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Research Article

Formulation And Evaluation Of Chewable Tablet Of *Solanum Nigrum*. L Leaf Extract

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ABSTRACT

The purpose of this research work is to formulate and evaluate chewable tablets by using Solanum nigrum L. leaf extract that disintegrates in the mouth and provide an effective treatment for glossitis. The present work is the phytochemical screening of the ethanolic extract the plant Solanum nigrum, followed by pre-formulation studies like organoleptic properties, solubility, compatibility studies by FTIR, and calibration studies using UV spectroscopy. These studies aimed to develop a chewable tablet formulation using the direct comparison method with various compositions. The studies of the chewable tablets are pre-compression parameters like angle of repose, bulk density, taped density, Carr's index, and Hausner ratio, and post-compression parameters like appearance, thickness, hardness test, friability test, weight variation test, disintegration test, and stability studies. Finally, all parameters are within the limit. So, the stability study of Formulation F3 revealed that the plant extract of Solanum nigrum was stable under accelerated and intermediate stability conditions for 3 months. Hence, Formula F3, containing the plant extract of Solanum nigrum at 700 mg, has been formulated as a chewable tablet by the direct compression method, which satisfied all the criteria for chewable tablets. Hence, it may be summarized that the tablets prepared by the direct compression method might be a perfect and effective formulation to prevent the treatment of glossitis

INTRODUCTION

Chewable tablets are tablets that are required to be broken and chewed in between the teeth before

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ingestion. These tablets are given to children who have difficulty in swallowing and to the adults who dislike swallowing. Chewable tablets are chewed and broken into smaller pieces prior to swallowing and are not to be swallowed intact. In this way, the time required for disintegration is reduced and the rate of absorption of the medicament may increase. For the preparation of chewable tablets, mannitol is used as the base. These tablets should have acceptable taste and flavour. They should disintegrate in a short time and produce cool sweet taste. Solanum nigrum commonly known as "Black night shade" belongs to solanacae family. It is called as Manathakkali in Tamil. It shows medicinal properties like anti-microbial, anti-oxidant, cytotoxic properties, anti-ulcerogenic, and hepato-protective activity. The literature survey based on chewable tablets, solanum nigrum and experimental design, Yerukali Sudha Rani et al., A review on Solanum nigrum, Santosh Kumar Bhatt et al., An Overview of the Role of Chewable Tablets. The aim of the present study is to formulate and evaluate by using chewable tablets of solanum nigrum L. Leaf extract that disintegrates in mouth and provide an effective treatment for glossitis. To formulate the herbal extract into a solid dosage form by direct compression method. The chewable tablet is easily accessible for self-medication and safe. Hence it is well accepted by patients.

MATERIALS AND METHODS

MATERIALS:

Table no: 1 List of Materials Used and Manufacturers

Sr. No.	MATERIALS	NAME OF THE SUPPLIERS
1.	Solanum nigrum	The Ethanolic Extract
2.	Microcrystalline cellulose 102	NB Entrepreneurs
3.	Pregelantized starch	Universal starch chemical allied
4.	Stevia powder	Shandong
5	Sorbitol powder	Roquette
6.	Citric acid monohydrate	Sunil Chemicals
7.	Peppermint oil encapsulated flavour	Bio Med Ingredients
8.	Banana Spray dried powder flavour	Flavour Aroma
9.	Magnesium Stearate	Parchin Chemicals

EQUIPMENT:

The equipment used in the present work are as follows,

Table no: 2 List of Instruments Used and Manufacturers

Sr. No	EQUIPMENT	MAKE
1.	Digital balance	Wensar
2.	pH meter	Eutech Ph 700
3.	Hardness tester	Electronic India
4.	Tablet compression machine	RIMEK
5.	Friabilator	Grace
6.	UV Spectrophotometer	Shimadzu
7.	FTIR Spectrophotometer	Shimadzu
8.	Disintegration	VSI electronic

METHODS:

PLANT COLLECTION AND AUTHENTICATION:

Solanum nigrum.L leaves plant was collected from during NOV 2023 from Pennagaram, Dharmapuri District, Tamil Nadu and India. The Plant was authenticated by Jagadeesh Assistant Professor, PG and Research Department of Botany, Sri Vijay Vidyalaya College of Arts and Science, Nallampalli, Dharmapuri, Tamil Nadu-636 807.

