Original Article

Development and Evaluation of Talisapatradi and Vyoshadi Choorna Lozenges: An Ayurvedic Traditional Formulation

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Abstract

In Ayurveda, *Talisapatradi choorna* (TPC) and *Vyoshadi choorna* (VSC) are commonly used medicines for cough, cold, asthma, and rhinitis. These symptoms are due to upper respiratory infections of predominantly of viral origin. Currently, there are no effective medicines except indiscriminate uses of antibiotics, local anesthetics, and pain killers. The conventional formulation of TPC and VSC is difficult to administer so an easy manufacturing lozenge formulation was developed. The phytochemical analysis was done by preliminary thin layer chromatography (TLC) derivatization studies. High-performance thin layer chromatography (HPTLC) analysis confirmed the presence of herbal actives in the lozenge formulations. The TLC analysis results showed that TPC and VSC contain phytochemicals of flavonoids, steroids and phytosterols, and alkaloids family. The herbal actives were found to be stable in the final formulation without any interference with the excipients used in the formulation. The lozenges formulated from TPC and VSC are found to be promising alternatives to traditional form for the traditional Ayurvedic preparation. Compatibility study was done using Fourier transform infrared spectroscopy and HPTLC study.

Keywords: *Characterization, formulation development, heavy metals, HPTLC analysis, lozenges, physicochemical analysis, Talisapatradi choorna, Vyoshadi choorna*

Introduction

Since thousands of years, Ayurveda medicines have been widely used for the treatment and wellness of human beings in India. As per World Health Organization (WHO), Ayurveda, an Indian system of medicine, has been recognized in the family of complementary and alternative medicines. In the last decades, application of Ayurvedic medicines has been increased as an alternative to modern medicines.[1] There are several dosage forms mentioned for oral administration of herbal medicines such as decoction (*kwaatha or kashyam*), fermented alcoholic fermentation (*asava and arishta*), medicated lipid formulation (*tailam and ghritam*), semisolid (*avaleha*), pills (*ghana vati*), and powder (*choorna*).[2] Among the oral dosage forms, *choorna* preparations are one of highly effective and commonly used formulations. They are prepared from either a single drug or a polyherbal combination.[3] Among Ayurvedic choorna preparations, *Talisapatradi choorna* (TPC) and *Vyoshadi choorna* (VSC) are popular medicines prepared from a combination of multiple herbs. The TPC and VSC are commonly used medicines for the treatment of various respiratory-related indications such as Ruchya (taste improvement), Deepana (digestion stimulant), kasa (cough), swasa (breathing problem), pliha (spleen disease), Parswa soola (pain), and Svasa (dyspnea).[4-7] TPC consists of six ingredients, viz., Talisapatra (*Abies webbiana* leaf), Maricha (*Piper longum* fruit), Sunthi (*Zingiber officinale* rhizome), Pippali (*P. longum* fruit), Dalchini (*Cinnamomum zeylanicum* steam bark), Ela (*Elettaria cardamomum* fruit), and crystallized sugar.[4] VSC is prepared from seven herbs, viz., Sunthi (*Z. officinale* rhizome), Maricha (*P. longum* fruit), Pippali (*P. nigrum* fruit), Tallesa (*A. webbiana* leaf), Chavika (*P. retrofractum* root), Amiavetasa (*Plumbago zeylanica* root.), Ajaji (*Cuminum cyminum* fruit), and jaggery powder.[7] Despite being very popular medicine, use of TPC and VSC is challenging for patients due to their highly pungent taste. In the present study, the TPC and VSC were converted into hard-boiled lozenges (HBL) formulation for better shelf life, easier dispense, dose fixation, and to increase the acceptance by patients. Lozenges are defined as solid form of single dose designed to be dissolved or disintegrated slowly in the buccal cavity when sucked. They are either prepared from sugar-like sucrose and dextrose or from sugar-free ingredients

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such as isomalt, sorbitol, and mannitol.[8] The HBL can be an alternative and consumer-appealing route of administration when compared with traditional choornam format. Patients having difficulty in swallowing can have easy access to the medicine by slowly sucking the lozenges. Moreover, slow sucking provides a better targeted and extended drug delivery which would be more suitable in the management of sore throat and cough. The formulated HBL was evaluated for physical and physicochemical parameters. Compatibility of the formulation was carried out with Fourier transform infrared spectroscopy (FTIR) study and high-performance thin layer chromatography (HPTLC) analysis to ensure phytochemical consistency.

