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FORMULATION AND EVALUATION OF TRADITIONAL MEDICINE BASED HERBAL LOZENGES, JELLIES AND DISPERSIBLE TABLETS

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ABSTRACT: Traditional medicine and herbal formulations have been used by mankind for the cure and treatment of various diseases and disorders. Since time immemorable natural sources have been used as medicines by the humans. As per Indian System of medicine, Ayurveda, Siddha, Unani plants are formulated in various types of dosage forms like churna, gutika, asavas, aristasavlehas, etc. Various formulations with either Ayurvedic reference or as a household remedy or as a folklore medicine are commonly used. Balguti, Sitopaladi churn, Sootshekharmatra are few such traditional formulations which have been used commonly in various households. These formulations have immunomodulatory, expectorant and antacid properties respectively. Here in our studies we have reformulated these traditional formulations into new unit dosage forms. Considering the significance of patient compliance and market competition with modern dosage forms, present study involved phytochemical analysis of extracts used and their formulation of lozenges, jellies and dispersible tablets containing herbal ingredients. It was observed that, formulations were passing quality control tests. These formulations, being herbal would be with less side effects and preferred by target population.

INTRODUCTION: Indigestion, acidity and cough are the common problems faced by the masses, accordingly, digestives, antacids and expectorants are consumed widely. In today's era of modern life style, fast food; lack of exercise and mental stress are considered as etiological factors responsible for many chronic and acute health issues to occur. In order to treat these problems, wide range of modern medicines are available, but after some time the body may develop resistance to them, making them redundant to treat these problems for long time.

Traditional system of medicine have promising solutions for these health issues. Several times, traditionally used oral formulations like formulations like Sitopladi churna, Soothshekhar churna are suggested by Ayurvedic practitioners to treat cough and problems related to acidity. In the Indian culture since time immemorable generations to generations a homemade formulations Balguti in the form of nano suspension is administered to the new born babies and young children, which acts as digestive, immunity booster and general tonic.

All these traditional formulations are composed of variety of herbs in specific ratio and formulated in specified manner. Herbs / Plants used in traditional system contain variety of secondary metabolites like alkaloids, glycosides, terpenes, tannins, flavonoids, which exhibit particular pharmacological activity pertaining to treatment of given

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disorders¹. Best examples that can be quoted are Triphala churna administered in indigestion and other gastric problems. It consists of powder of three different dried fruits namely, Amla (*Emblia officinalis*), Hirda (*Terminalia chebula*) and Beheda (*Terminalia belerica*). It has been proved that, these fruits are rich in tannins which have ability to precipitate proteins and increase the gastric motility². Adulsa syrup, containing extract of *Adhatoda vasica* leaves is used as expectorant in treatment of cough².

The traditional formulations though effective are at times non responsive too, and this can be attributed to the lack of unit dosage forms of these formulations. Considering this aspect, it is outmost rational to formulate them into unit dosage forms for better efficacy and patient compliance. Here we designed these oral formulations, containing these active metabolites with a better perception of patient compliance and ease of administration for the paediatric patients³. Now, in pursuit of the best oral formulation with natural ingredients, the present research work was aimed towards development of easy to use and palatable formulations of Sitotpladi churna, Soothshekhar churna and Balguti into dispersible tablets, jellies and lozenges⁴.

MATERIALS AND METHOD:

Preparation of Balguti Extract: Adulsa, Ashwagandha, Awala, Badam, Badishep, Bahava, Balantshopa, Bakul, Behada, Brahmi, Dikemali, Dink, Gulvel, Hirada, Honey, Jayphal, Jyesthemadh, Khajur, Murudsheng, Nagakeshar, Nagarmotha, Owa, Pimpli, Ringani, Sagargota, Sunthi, Vaccha, Vavdinga, Vekhand were procured from local market. All procured material were added in equal quantities and about 200 gm of powder was extracted with 500 ml distilled water using Soxhlet apparatus for 6 h. Then, extract is filtered and concentrated to its 40 % by volume. This crude extract was then store in refrigerator up to further use in formulation.

Formulation of Balgutisoft Lozenges:⁶ Firstly, about 100 gm of chocolate was melted in beaker on water bath to which about 10 gm of crude extract was added, stirred and mixed well. The mixture was then poured into moulds and allowed to cool at room temperature and solidify⁴.