Figure no: 1 Plant of Solanum nigrum.L

EXTRACTION PROCEDURE:

The leaves of Solanum nigrum were washed to remove dust and dried under shade for about 2 weeks at room temperature (25±2℃). To get a constant weight, the dried plant materials were grinded to coarse powder separately by mechanical device, stored and used in this work throughout the study period. In this process, 100gm of the leaves of the Solanum nigrum was coarsely powdered crude drug is placed in an individual closed vessel with the Ethanol and allowed to stand at room temperature for a period of seven days with frequent agitation until the soluble matter has dissolved. The mixture then is strained, the marc the damp solid material is pressed and the liquids are clarified by filtration or decantation after standing. The filtrate was concentrated on the water bath. Finally dried form of powder was obtained and the dried extract was collected and stored in a dessicator.

QUALITATIVE PHYTOCHEMICAL ANALYSIS:

Phytochemical evaluation is used to determine the nature of phytoconstituents present in the plant. The chemical tests for various phytoconstituents in the extracts of Leaf of Solanum nigrum were carried out as described below:

Table no: 3 Qualitative Phytochemical Analysis

Sr. No	EXPERIMENT	OBSERVATION	INFERENCE
1.	**Test for carbohydrates** To 2ml of plant extract, 1 ml of Molisch's reagent and few drops of concentrated sulphuric acid were added	Purple Colour formation	Indicates the presence of carbohydrates
2.	**Test for Tannins** To 1ml of plant extract, 2ml of 5% ferric chloride was added	Formation of greenish black	Indicates the presence of Tannins
3.	**Test for Saponins** To 2ml of plant extract, 2ml of distilled water was added and shaken in a graduated cylinder for 15 minutes lengthwise	Formation of 1 cm layer of foam	Indicates the presence of saponins
4.	**Test for Flavonoids** 5ml of dilute ammonia solution was added to a portion of the aqueous filtrate of plant extract followed by addition of concentrated sulphuric acid.	Appearance of yellow coloration	Indicates the presence of Flavonoids
5.	**Test of Alkaloids** To 2ml of plant extract, 2ml of concentrated hydrochloric acid was added. Then few drops of Mayer's reagent were added	Presence of green color	Indicates the presence of alkaloids.
6.	**Test for Anthocyanin and Betacyanin**		

	To 2ml of plant extract, 1ml of 2N sodium hydroxide was added and heated for 5 minutes at 100°C	Formation of yellow color	Indicates the presence of Betacyanin
7.	**Test for Glycosides** To 2ml of plant extract, 3ml of chloroform and 10% ammonia solution was added	Pink color formation	Indicates the presence of Glycosides
8.	**Test for Phenols** To 1ml of the extract, 2ml of distilled Formation of green water followed by few drops of 10% color ferric chloride was added	Formation of green color	Indicates the presence of phenols

PRE-FORMULATION STUDIES:

ORGANOLEPTIC PROPERTIES:

The organoleptic properties like color, odour and taste of plant extract were evaluated.

COLOR AND NATURE:

Transferred small quantity of the sample on a white piece of paper, spreader the powder and examined visually.

TASTE AND ODOUR:

Very less quantity of Plant extract was used to get taste with the help of tongue as well as smelled to get the odour.

SOLUBILITY:

The plant extract was dried in desiccators over CaO. Its solubility in water, methanol, ethanol, chloroform, petroleum ether, dil. NaOH, and dil. HCl was determined as follows: 1 mg of the dried extract was dissolved in 1 mL of the solvent at room temperature. Its solubility in each solvent was assessed qualitatively by visual observation.

CALIBRATION CURVE USING UV-VISIBLE SPECTROSCOPY:

The standard stock solution of solanum nigrum.L. Leaf extract was prepared by accurately weighing and transferring 10 mg of the extract to 100 ml of volumetric flask. Then 2ml of the solution was added to 10ml volumetric flask and final volume was made up with phosphate buffer (PH 6.8) to get final standard stock solution(20µg/ml) was further diluted water to obtain 05-25µg/ml Solanum nigrum L. Leaf extract These solutions were scanned in the range of 760nm. The calibration curve was plotted between absorbance values against concentration.