Materials and Methods

Materials

The crude herbal raw materials used in the formulation were purchased from local vendors and cleaned to remove the extraneous and foreign matter, dried in shade, and packed in an airtight container. All the reagents like solvents used were of analytical grade procured from Rankem and Qualigens. The reagents like anisaldehyde sulfuric acid, bismuth subnitrate, potassium iodide, aluminum chloride, vanillin, and ferric chloride were purchased from Loba Chemie, Rankem, Fine-Chem, Spectrum Chemicals, etc. The liquid glucose used in the lozenges formulation was from Roquette, and Isomalt was from Beneo GmbH (Germany).

Preparation of *Talisapatradi choorna* and *Vyoshadi choorna*

The choorna was prepared as per the procedure mentioned in the Ayurvedic Formulary of India. All the herbal ingredients are cleaned and dried properly. They are powdered separately by disintegrators and sieved through a 80-mesh sieve to make a fine powder. Each of the powder weighed and mixed in the specified portion to make the final choorna.[9,10]

Preliminary analysis of the choornam

Preliminary quality analysis of choorna was carried out for different parameters including water extractive value, alcohol extractive value, ash value, water-soluble ash, loss on drying, and pH (2% solution). The choorna was analyzed by employing various physicochemical parameters such as loss on drying at 110°C, ash value, acid-insoluble ash, pH value, water-soluble extractive value, alcohol-soluble extractive value, and qualitative analysis for various phytochemical groups. For determination of water-soluble extractive value and alcohol-soluble extractive value, 4 g of sample was macerated with water and alcohol separately for 24 h in a closed conical flask. The extracted solution is filtered and 25 mL of each of filtrate is dried on a porcelain dish and on a water bath. The resulting residue is weighed, and percentage of extractive values is determined with respect to the filtrate taken. For determination of the total ash value, 2 g of powder sample was taken in a pre-weighed silica crucible and incinerated at 450ºC in a muffle furnace till it turned into white ash. Then the crucible is kept inside a desiccator to avoid moisture exposure till cooling. Percentage of total ash value was determined on the basis of the sample taken. For determination of acid-insoluble ash content, 25 mL of dilute hydrochloric acid is added to the above-obtained ash. It was boiled for 5 min and filtered through the ash-less filter paper and eluted with the hot water. The residue obtained on ash-less filter paper was transferred to the crucible and dried on the hot plate to constant weight. The content of acid-insoluble ash value was calculated.[11,12]

Thin layer chromatography (TLC) analysis of TPC and VSC

The TLC analysis was carried out for TPC and VSC for preliminary identification of major class of compounds. Aluminum precoated silica gel $60F_{254}$ was used for TLC analysis. One gram of choorna was extracted with 10 mL of methanol under reflux for 4 h and the filtrate was adjusted up to 10 mL. The methanolic extracts of both the choorna were used for TLC analysis. Various combinations of solvent was tried for mobile phase and finally toluene–ethyl acetate–formic acid (8:2:0.5; v/v/v) was used for TLC analysis which provided better resolution of the spots on the TLC plate. After development, the plates were visualized in 254 and 366 nm and derivatized with vanillin sulfuric acid, anisaldehyde sulfuric acid, Lieberman–Burchard reagent and heated at 105°C till colored spots developed. The plates were derivatized with Dragendorff reagent and visualized in white light.[13,14]

Preparation of lozenges from TPC and VSC

The lozenges of VS and TPC were formulated [Table 1] using the conventional candy molding process consisting of heating

Table 1: Formulation details of TPC and VSC lozenges

Ingredient	Quantity (%w/w) VSC-SB	Quantity (%w/w) VSC-SF	Quantity (%w/w) TPC-SB	Quantity (%w/w) TPC-SF
Choorna	20.00	20.00	20.00	20.00
Sugar	47.00	—	47.00	—
Liquid glucose	32.00	—	32.00	—
Isomalt	—	79.00	—	79.00
Water	8	20	8	20
Citric acid	0.1	0.1	0.1	0.1
Acacia gum	1.00	1.00	1.00	1.00

