Development of Standard Operative Procedure (SOP) of a Toothpaste Prepared with the Ingredients of Sunun Poste Mughilan

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Abstract

The present study was designed to convert a classical Unani pharmacopoeial preparation 'Sunun Poste Mughilan' (a tooth powder) into toothpaste form with the same ingredients as contained in powder form. This work was undertaken with the objective of developing the Standard Operating Procedure (SOP) for manufacturing process of toothpaste. The legitimacy of SOP was determined by assessing the quality of product in three different batches. Each batch was assessed three times for spreadability, foam formation and dispersion time in water. The group which was in range with standard limits was selected as standard batch. The procedures adopted for the preparation of standard batch was taken as the SOP.

Keywords: SOP, Sunun, Toothpaste, Spreadability, Tooth powder.

Introduction

In Unani system of medicine, toothpowders are commonly known as Sunun which contain finely powdered drugs. Toothpowders are prepared both with herbal and mineral drugs but more often by combining the two. These powders usually contain more than one ingredient. Apart from the maintenance of oro-dental hygiene toothpowders are also described in Unani medicine to be used in various pathological conditions of tooth, gum, throat and buccal cavity. Although toothpowders are in use since ancient periods but due to rapid changes in modern cult, use of toothpowder is declining day by day even in rural population. Further toothpastes also have definite advantages over toothpowders which also pave the way for its wider acceptability. Toothpowders bear less spreadibility than toothpaste and usually contain coarse particles, hence chances of abrasions, friction to enamel, dentin and soft tissue ablations are much high, leading to various periodontal diseases like dental caries, hypersensitivity of teeth, pyorrhoea, toothache, bleeding gums, gingivitis and recession of gums etc. Secondly, it is very difficult to protect powders usually containing hygroscopic, deliquescent (tending to melt or dissolve in humid environment) and aromatic materials from decomposition. Thirdly, the toothpaste has largest share of dental cleansing and care preparations. Further, chances of least wastage at use, attractive consistency, and easy distribution in mouth, and over all convenient and soft use further add to their acceptability.

In recent years acceptability and demand for natural products has increased many fold mainly because of the safety concern which is almost unavoidable with most

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of the products prepared with synthetic raw materials. In Unani system of medicine a number of formulations intended to be used to maintain the oral health and hygiene and to ameliorate various diseases of tooth, gum, mucus membrane and throat etc are available but most of them are available in powder form such as Sunun, Zaroor, Qula and Mazmaza etc. The age-old Pharmacopoeial formulation Sunun Poste Mughilan (SPM) is used to strengthen the dental roots and impart the sparkle to the teeth (Said, 1997; Kabiruddin, ynm) and used commonly by the patients and healthy person alike. However, the change of its form is desired in view of the advantage of paste over powder and also the convenience of use of paste form. Therefore an attempt has been made to convert SPM into toothpaste. The Standardization of its procedure and product has also been undertaken to set the standard of a genuine sample and establish the SOP. Three variables i.e. spreadibility, foaming power and dispersion time were taken as the attributes for its standardization and quality determination. During the conversion of SPM into the toothpaste, different batches (F-1, F-2, and F-3) were prepared and assessed on three variables as mentioned above.

Materials and Methods

Procurement of Raw drugs

All the ingredients of SPM were procured from the raw drug dealer, except the bark of *Acacia arabica* which was collected from the campus of National Institute of Unani Medicine (NIUM), Bangalore. Dr. R. Sumathi, Botanist at RMR, FRLHT-IAM, Bangalore authenticated the plant drugs. The voucher specimens (*Areca catechu*-2741, *Acacia catechu*-2742, *Zingiber officinalis*-2743, *Piper nigrum*-2744, *Acacia arabica*-2745) have been deposited in the museum of the Institute of Ayurveda and Integrative Medicine, Bangalore. Other constituents needed to prepare the toothpaste were procured from the Srinivasa Products, 5th Block, Rajaji Nagar, Bangalore.