COMPATIBILITY STUDIES USING FTIR SPECTROSCOPY:

The plant extract and excipients mixture of 1:1 ratio was accurately weighed and compatibility of freshly prepared mixtures was determined by FT-IR spectroscopy. FT-IR spectra of the plant extract, excipient and the physical mixture of the plant extract and excipients were recorded on a Fourier-transform infrared spectrophotometer (Shimadzu FT-IR, Japan) in the range of 4000-400 cm-1 and observed for any interaction between the plant extract and excipients.

Table no: 4 Plant extract - Excipients Compatibility Protocol

Sr. No.	Plant Extract and Excipients	Ratio
1.	Solanum nigrum + Microcrystalline cellulose 102	1:1
2.	Solanum nigrum + Pregelantized starch	1:1
3.	Solanum nigrum + Stevia	1:1
4.	Solanum nigrum + Sorbitol	1:1
5.	Solanum nigrum + Citric acid monohydrate	1:1

6.	Solanum nigrum + Peppermint oil encapsulated flavor	1:1
7.	Solanum nigrum + Banana Spray dried powder flavor	1:1
8.	Solanum nigrum + Magnesium Stearate	1:1

FORMULATION OF CHEWABLE TABLET BY DIRECT COMPRESSION METHOD:

The chewable tablets containing 200 mg the plant extract of solanum nigrum were prepared with a total tablet weight of 700 mg. All the formulation were prepared by direct compression.

PROCEDURE:

Step: 1

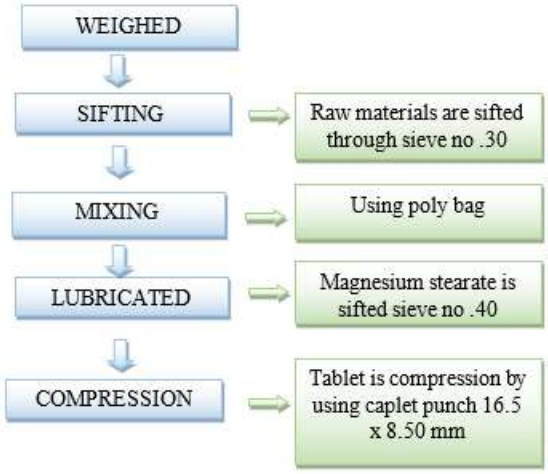
Solanum nigrum powder and all the other ingredients were individually passed through a sieve no.30

Step: 2

All the ingredients were mixed thoroughly by triturating up to 5 min by using poly bag

Step: 3

Magnesium Stearate is sifted through sieve no.40 added with Step: 2 mixing for 3 minutes. The tablets were prepared by using direct compression method according to the formulation table. Then the blend was compressed using caplet punch 16.50 x 8.50 mm



Flow chat no: 1 Procedure of formulation of chewable tablet by direct compression method

Composition of the different formulation for chewable tablet by direct compression method

Table no: 5 Formulation of Solanum nigrum Chewable Tablets

	Quantity in mg/ tablet and percentage				
Name of ingredients	**F1**	**F2**	**F3**	**F4**	**F5**
Solanum nigrum	200	200	200	200	200
Microcrystalline cellulose 102	25	25	25	25	25
Pregelantized starch	101	101	106	96	102
Stevia powder	15	15.5	15	14.5	15
Sorbitol powder	306.2	301.2	301.2	301.2	301.2
Citric acid monohydrate	30	30	30	30	30
Peppermint oil encapsulated flavor	1	0.5	1	1.5	NA
Banana Spray dried powder flavor	15	20	15	25	20
Magnesium Stearate	6.8	6.8	6.8	6.8	6.8
Total tablet weight	**700**	**700**	**700**	**700**	**700**

Figure no: 2 Powder of Granulation

Figure no:3 Solanum nigrum chewable tablet

EVALUATION STUDIES OF CHEWABLE TABLET:

PRE-COMPRESSION PARAMETERS:

ANGLE OF REPOSE:

Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane. The frictional force in a loose powder or granules can be measured by angle of repose.

$$\tan \Theta = h / r,$$

$\Theta = \tan^{-1} (h/r)$

Where, Θ is the angle of repose, h is height of pile, R is radius of the base of pile

Relationship between Angle of Repose (Θ) and flow properties.