TPC-SB = *Talisapatradi Choorna* Sugar-based Lozenges Formulation, TPC-SF = *Talisapatradi Choorna* Sugar-free Lozenges Formulation, VSC-SB = *Vyoshadi Choorna* Sugar-based Lozenges Formulation, VSC-SF = *Vyoshadi Choorna* Sugar-free Lozenges Formulation

and congealing methods.[15] The concentration of sugar and liquid glucose was optimized after trial with their varying compositions, which makes lozenges having ideal hardness and appearance. The various compositions of sugar and liquid glucose used in the preparations of lozenge formulations were 50:29, 29:50, 40:39, and 47:32. The manufacturing procedure involves preparation of syrup from sugar and liquid glucose under gentle heating at the temperature range of 140–150°C till it reaches a glassy consistency and maximum water is removed. Then the temperature is reduced to 90–100°C; during this stage, glycerin is added to provide fluid nature and then the choornam was added and mixed thoroughly to form a homogeneous mixture. Then this molten syrup is molded to required shapes. Each of lozenge formulation contains about 80% of the lozenges base such as sugar, liquid glucose, and isomalt. The *Vyoshadi Choorna* Sugar-based Lozenges Formulation (VSC-SB) and *Vyoshadi Choorna* Sugar-free Lozenges Formulation (VSC-SF) lozenges contain 200 mg of the choornam, i.e., 28.57 mg of each of the herbal actives per 1 g of lozenges formulation. The *Talisapatradi Choorna* Sugar-based Lozenges Formulation (TPC-SB) and *Talisapatradi Choorna* Sugar-free Lozenges Formulation (TPC-SF) contain 200 mg of choornam prepared from Tailesapatra (*A. webbiana* leaf)-18.21 mg, *Maricha* (*P. nigrum* fruit)-36.35 mg, *Sunthi* (*Z. officinale* rhizome)-54.57 mg, *Pippali* (*P. longum* fruit)-72.71 mg, *Dalchini* (*C. zeylanicum* steam bark.)-9.06 mg, and *Ela* (*E. cardamomum*, fruit)-9.06 mg. The prepared lozenges were then packed in a met-pet wrapper. Two lozenges were prepared from TPC and VSC separately using the above procedure. Preparation of isomalt-based lozenges was similar to that of sugar-based lozenges using isomalt in place of sucrose and liquid glucose.

Physicochemical evaluation of TPC and VSC lozenges

The prepared formulation of lozenges was evaluated for its quality parameters such as physical appearance, hardness, weight variation, friability, thickness, and mouth-dissolving time as per methods from Indian pharmacopoeia.[16,17] Hardness of the lozenges was tested using a Monsanto hardness tester to determine the mechanical strength or crushing strength. It is the force required to break the lozenges by compression. Friability of the lozenges was determined in a Roche friabilator. Twenty lozenges were weighed and placed in a friabilator and operated at 100 rpm. The lozenges were dusted and reweighed. The percentage of weight loss was determined as friability, should not be more than 1% of their weight. Vernier caliper was used (Aerospace digital vernier caliper 0–150 mm) to measure diameter and thickness of the lozenges. Twenty lozenges of each of the formulation were weighed individually using an electronic balance and their average weight was determined. For determining the mouth-dissolving time, the USP disintegration apparatus was used without using the plastic disc. The test was carried out by using tablet disintegration apparatus (Model ED-2L; Electrolab, Mumbai, India). Phosphate buffer (pH 6.8) was used as the disintegration medium with temperature maintained at 37 ± 2°C. The time when the lozenges were completely dissolved in the medium was noted.

Standardization of lozenges

For quality control purposes, the standardization of lozenges was done by quantification of total flavonoids concentration. Total flavonoids were determined by a slightly modified method as described by Sani *et al.* with extraction of the lozenges with ethyl alcohol.[18] Two grams of each of the lozenges was powdered and extracted with 10 mL of ethyl alcohol by sonicating for 30 min. The alcohol-soluble extract was dried over a water bath, and the residue was calculated as the total flavonoid value.

Compatibility study

The interaction study between the herbal drugs and the excipients used in the lozenges formulation was studied using HPTLC and attenuated total reflection-FTIR.

High-performance thin layer chromatography analysis

The HPTLC analysis was carried out for the verification of herbal drugs in the lozenge formulations to enable quality control. About 1 g of each of the raw materials of the TPC and VSC was extracted with 10 mL methanol under sonication. For HPTLC analysis, 2 g of each of the lozenges of TPC and VSC was powdered and extracted with 10 mL of methanol. An aliquot of 8 µL of each of the samples was applied in bands on aluminum-precoated silica gel GF_{254} HPTLC plates (Merck, Germany) by a Linomat V Applicator. The plates were developed in a CAMAG twin trough glass tank pre-saturated with mobile phase consisting of combination of toluene–ethyl acetate–formic acid (8:2:0.5 mL). The solvent system was optimized after trial with several solvent systems of varying compositions. Following the development, the plates were dried using a hair dryer at a mild rate and observed under a CAMAG UV-cabinet. The plates were then derivatized with anisaldehyde sulfuric acid and visualized under white light after heating at 105°C till colored zones are developed.

