication of Nirmalaya Churna. The set parameters were found to be sufficient to standardize the Nirmalaya Churna and can be used as reference standards for the quality control/ quality assurance study mostly on plant drugs for their primary health care needs

**Keywords:** Herbal Formulation, Nirmalaya Churna

**INTRODUCTION**

Laxatives (purgatives, aperients) are foods, compounds or drugs taken to loosen the stool, most often taken to treat constipation. Certain stimulant, lubricant and saline laxatives are used to evacuate the colon for rectal and/or bowel examinations, and may be supplemented by enemas under certain circumstances. Sufficiently high doses of laxatives may cause diarrhea. Laxatives work to increase the movement of feces along the colon. Lubricant laxatives, such as mineral oil, taken by mouth encourage bowel movements by coating the bowel and the stool mass with a waterproof film. This keeps moisture in the stool. The stool remains soft and its passage is made easier. Stimulant laxatives, also known as contact laxatives, encourage bowel movements by acting on the intestinal wall. They increase the muscle contractions that move along the stool mass. Stimulant laxatives are a popular type of laxative for self-treatment. However, they also are more likely to cause side effects. One of the stimulant laxatives, dehydrochloric acid, may also be used for treating certain conditions of the biliary tract. Stool softeners encourage bowel movements by helping liquids mix into the stool and prevent dry, hard stool masses. This type of laxative has been said not to cause a bowel movement but instead allows the patient to have a bowel movement without straining. An Ayurvedic polyherbomineral formulation, consist of *Foeniculum vulgare*, *Terminalia chebula*, *Zingiber officinale*, *Saindhava*, *Centratherrum anthelminticum*, Silicate of alumina, Salt, Khane ka soda, Black Salt.

**MATERIALS AND METHODS****Collection & Preparation of Nirmalaya churna**

The crude drugs used in preparation of Nirmalaya churna were collected from local Market of Dehradun in March 2013. All plant parts were then dried in shade, powdered and passed through sieve no. 60 and lastly packed in a well closed container to protect them from moisture. Each ingredients 5gm weight and separately, mixed together to obtain a homogeneous blend.

**Organoleptic Characteristic:** The formulated powder was tested for organoleptic characteristic. (Table 1)

Colour- Reddish Brown, Odour- Characteristic, Taste- bitter, salty, Texture: Smooth

**Pharmacognostical Studies<sup>2</sup>**

The leaf powder was studied for their physico-chemical constant which include ash values, extractive values. (Table 2)

**Determination of Physical Characteristics:** The powdered drug was taken and was kept for determination of powder characteristics like bulk density, true density, angle of repose, hausner's ratio etc.<sup>3</sup> (Table 3)

**Determination of Moisture Content**

To estimate the loss on drying 3 gm of air dried crude drug or the prescribed quantity of the material as specified for that specific substance is accurately weighed in a dried and tared petridish.<sup>2</sup> the substance is to be dried to constant mass or for the prescribed time as specified. (Table 3)

**Determination of Florescence analysis of Powder:** One mg of powdered drugs of each formulation was exposed to ultraviolet light at wavelength of 254 nm and 365 nm and in daylight while wet after being treated with different reagents<sup>4</sup> (Table 4).

**Preliminary phytochemical test:** Preliminary phytochemical test for hexene, benzene, chloroform and alcohol extract of the drug were carried out. It shows the presence of alkaloids, flavonoids, sugars, tannins, saponins.<sup>5</sup> (Table 5)

**Powder microscopy:** The churna powder was taken and was examined microscopically to identify the various features like phloem fibres, parenchyma, starch grains, endosperms, calcium oxalate crystals, oil glands etc by using various reagents.<sup>5</sup> (Table 6)

Table 1. Organoleptic properties of Nirmalaya Churna

Parameter	Result
Color	Reddish Brown
Odour	Characteristic
Taste	Bitter, Salty
Form	Powder

Table 2. Extractive values of Nirmalaya Churna

Types of extractive value	Percentage yield
Petroleum ether	3%
Chloroform	3%
n- hexane	1%
Ethanol	4%
Water	35%

Table 3. Pre formulation studies of Nirmalaya Churna

Parameters	Value
Bulk density gm/cm <sup>3</sup>	0.649
Tapped density	0.78125
Hausner's ratio	1.20
Carr's index	16.928
Angle of repose	43.7
Loss on drying	5%