Table no: 6 Flow Properties and Corresponding Angle of Repose

ANGLE OF REPOSE (Θ)	TYPES OF FLOW
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

BULK DENSITY:

Calculated amount of the model drug was introduced in a 100ml graduated cylinder. Powder level was noted without compacting shows in table-19, Bulk density was calculated using the following equation:

$$\text{Bulk density} = M/Vo$$

Where, M =Mass of the test sample,

VO =Unsettled apparent volume

TAPPED DENSITY:

Calculated amount of the model drug was introduced in a 100ml graduated cylinder. Mechanically the cylinder was tapped using the tapped density apparatus by raising the cylinder and allowing it to drop under its own weight that provides a fixed drop of 14±2 mm at a normal rate of 250 drops per minute. The cylinder was tapped 1250 times initially and tapped volume measured. Tapped density was calculated using the following equation:

$$\text{Tapped Density} = (M)/Vf$$

Where M = Mass of test sample,

Vf = Final tapped volume

CARR'S INDEX:

This parameter is the measure of propensity of powder to be compressed and reflect the relative importance of inters particulate interaction.

$$\text{Carr}^{\wedge}\text{' s Index} = (100(TD-BD))/TD$$

HAUSNER RATIO:

The Hausner ratio is a number that is used to correlate the flow ability of drug substance.

$$\text{Hausner Ratio} = (\text{Tapped Density})/(\text{Bulk Density})$$

Flow ability of powder on the basis of Carr's index and Hausner Ratio

Table no 7: Flow ability of powder on the basis of Carr's index and Hausner Ratio

Carr's Index	Flow character	Hausner ratio
<10	Excellent	1.00-1.11

11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very poor	1.46-1.59
>32	Very, very poor	>1.60

POST-COMPRESSION PARAMETERS:

SHAPE AND COLOUR:

Uncoated tablets were examined under a lens for the shape of the tablet and colour was observed by keeping the tablets in light.

THICKNESS:

The crown thickness of individual tablet may be measured with a Vernier caliper, which permits accurate measurements and provides information on the variation between tablets. Other technique employed in production control involves placing 5 or 10 tablets in a holding tray, where their total crown thickness may be measured with a sliding caliper scale. The tablet thickness was measured using Vernier caliper.

HARDNESS TEST:

Tablets require a certain amount of strength, or hardness and resistance to friability, to withstand mechanical shocks of handling in manufacture, packaging and shipping. The hardness of the tablets was determined using Monsanto Hardness tester. It is expressed in Kg/cm2. Three tablets were randomly picked from each formulation and the mean and standard deviation values were calculated.

FRIABILITY TEST:

It is the phenomenon where by tablet surfaces are damaged and show evidence of lamination or breakage when subjected to mechanical shock or attrition. The friability of tablets was determined by using Roche Friabilator. It is expressed in percentage (%). Ten tablets were initially weighed (W initial) and transferred into Friabilator. The Friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (W final). The percentage friability was then calculated by,

F=(W(inital)-W(final))/(W(inital)) X 100

% Friability of tablets less than 1% is considered acceptable.

WEIGHT VARIATION TEST:

The tablets were selected randomly from each formulation and weighed individually to check for weight variation. The U.S Pharmacopoeia allows a little variation in the weight of a tablet. The percentage deviation in weight variation is shown in table

Table 8: Percentage deviation in weight variation

Average weight of a tablet	Percentage deviation
700 mg (680 to 720 mg)	±20 mg

ASSAY:

20 tablets were accurately weighed and crushed in a mortar, a quantity of powder equivalent to label claim was disperse in methanol, shake and diluted to 100ml with methanol and filtered. 20m1 of the filtrate was diluted to 100ml with methanol. Absorbance was measured at 760nm in UV spectrophotometer.

Calculation = Drug content/label claim x 100

IN-VITRO DISINTEGRATION TIME:

The process of breakdown of a tablet into smaller particles is called as disintegration. The in-vitro disintegration time of a tablet was determined using disintegration apparatus as per I.P. specifications.