Fourier transform infrared spectroscopy

The physical and chemical interaction between the herbal actives-excipients used in the formulation was studied using FTIR spectroscopy. The infrared spectrum of the herbal choorna and the lozenges formulation was recorded by using an FTIR spectrophotometer. Scanning was done in the range of 400–4000 cm^{-1}.

Heavy metal analysis

Heavy metal analysis was done according to the method mentioned in AOAC using ICP-MS for both lozenges formulation.[19] The standards of the heavy metals Pb, Cd, Hg, and As used as reference analytes for quantitative analysis of heavy metals were procured from Merck, Germany. The analytical measurement of heavy metals in the digested samples was carried out using the instrument PerkinElmer NexIon 2000 ICP-MS. For assessment of heavy metals, 1 g of each of lozenges sample was digested with ultrapure nitric acid in a microwave digester (PerkinElmer-Titan MDS). The sample was aspirated into ICP-MS. The operating condition of the ICP-MS is provided in Table 2.

Table 2: Operating condition of the ICP-MS

S. no.	Standard	Helium KED	Helium KED Custom	Ammonia DRC	Helium KED unlink	Description	Step value	Setting time (s)	Minimum value
1.	1.04	1.04	1.04	1	1.04	Nebulizer gas flow (NEB)	0.02	10	0
2.	0	0	0	0	0	AMS gas flow	0.005	10	0
3.	1.2	1.2	1.2	1.2	1.2	Auxiliary gas flow	0.025	10	0.6
4.	15	15	15	15	16	Plasma gas flow	0.5	10	10
5.	1600	1600	1600	1600	1600	ICP RF power	50	15	400

Results and Discussion

Preliminary analysis of the choorna

Both TPC and VSC lozenges [Figure 1] showed more water-soluble extractive values when compared with that of alcohol-soluble extractive values, indicating better solubility of choorna components in saliva fluid. The physicochemical parameters of both the choorna are mentioned in Table 3. Qualitative phytochemical analysis on the basis of TLC reveals the presence of various phytochemicals such as alkaloids, sterols, and terpenoids in the choorna. TPC and VSC choorna showed colored zones with anisaldehyde sulfuric acid indicating presence of terpenoids. Pungent and bitter principles showed positive reaction with VS indicating the presence of terpenoids and lignans; triterpenes and steroids were confirmed on the basis of color zone with LB reagent. Both the choorna reveals orange color with Dragendorff reagent indicating the presence of alkaloids.

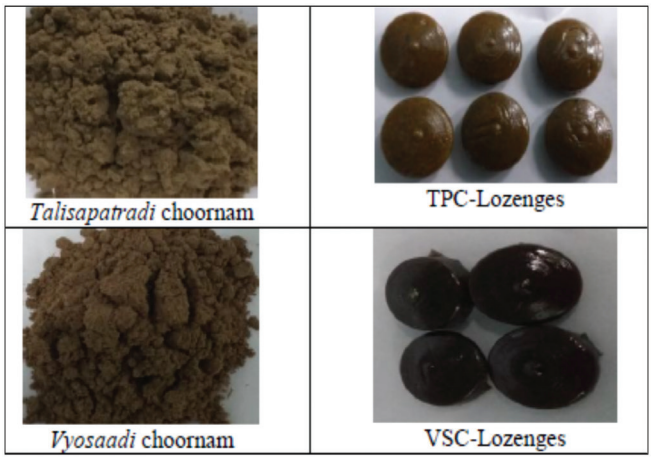

Figure 1: Photo presenting the picture of TPC and VSC choorna and lozenges

Standardization of lozenges

The total flavonoids TPC lozenge was found to be 7.76%, whereas VSC lozenge was found to be 14.2% on the basis of ethyl alcohol extractive value. These values can be used for the standardization of the lozenges formulation.

Thin layer chromatography analysis of TPC and VSC

Preliminary phytochemical screening of the TPC and VSC indicated the presence of various secondary metabolites [Figure 2] such as alkaloids, steroids, triterpenoids, and lignans.

Evaluation of quality parameters of lozenges

Out of the various lozenges formulations, sugar and liquid glucose in the ratio of 47:32 were found to be having ideal texture, glassy appearance, shape and hardness properties, whereas other lozenges formulations crystallize and have hygroscopic, sticky, and soft texture. The optimized lozenges of TPC and VSC showed satisfactory results [Table 4] with hardness, friability, weight variation, and mouth-dissolving time. The calculated average weight of the lozenges was equal to 2.26 and 2.44 g for isomalt-based lozenges and sugar-based lozenges, respectively. The formulated lozenges had an average hardness of 16 and 17 kg/cm^2 for both lozenges that ensure their satisfactory strength. The friability calculated for the lozenges was 0.78 and 0.69, which is in accordance with the maximum limit of 1% as per the Indian Pharmacopoeia standards.[16] The mouth-dissolving time was 6 and 9 min for isomalt-based lozenges and sugar-based lozenges, respectively. The isomalt lozenges were found to dissolve faster when compared with sugar-based lozenges. The rapid dissolving time of the lozenge is due to the polar nature and good aqueous solubility of the excipients used in the formulation.