Preparation of extracts

The crude drugs (Table 1) were dried in oven at 35^{0}C and coarse powder was prepared after grinding each drug separately. Then each powder was extracted separately by continuous hot extraction (Soxhlet extractor) with double distilled water at 100^{0}C. The extracts were dried on water bath.

All the ingredients of SPM were used in the ratio of 4:1:1:1:0.1:0.1 as mentioned in Hamdard Pharmacopoeia (Table 2). Toothpaste was prepared by taking extract of all the plant drugs while the mineral drug (Silicate of magnesia) was taken as such and mixed with the extracts. Ten percent of total amount of extract of all the

Table 1 : Ingredients of Sunun Poste Mughilan

	Unani Name	Scientific Name	Part Used	
1	Post Kikar	*Acacia arabica*	Bark	400gms
2	Burnt Supari	*Areca catechu*	Nut	100gms
3	Sange Jarahat	Silicate of magnesia	Stone	100gms
4	Kath Safaid	*Acacia catechu*	Extract	100gms
5	Zanjabeel	*Zingiber officinalis*	Dried Rhizome	10gms
6	Filfil Siyah	*Piper nigrum*	Seed	10gms

Table 2 : Composition of extracts of Toothpaste

Sl.No.	Ingredients	Gm
1	*Acacia Arabica*	5.56
2	*Areca catechu*	1.39
3	Silicate of magnesia	1.39
4	*Acacia catechu*	1.39
5	*Zingiber officinalis*	0.14
6	*Piper nigrum*	0.14
	Total	10

plant drugs and Sange Jarahat was taken for the formulation of toothpaste. Other ingredients required to give the form of paste were also used (Table 3).

Preparation of Toothpaste

Heated Liquid-Phase Process

Ten gm of extract of all plant drugs and Sange Jarahat was weighed first in the ratio of 4:1:1:1:0.1:0.1. All the ingredients were mixed with Sorbitol, Water and Saccharin sodium dehydrate in container No. 1. The solution was then heated with continuous stirring for 15 minutes at 40 ^{0}C.

In another container (No. 2), Calcium Carbonate, Carboxy Methyl Cellulose and Preservatives (Methyl Paraben and Propyl Paraben) were taken and mixed properly. A hot solution of humectants, water, extracts and sweetener which was prepared after proper heating and stirring was then, slowly added with mixing to the powder which was prepared in No. 2 container. The resulting mass was mixed

Table 3 : Composition of Toothpaste

Sl. No.	Ingredients	Formulations			Property
		Qty. Used (%) (% w/w)			
		F1	F2	F3	
1.	Extracts	10	10	10	Active Ingredient
2.	Calcium carbonate	35	45	25	Abrasive
3.	Sodium lauryl sulphate	1.5	2.5	1.5	Surfactant
4.	Sorbitol	30	20	20	Humectant
5.	Sodium Carboxy Methyl Cellulose (CMC)	1	1	1	Binding agent
6.	Sodium saccharine	0.3	0.3	0.3	Sweetener
7.	Methyl paraben	0.1	0.1	0.1	Preservative
8.	Propyl paraben	0.02	0.02	0.02	Preservative
9.	Titanium dioxide	0.5	0.5	0.5	Opacifier
10.	Peppermint oil	1	1	1	Flavouring agent
11.	DD Water	20.58	19.75	40.58	

well to get thick paste. Finally the Sodium Lauryl Sulphate, peppermint oil, Titanium dioxide were added and mixed properly.

Determination of spreadibility, foaming and dispersion time

Three different batches of toothpaste were prepared with different percentage of ingredients. Each batch was assessed three times for spreadability, foam formation, and dispersion time in water.