Method

For a drug to be absorbed from a solid dosage form after oral administration, it must first be in solution, and the first important step toward this condition is usually the break- up of the tablet, a process known as disintegration. The disintegration time of chewable tablets was determined in accordance with the official “United states of pharmacopoeia Chewable tablets” stating a maximum disintegration time of 5 minutes (USP 36). One tablet in each of the 6 tubes of the basket is to be placed and the apparatus subjected to run.

The assembly should be raised and lowered between 50 cycles per minute. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded. Disintegration or more specifically dispersion times were measured in 900 ml purified water according to the I.P. method without using disc at room temperature (25°C ± 2°C).

STABILITY STUDIES:

Stability of a drug has been defined as the ability of a particular formulation, in a specific container, to remain within its physical, chemical, therapeutic and toxicological specifications. The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light and enables recommended storage conditions, re-test periods and shelf lives to be established. In the present study, the Chewable Tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for intermediate and accelerated studies.

1. 25 ± 2°C/60±5% RH
2. 40 ± 2°C/75±5% RH

The tablets were withdrawn after period of 1, 2 and 3 Months and analyzed for physical characterization (Appearance, hardness, friability, disintegration etc.,) and drug content.

RESULT AND DISCUSSION:

EXTRACTION:

Extraction with the ethanol solvent were performed, percentage yield and phytochemical analysis were done. The percentage yields of each extract are tabulated below.

Table 9: Percentage yields of successive extracts of Leaf of solanum nigrum.L

Sr. No	Extract	Physical nature	Colour	Percentage Yield (%w/w)
1.	Ethanol	Solid Powder	Greenish	7.3

DISCUSSION:

The plant was extracted using ethanol in maceration method. The semisolid extract, so obtained was extractive value is 7.3.

PHYTOCHEMICAL SCREENING:

The Preliminary phytochemical analysis of various extracts was performed Note: + ve indicates positive result, - ve indicates negative result

Table 10: Preliminary phytochemical analysis of Ethanol extracts

Sr No	TEST	ETHANOLIC EXTRACT
1.	Carbohydrates	_
2.	Tannins	+
3.	Saponins	_
4.	Flavonoids	+
5.	Anthocyanin and Betacyanin	–
6.	Alkaloid	+
7.	Quinines	+
8.	Glycosides	+
9.	Phenol	+

Discussion:

The ethanol extracts of solanum nigrum.L are tested to find the presence of different class compounds. Various qualitative chemical tests for the preliminary phytochemical screening of the extract of ethanol were applied. The phytochemical test on an extract of the solanum nigrum.L revealed the presence of Tannins, Flavonoids, Alkaloid, Quinines, Glycosides and Phenol.

PRE-FORMULATION STUDIES:

ORGANOLEPTIC PROPERTIES:

Table 11: Organoleptic Properties of solanum nigrum extract

Sr. No	ORGANOLEPTIC	PROPERTIES
1.	Appearance	Granular powder

2.	Colour	Creamiest to off white Colour
3.	Taste	Mint with Banana
4.	Oduor	Herbal Oduor

Discussion:

The organoleptic properties like color, odour and taste of the plant extract were evaluated. The color of the plant extract of solanum nigrum was found to be Granular powder appearance, Creamiest to off white colour, Herbal odour and Mint with Banana taste was observed in the study.

SOLUBILITY TEST:

Table 12: Solubility Analysis of Solanum nigrum extract

Sr. No	SOLVENT	RESULT
1.	Water	+
2.	Methanol	+
3.	Ethanol	+
4.	Petroleum ether	-
5.	Chloroform	-
6.	Dilute NaOH	+
7.	Dilute HCl	+

Discussion:

The solubility analysis of the plant extract indicates that soluble in water, methanol, ethanol, dilute NaOH and Dilute Hcl.