Compatibility study

FTIR study

The FTIR spectra of the TPC, VSC, and their lozenges formulations are mentioned in Figure 3. The FTIR peaks (cm^{-1}) and the corresponding functional groups are mentioned below.

TPC

3301.91 (-OH groups), 2935.46 (-CH_2), 2861.20 (C = C), 1738.71 (C=O), 1650.95 (C=O), 1449.41 (aromatic stretching), 1365.51 (C-C), 1232.46, 1162.03 (C-C), 1043.42 (C-O).

TPC-SB

3332.76 (-OH groups), 2936.42 (-CH_2), 2889.17 (C = C), 1734.85 (C = O), 1651.92 (C = O), 1456.16 (aromatic stretching), 1363.58 (C-C), 1230.50 (C-O), 1159.14 (C-C), 1053.36 (C-O).

TPC-SF

3380.02 (-OH groups), 2932.56 (-CH_2), 1649.02 (C = O), 1456.16 (aromatic rings), 1155.28 (C-C), 1079.10 (C-O), 1023.17 (C-O).

Table 3: Physicochemical parameters of TPC and VSC

S. no.	Parameters	Vyoshadi choorna	Talisapatradi choorna
1	Description	Dark brown-colored powder characteristic aromatic odor and flavor	Yellowish white powder with characteristic aromatic odor and flavor
2	Water-soluble extractive value (%w/w)	32.51	33.58
3	Alcohol-soluble extractive value (%w/w)	5.72	8.75
4	Total ash (%w/w)	5.41	3.50
5	Water-soluble ash value (%w/w)	0.995	1.50
6	Acid-insoluble ash value (%w/w)	2.48	2.18
7	pH (3% solution)	5.91	5.96
8	LOD (%w/w)	1.85	1.64