Determination of Spreadibility

One gm of paste was placed at the centre of the glass plate (10X10 cm) and another glass plate was placed over it carefully. Above the glass plates 2 kilogram weight was placed at the centre of the plate. Sliding of the plate was avoided. The area (cm) of spread of paste was measured. The experiment was repeated three times and the average was recorded (Akelesh *et al.*, 2010; Pael and Kamani, 2009).

Determination of Foaming Power

Five gram of paste was placed in a 100 ml glass beaker. To this 10 ml of water was added and the beaker was covered with a watch glass and allowed to stand

for 30 minutes, this operation was carried out to disperse the toothpaste in water. The contents of the beaker were stirred with a glass rod and the slurry was transferred to a 250 ml graduated measuring cylinder. During this transfer it was ensured that no foam was produced and no lump paste went into the measuring cylinder. The residue left in the beaker was transferred with further portion of 5-6 ml of water to the cylinder. The content of cylinder was adjusted to 50 ml by adding sufficient water and the content was maintained at 30°C. The contents of the cylinder were stirred with a glass rod to ensure a uniform suspension. Stirring was stopped when the temperature of the content reached to 30 ^{0}C and then 12 complete shakes were given by hand. The cylinder was then allowed to stand for 5 minutes and the volume of foam with water and the volume of water only was noted.

Foaming power was determined by the following formula (Akelesh *et al*., 2010):

Foaming power = V1 – V2

V1 - Volume in ml of foam with water

V2 - Volume in ml of water only

Determination of Dispersion Time in Water

The USP tablet disintegration test unit was used. 150 ml of distilled water at 37^{0}C+1 was placed in the cylinders of the apparatus. One gram of the toothpaste was placed, cautiously, onto the gauze of the basket. The movement of the basket was maintained at the normal speed of the apparatus and the temperature was kept at 37^{0}C+1. The time elapsed till no paste was present on the gauze was determined and was taken as a measure of dispensability of the paste in water. A time ranging from 10-30 minutes is considered satisfactory (Pander, 1993).

Results

The quality of the toothpaste was determined by assessing each batch three times for spreadability, foam formation and dispersion time in water and the mean was regarded as standard parameter value with an aim that if the paste will qualify the criteria of quality then it will be assumed that the procedure adopted to prepare the paste is also standard. The results of all batches are given in Table 4 and Fig. 1. The batch F3 with abrasive and humectant shows spreadability, foam formation and dispersion time in water as 7.47 ± 0.09 cm, 122.33 ± 1.20 ml and 26 ± 0.58 min, respectively. Most appropriate result among three batches was found in this group. The values of all the above parameters were compared with the standard values given by Bureau of Indian Standards and with other published work (Table 5) (Fig 2). The findings on comparison were found to be within the normal range.

Table 4 : Results of Formulations Batches

Sl. No.	Formulations	Spreadability (cm)	Foam formation (ml)	Dispersion time (min)
1	F1	6.00 ± 0.12	97 ± 1.2	45 ± 0.63
2	F2	4.2 ± 0.12	11 ± 0.58	55.89 ± 0.35
3	F3	7.47 ± 0.09	122.33 ± 1.20	26 ± 0.58