Formulation of Balgutihard Lozenges: About 40 gm of crude extract was added to 85 gm sugar and 20 ml water. Mixture was then boiled to get syrup. Further, 15% gelatine was added to it. Then, mixture was poured into moulds and allowed to solidify at room temperature⁶.

Formulation of Sitopaladi Jelly: Sitopaladi⁵ jelly was prepared using following formula **Table 1**.

TABLE 1: INGREDIENTS OF SITOPALADI EXPECTORANT JELLY

S. no.	Sanskrit name	Regular / Botanical Name	Quantity
1	Sitopala	Sugar	16 Parts
2	Vamshalochana	<i>Bambusa bamboos</i>	8 Parts
3	Pippali	<i>Piper longum</i>	4 Parts
4	Ela	<i>Elettaria cardamom</i>	2 Parts
5	Twak	<i>Cinnamum zeylanicum</i>	1 Part
6	Turmeric	<i>Curcuma longa</i>	4 Parts
7	Pimpali	<i>Piper longum</i>	2 Parts
8	Sunthi	<i>Zingiber officinale</i>	4 Parts
9	Yesthimadhu	<i>Glycyrrhiza glabra</i>	8 Parts
10	Ringani	<i>Solanum xanthocarpum</i>	1 Part
11	Adulsa	<i>Adhatoda vasica</i>	4 Parts
12	Bakul	<i>Mimosops elengi</i>	3 Parts
13	Vaccha	<i>Acorus calamus</i>	4 Parts
14	Nagakeshar	<i>Messuaferreae</i>	4 Parts
15	Pimpalparosa	<i>Thespepsia populnae</i>	1 Part

Preparation of Jellies:⁷ Firstly, decoction was prepared by heating all accurately weighed ingredients in 1000 ml distilled water up to reduction of volume by 500 ml. Extract so obtained was then filtered. Then, 25 gm of gelatine and 37.5 ml of distilled water were heated separately on water bath and 37.5 ml of glycerine was added to it and heated.

Further, 10 gm sucrose was added. To clear solution, about 10 ml of extract was added and heating stopped. Lastly, orange oil was added as flavouring agent. Then, mixture was poured into moulds and allowed to cool at room temperature.

Formulation of Sootshekhar Churna⁸ - Dispersible Tablets: Sootshekhar churna - dispersible tablets were prepared using following formula **Table 2**.

Preparation of Sootshekhar Churna - Dispersible Tablets:⁹ The ingredients Sutshekhar, Nagakeshar, Triphala churna, Jeshtamadh, Nagarmotha, Anantmul churna were mixed and granules were prepared by wet granulation method. To it saccharin was used as sweetening agent.

Starch was used as binder while magnesium stearate and talc were used as lubricants. Further, granules were prepared and compressed into tablets by using 12.7 mm punch.

All these formulations were prepared and evaluated for specific parameters by standard quality control tests.

TABLE 2: INGREDIENTS OF SOOTSHEKHAR CHURNA – DISPERSIBLE TABLETS (FOR 20 TABLETS)

S. no.	Ingredients	Botanical name	Quantity for 20 tablets
1	Sutshekhar	Mesuaferrea	31.5 mg
2	Nagakeshar	<i>Cyperus rotundus</i>	31.5 mg
3	Triphala Churna	<i>Emblica officinalis</i> <i>Terminalia chebula</i> <i>Terminalia belerica</i>	125 mg
4	Jeshtamadh	<i>Glycyrrhiza glabra</i>	125 mg
5	Nagarmotha	<i>Hemidesmusindicus</i>	62.5 mg
6	Anantmul Churna	Herbo-metal preparation	62.5 mg
7	Starch	-	60 mg
8	Talc	-	4 mg
9	Magnesium stearate	-	4 mg
10	Magnesium stearate	-	4 mg
11	Mannitol	-	200 mg
12	Saccharin	-	4 mg

Preparation of Sootshekhar Churna – Dispersible Tablets:⁹ The ingredients Sutshekhar, Nagakeshar, Triphala churna, Jeshtamadh, Nagarmotha, Anantmul churna were mixed and granules were prepared by wet granulation method. To it Saccharin was used as sweetening agent. Starch was used as binder while magnesium stearate and talc were used as lubricants. Further, granules were prepared and compressed into tablets by using 12.7 mm punch.

All these formulations were prepared and evaluated for specific parameters by standard quality control tests.

RESULTS AND DISCUSSION:

Evaluation of Balgutisoft Lozenges: Soft lozenges were evaluated for various Quality control (QC) parameters **Fig. 1** and **Table 3**.