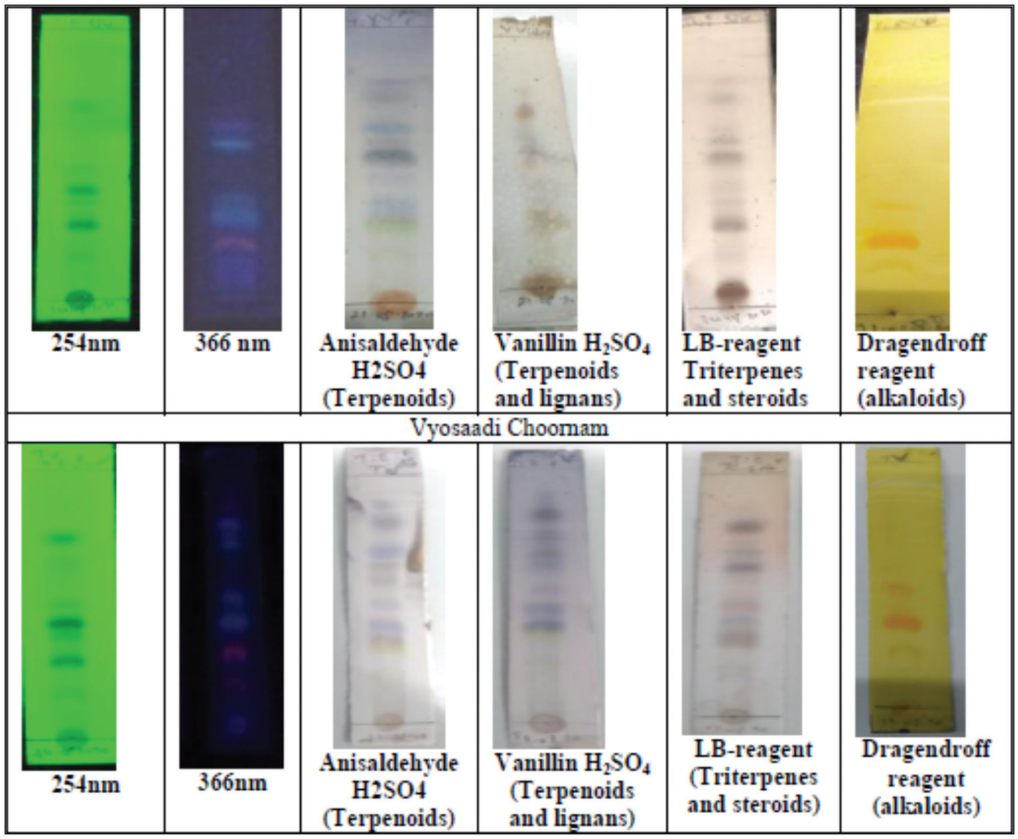

Figure 2: TLC analysis of Talisapatradi and Vyoshadi choorna

Table 4: Physical parameters of lozenges formulations

S. no.	Parameters	TPC-SF	TPC-SB	VSC-SF	VSC-SB	Acceptable limit
1	Diameter (mm)	16.76	16.78	16.74	16.58	15–17
2	Thickness (mm)	7.43	7.44	7.42	7.44	7–8
3	Average weight (g)	2.26	2.44 g	2.41	2.47	2.0–3.0
4	Hardness (kg/cm^2)	17	16	15	16	Not less than 15
5	Friability (%w/w)	0.78	0.69	0.91	0.87	Not more than 1.0
6	Mouth-dissolving time (min)	9	7	8	7	Not less than 6 min
7	pH (2% solution) at 25°C	4.562	4.74	4.78	5.2	4.5–5.5

TPC-SB = *Talisapatradi Choorna* Sugar-based Lozenges Formulation, TPC-SF = *Talisapatradi Choorna* Sugar-free Lozenges Formulation, VSC-SB = *Vyoshadi Choorna* Sugar-based Lozenges Formulation, VSC-SF = *Vyoshadi Choorna* Sugar-free Lozenges Formulation

VSC

3472.45 (-OH groups), 2903.56 (-CH_2), 2859.31 (C = C), 1635.52 (C = O), 1453.26 (aromatic stretching), 1382.87, 1318.25 (C-C), 1249.79 (C-O), 1160.10 (C-C), 1025.10 (C-O).

VSC-SB

3380.02 (-OH groups), 2930.63 (-CH_2), 2890.13 (C = C), 1649.99 (C = O), 1456.16 (aromatic stretching), 1363.58 (C-C), 1338.51 (C-C), 1157.21 (C-C), 1054.99 (C-O).

Table 5: Heavy metal limits of TPC and VSC lozenges

Parameters	Results in ppm TPCL-SB	Results in ppm TPCL-SF	Results in ppm VSCL-SB	Results in ppm VSCL-SF	Limits as per WHO
Lead (Pb)	0.171	0.134	0.113	0.101	NMT 0.3 ppm
Arsenic (As)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	NMT 10.0 ppm
Cadmium (Cd)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	NMT 1.0 ppm
Mercury (Hg)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	BLQ (LOQ-0.05)	NMT 3.0 ppm

TPCL: Talisapatradi choorna lozenges, VSCL: Vyoshadi choorna lozenges, SB: sugar-based, SF: sugar-free