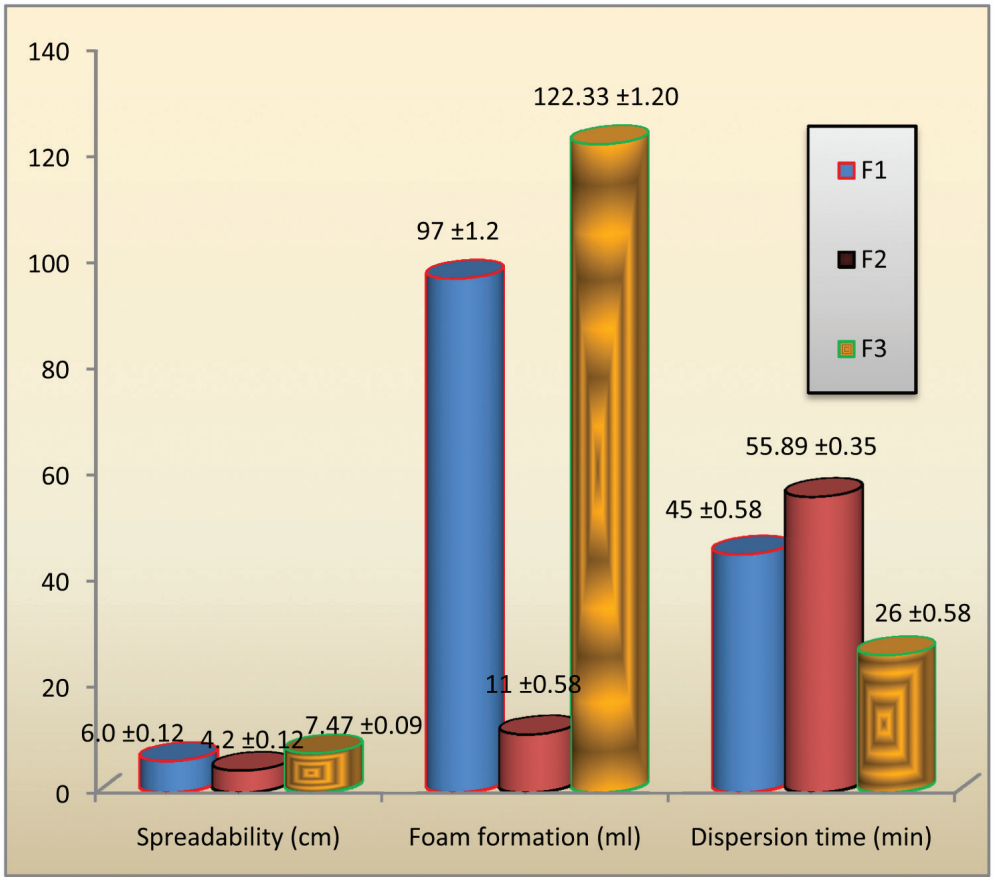

Fig. 1

Table 5: Comparison of F3 with the optimum values mentioned in Bureau of Indian Standard

Values	Spreadability (cm)	Foam Formation (ml)	Dispersion time in water
Toothpaste value	7.47	122	26
Standard value	(Max.) 8.5	Min 50	10-30 min