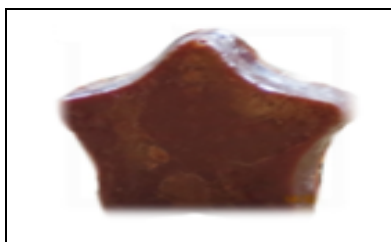


FIG. 1: SOFT LOZENGE

TABLE 3: EVALUATION OF SOFT LOZENGES

QC parameter	Result
Shape	Star
Colour	Brown
Flavour	Chocolate
Taste	Sweet
Hardness	8.58 kg/cm ²
Thickness	10.64 mm
Avg. diameter	6.41 mm
Avg. weight	7.88 g (1.2 % variation)

Evaluation of Hard Lozenges: Hard lozenges were evaluated for various quality control (QC) parameters **Fig. 2** and **Table 4**.

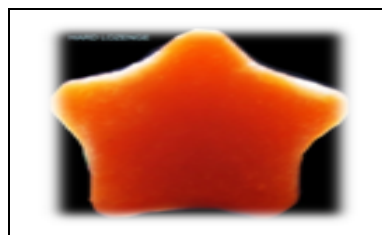


FIG. 2: HARD LOZENGE

TABLE 4: EVALUATION OF HARD LOZENGES

QC parameter	Result
Shape	Star
Colour	Orange
Flavor	Orange
Taste	Sweet
Hardness	12.58 kg/cm ²
Thickness	10.47 mm
Avg. diameter	6.39 mm
Avg. weight	7.31 g (1.6 % variation)

Evaluation of Sitopaladi Expectorant Jellies: Sitopaladi expectorant jellies were evaluated for various quality control (QC) parameters¹⁰ **Fig. 3** and **Table 5**.



FIG. 3: SITOPALADI EXPECTORANT JELLIES

TABLE 5: EVALUATION OF SITOPALADI EXPECTORANT JELLIES

QC parameter	Result
Shape	Rectangular
Colour	Light brown
Flavour	Orange
Taste	Sweet
Hardness	6.58 kg/cm ²
Thickness	11.46 mm
Avg. diameter	8.71 mm
Avg. weight	12.16 g (1.7% variation)

Evaluation of Sootshekhar Churna – Dispersible Tablets: Sootshekhar churna - dispersible tablets were evaluated for various quality control (QC) 11 parameters **Fig. 4** and **Table 6**.



FIG. 4: SOOTSHEKHAR CHURNA – DISPERSIBLE TABLETS

TABLE 6: EVALUATION OF SOOTSHEKHAR CHURNA - DISPERSIBLE TABLETS

QC parameter	Result
Shape	Round
Colour	Brown
Hardness	3.8 kg/cm ²
Thickness	4.47 mm
Avg. diameter	12.5 mm
Avg. weight	649.34 g (0.9 % variation)
Disintegration time	2.10 min
% Friability	0.36 ± 0.21

Here in our research, traditional formulations were successfully formulated into modern dosage forms and were found to be advantageous over the traditional forms, with ease of administration for paediatrics and geriatrics and improved patient compliance. Phytochemical screening of mixture of all plant material showed presence of various secondary metabolites having pharmacological actions¹² on various anatomical and physiological systems of human body and proved to be used in treatment of various diseases. Moreover, the developed dosage will have a fixed amount of content so minimizing the risk of administration of under dosage or over dosage of the formulation which will result in desired pattern of therapeutic action.

These formulations were palatable for children as they love jellies, and measured dose is also administered. It's difficult to administer churns and jams in fixed measured doses, this problem has been overcome, as these formulations provide measured doses. Being an Ayurvedic formulation there is less chance of side effects and is safe. They can be formulated in various shapes and size, so they look attractive and elegant. They can be formulated using various flavours, so are palatable.

As children do not like the tastes of syrups, so they refuse to administer. So these formulations were formulated as it makes it palatable, hence children consume easily. Children like toffees, candies and sweets. So this preparation would be most accepted by them.

CONCLUSION: These studies can be considered as reverse F & D of traditional formulations, converting age old bulk formulations into new unit dosage forms. All the three formulations viz; Balguti, Sitopaladi churna and Sootshekhar were redesigned and formulated into lozenges, jellies and dispersible tablets. Further work on the analysis and release pattern of drugs is underway, which will further substantiate the claims.

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CONFLICT OF INTEREST: There are no conflicts of interest.

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