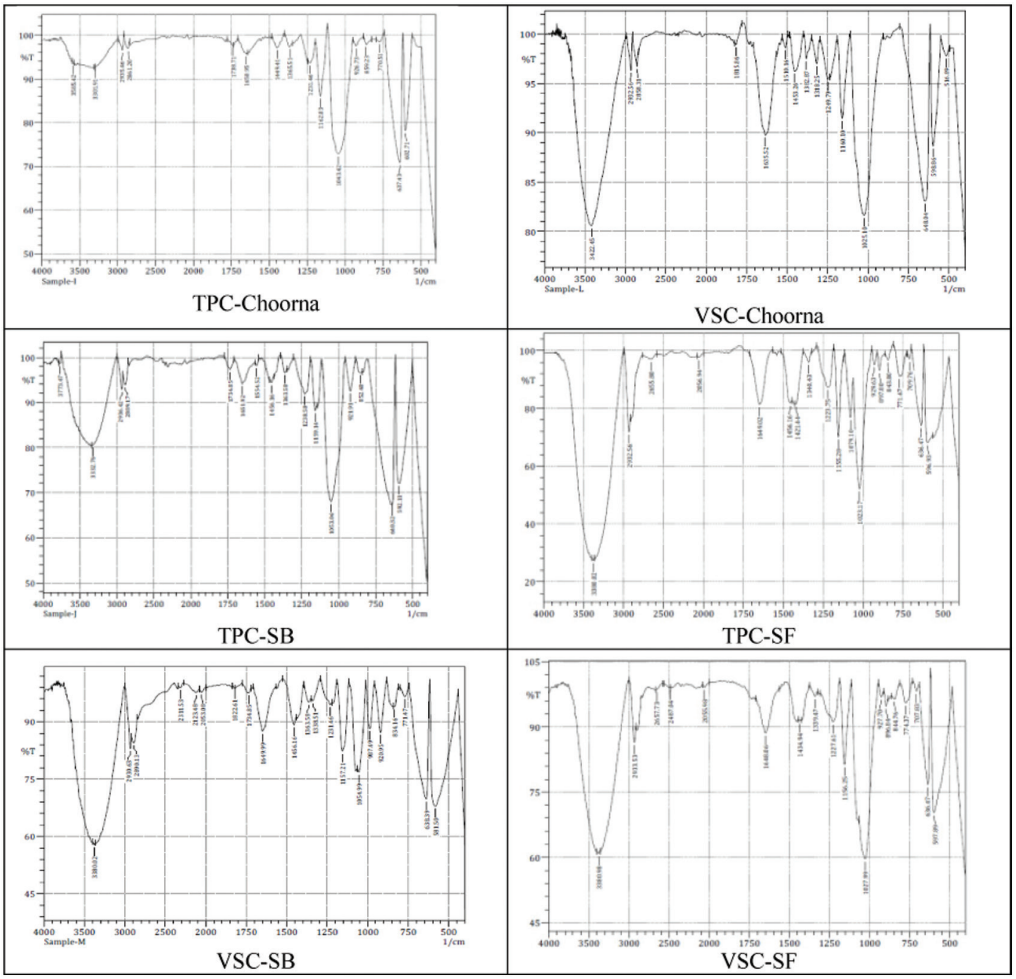

Figure 3: FTIR spectra of TPC, VSC, and lozenges formulation

VSC-SF:

3380.98 (-OH groups), 2933.53 (-CH_2), 2657.73 (C = C), 2487.04 (C = C), 1648.06 (C = O), 1434.94 (aromatic stretching), 1227.61 (C-O), 1156.25 (C-C), 1027.99 (C-O).

The FTIR spectra of both the choorna showed a characteristic and unique fingerprint revealing their differentiated chemical makeup. The FTIR fingerprint of the formulation showed all the prominent peaks of the choornas, indicating that there is no interaction between the choorna and excipients in their lozenges formulation.

HPTLC fingerprint of lozenges formulations

The preliminary HPTLC fingerprint profile of lozenges formulation was developed and depicted in Figure 4. This can be used for validating the formulation and to ensure the batch-to-batch consistency of final formulation. Both the lozenges formulation of TPC showed nine spots in 254 nm at Rf of 0.14, 0.26, 0.29, 0.35, 0.40, 0.48, 0.58, 0.64, 0.73, and 0.88 from the herbal ingredients used in the formulation. Nine formulation spots are Rf at 0.14 from track 3, at 0.26, 0.64, and 0.73 from track 1, at Rf 0.48 from track 4, at Rf 0.29 from track 6, at Rf 0.40 from track 7, and at Rf 0.90 from track 8. These spots