Table 4. Fluorescence Analysis of Nirmalaya Churna

Sample	Visible light	Short UV 254 nm	Long UV 365 nm
Drug	Yellowish brown	Brown	Blackish brown
Drug+ acetic acid	Yellowish brown	Brown	Dark brown
Drug+ FeCl <sub>3</sub>	Greenish brown	Greenish brown	Dark brown
Drug+ HNO <sub>3</sub>	Reddish brown	Brown	Dark brown
Drug+ bromine	Light brown	Brown	Dark brown
Drug+ iodine	Brown	Brown	Blackish brown
Drug+ H <sub>2</sub> SO <sub>4</sub>	Brown	Yellowish brown	Black
Drug+ KOH	Dark yellow	Greenish	Blackish brown
Drug+ NaOH	Orange	Greenish	Dark brown

Table 5. Phytochemical Screening of Nirmalaya Churna

Test	Method	Chloroform	Petroleum ether	Ethanol	Water
Carbohydrates	Molisch test	-	-	-	-
	Fehling test	-	-	-	-
Alkaloids	Mayer's test	+	+	+	+
	Dragendroff's test	+	+	+	+
	Hager's test	+	+	+	+
Glycosides	Brontrager's test	-	-	+	+
	Legal test	-	-	-	-
Saponin	Hemolysis test	-	-	-	-
	Foam test	-	-	-	-
Flavonoids	Shinoda Test	-	-	-	+
Tannin	Catechin test	-	-	+	+
	Match stick test	+	+	+	+
Amino acid & Proteins	Ninhydrin test	-	-	-	-
	Biuret test	-	-	-	-

Table 6. Powder microscopy of Nirmalaya Churna

Reagent Used	Observation
Phlorogucinol + HCl	Vascular bundles, fibres
Iodine solution	----
HCl	Calcium oxalate
Picric acid	----
Ruthenium red	----

**RESULT AND DISCUSSION**

In house formulation was prepared in accordance with the Ayurvedic Formulary of India. As part of standardization procedure, the finished product Nirmalaya churna was tested for relevant physical and chemical parameters. The churna is brown in colour. The powder was smooth, having Colour- Reddish Brown , Odour- Characteristic, Taste- Bitter, Salty. Quality tests for different Nirmalaya churna and its individual ingredients were performed for moisture content; ash content, water soluble extractive, methanol soluble extractive, acid insoluble ash and water insoluble ash were found to be within standard ranges. The extractive values and ash values of churna, is given in Table 2. Variations were observed in most

of the physicochemical parameters studied. The total Ash value was found 4% w/w. Acid insoluble ash value was found to be .8% w/w. On the contrary, water soluble ash percentage was found 2.2 % w/w and sulphated ash was found to be 0.2% w/w. The extractive values of formulations in water were found to be much higher than other solvent's extractive values. Loss on drying at (105°C) is also presented in Table 3. In fluorescence analysis the powder samples were exposed to ultraviolet light at wavelength of 254nm and 366nm and day light after being treated with different reagents as reported in Table 4. Fluorescence analysis results shows whether any fluorescent ingredients are present or not, here we have found there was no such material found in any

of formulation and individual ingredients either. The true and bulk density was calculated and to find the good flow angle of repose was also observed, the flow ability of the formulation was found to be poor in both market formulation and in house formulation, which was further confirmed by high values of Hausner ratio (Table 3). Presence of reducing sugars, steroids, flavanoids, saponins and tannins are prominent in various extracts (Table 5). Presence of starch grains and calcium oxalate in powder microscopic evaluation. (Table 6)

#### SUMMARY AND CONCLUSION

Ayurvedic medicine Nirmalaya churna has been standardized by intervention of scientific quality control measures in the traditional preparation describe in classical texts. Pharmacognostic characters established for the raw material could be employed as Q.C, standards for evaluating its identity and can be used for routine analysis of Purity and potency of the material and formulations following procedure given could be performed in QC/QA laboratory of pharmaceutical house. Our findings suggest that, ayurvedic polyherbal preparations extracts have great potential as laxative and can be used in the treatment of diarrhoea.

Scientific evaluation of these herbal preparations gives better information regarding the laxative efficacy of herbal medicine available in India. This study supports the use of these herbal preparations not only as the dietary supplement but also as agent to prevent or control the constipation, gases and chronic acidity case.

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