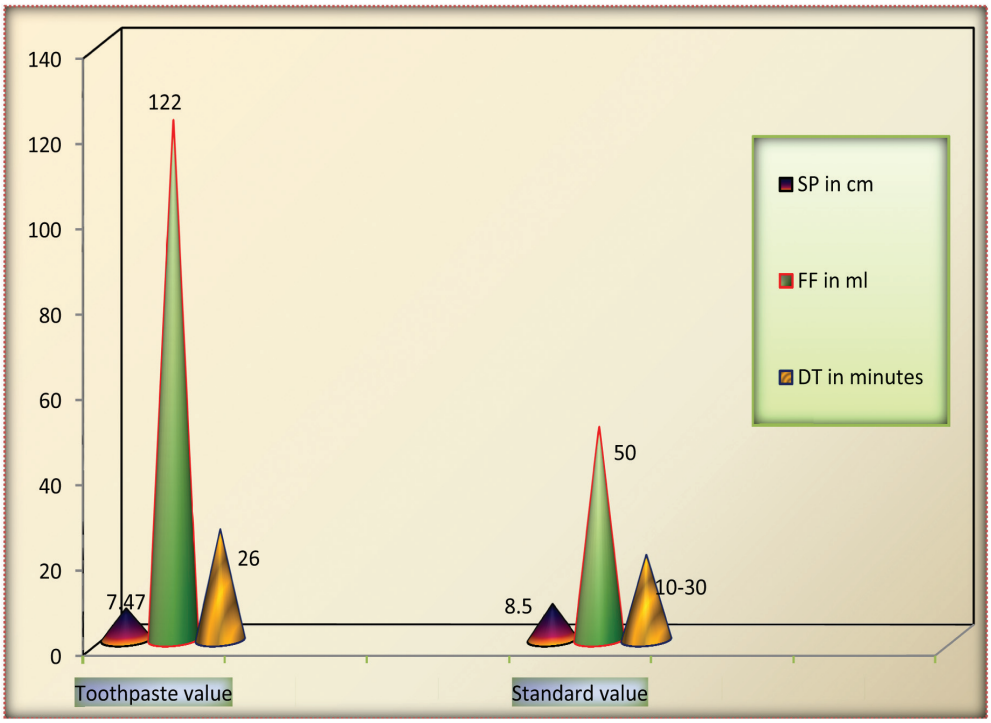

Fig. 2

Discussion

An important Unani powdery dentifrice SPM was successfully converted into paste form using the standard procedures and approved excipents while retaining the ingredients of the formulation. The quality standards of the newly converted formulation were tested on some important variables and it was found that the formulation qualify the criteria necessary to establish its standard and thereby the genuineness. The study demonstrated that the paste attained almost same standard as that mentioned in Bureau of Indian Standard suggesting that the procedure adopted to prepare the paste was also genuine and standard and may be taken as the standard operating procedure.

One of the criteria for paste to meet quality standard is that it should possess good spreadability. The spreadability is used to denote the extent of area to which a paste readily spreads on application to the skin or affected part, as the therapeutic efficacy of a formulation also depends upon its spreading ability (Patel, 2012). Spreadability is imperative characteristic of toothpaste and shows the consistency of paste. The toothpastes are homogenous in nature and it should not separate into liquid and solid ingredients. The large spread area as seen in case of the paste of SPM demonstrated that it possesses good consistency (Das *et al.*, 2013). Thickness or the consistency felt in the mouth upon using the toothpaste is important because it is directly related to the usage of the dentifrice. If toothpaste

is too thick, it may be difficult to spread around the teeth and it may not be used properly. If toothpaste is too thin, it may not be too effective in cleaning. Additionally, an adequate amount of thickness in paste is required to keep the abrasives properly dispersed throughout the toothpaste (Mason Stephen, 2000). This depends heavily on the amounts of gelling agents in the toothpaste, as well as on the fraction of the toothpaste which is solid. Hence, determination of spreadability is very important in evaluating paste characteristics. The mean value of spreadability of toothpaste was found to be 7.47 ± 0.09 cm which is almost equal to that of the standard value of 8.5.

A controlled level of the foam in toothpaste is necessary for suspending and removing the debris, rinsing the mouth and giving an intense perception of cleaning action. This is due to the surface tension reducing properties of detergents (Nanda *et al.*, 2009). The quality of the foam, i.e. volume and stability or lifetime, depends upon many factors such as, the amounts and properties of humectants, polymers, and abrasives used (Pader Morton, 1997). The foam volume depends mainly on the amount of surfactant. The ratio of amount of surfactant and foam volume can be best fit line for experimental data. The foaming character was studied for nature, stability and washability of toothpaste (Mithal and Saha, 2010). The mean value of foaming power of toothpaste was found to be 122.33 ± 1.20 ml which is significantly higher than the minimum required value of 50.

Dispersion time is used to measure dispersion power of toothpaste in water. A time ranging from 10-30 minutes is considered satisfactory. The mean value of dispersion time in water was found to be 26 ± 0.58 min which was found to be within the normal range of 10-30. Thus the all three parameters the paste form of the preparation was tested for were found to be commensurate with the standard values.

Conclusion

The study demonstrated that the conversion of 'Sunun Poste Mughilon' (SPM) into paste form was successful as the finished product was found to qualify all the criteria laid down for toothpastes of standard quality. It was concluded therefore that the procedure used to prepare the toothpaste is also standard and it may be used as the SOP for preparation of other herbal and herbo-mineral toothpastes.

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