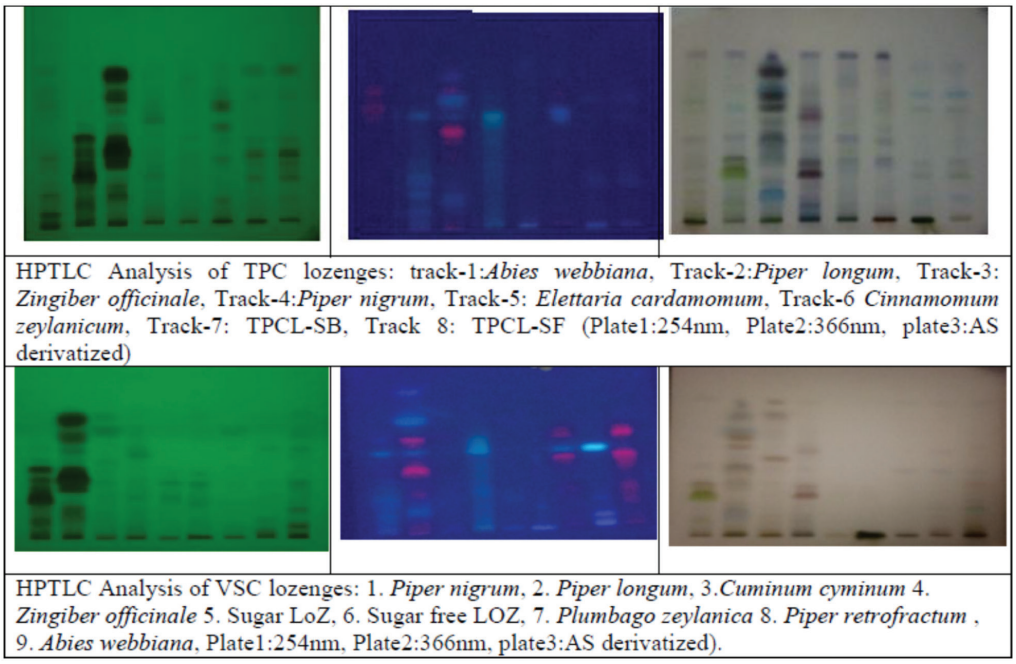

Figure 4: HPTLC chromoplate of lozenges with herbal ingredients. AS: anisaldehyde H_2SO_4

are specific to these ingredients and help in their detection of the formulation. A spot with Rf value of 0.73 was observed in tracks 1, 4 and 7, so the corresponding spot is a mixture of three compounds having the same Rf in the chromoplate. Similarly, the lozenges formulation of VSC showed a total of seven spots at Rf of 0.25, 0.37, 0.41, 0.43, 0.66, 0.71, and 0.89. Similar to the above TPC lozenges, VSC lozenges formulation at 254 nm showed spots at Rf 0.26 from track 2, 0.7 from track 1, 0.41 from track 2, 0.43 from track 4, 0.66 from track 8, 0.66 from track 7, 0.89 from track 2 and track 9, and 0.71 from track 1 and track 9. In 366 nm, the TPC lozenges formulation showed 11 spots at Rf of 0.22, 0.29, 0.34, 0.39, 0.45, 0.53, 0.64, 0.67, 0.71, 0.80, and 0.96. These are Rf at 0.14 from track 4, 0.38 from track 1, Rf 0.22 from track 9, 0.28 from track 2, 0.34 from track 8, 0.38 from track 1 and track 7, 0.44 from track 1 and track 7, 0.53 from track 3, 0.64 from track 1, 0.69 from track 3, 0.96 from track 3, and 0.71 from track 8.

Heavy metal limits

The results of analysis of heavy metals in sugar-based and sugar-free isomalt-based lozenges for TPC and VSC are summarized in Table 5. Heavy metals As, Cd, and Hg were found to be below the limit of quantification in the formulation. Concentration of lead-Pb was found to be 0.171 and 0.134 in TPC sugar-based and sugar-free lozenges and 0.113 and 0.101 in VSC sugar-based and sugar-free lozenges. respectively. The permissible limits of heavy metals as per the AYUSH standards are 10 ppm for Pb, 0.3 ppm for Cd, 3 ppm for As, and 1 ppm for Hg. AS per WHO, it is 10 ppm for lead and 0.3 ppm for cadmium and as per European Pharmacopoeia monograph it is 5, 4, and 0.1 ppm for Pb, Cd, and Hg, respectively.[20-23] Therefore, all the heavy metals were in the permissible limits as per the limits defined by various monographs.

Conclusion

In this study, lozenges' formulation of well-known Ayurvedic choorna Talisapatradi and Vyoshadi choorna was developed. Various quality parameters such as organoleptic, physicochemical, and phytochemical analysis were carried out for the choornas. Physicochemical standardization of choorna was carried out as per the Pharmacopoeial Standards and can be used for quality control of the drug. TLC and FTIR fingerprint were found to be simple, unique, and rapid methods for each choorna and can be used as a diagnostic tool for the identification and authentication of the choorna. These FTIR spectral data can be referred for the development of monographs for Ayurvedic choorna. The heavy metal in the formulation was found to be as per the permissible limit in accordance with the various guidelines such as WHO and European monographs. The HPTLC method developed for analysis can be used a preliminary tool to ensure authenticity of lozenges formulation. The developed lozenges will be having improved taste and attractive appearance with ease of administration. This will further enhance its ease of administration and patient compliance. The FTIR and HPTLC fingerprint showed that choorna was stable in lozenges formulation, and there was no interaction between herbal actives and the lozenges excipients. These findings infer that lozenges formulation could be considered a useful drug delivery system for traditional choorna form of formulation. These findings could be of potential use in designing more such Ayurvedic traditional formulations for better patient compliance.

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Conflicts of interest

There are no conflicts of interest.

Authors' contribution

1.MRS: The author has done concept development, literature search, data analysis, manuscript preparation, and manuscript editing.
2.UMS: Has contributed in the concept, manuscript editing, and review.
3.RRV: Has contributed in the concept and manuscript review.

Ethical approval

Not applicable, as the study does not include any human or animal studies.

Data availability

All data presented in the manuscript.

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