CALIBRATION CURVE OF SOLANUM NIGRUM IN 0.1 N PHOSPHATE BUFFER

Table 13: Calibration curve of Solanum nigrum in 0.1 N phosphate buffer

Concentration (µg/ml)	Absorbance at 760 nm
5	0.175
10	0.296
15	0.432
20	0.621
25	0.763

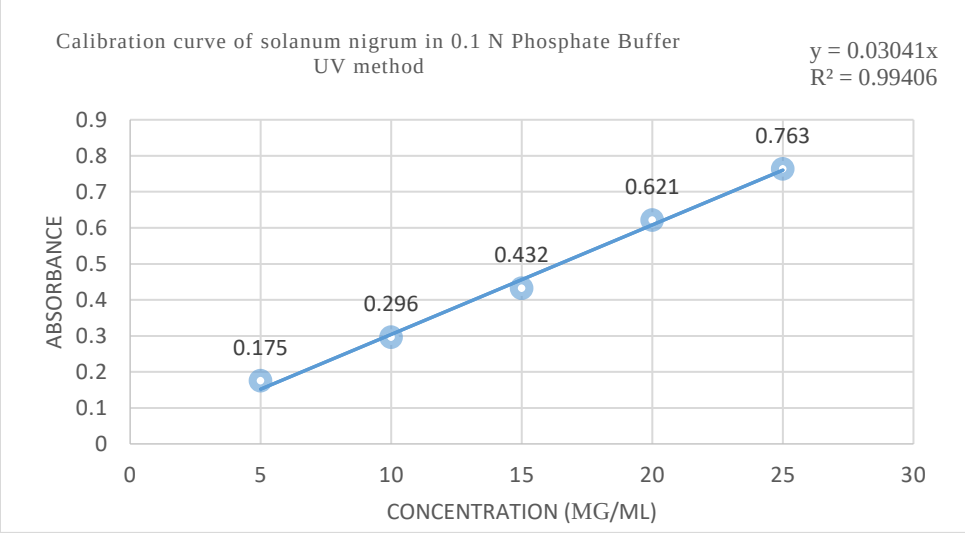


Figure no: 4 Calibration curve of Solanum nigrum in 0.1 N phosphate buffer

COMPATIBILITY STUDIES USING FTIR SPECTROSCOPY

IR Spectra of Solanum nigrum:

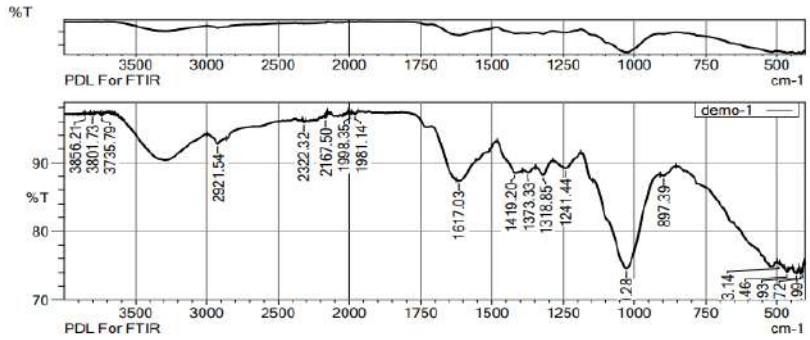


Figure no: 5 FT-IR spectrum of Solanum nigrum

IR Spectra of Solanum nigrum + Microcrystalline cellulose 102:

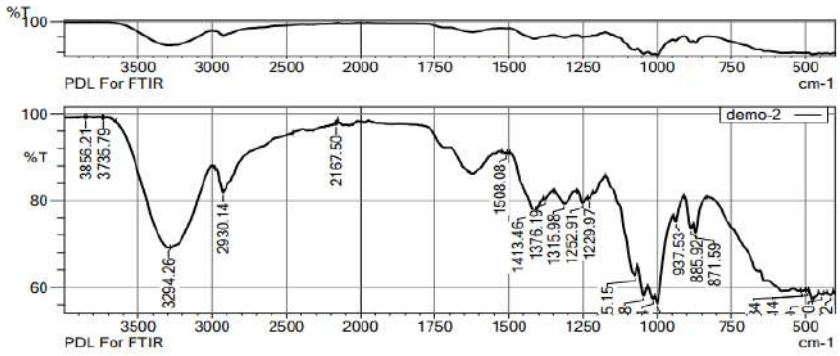


Figure no: 6 FT-IR spectrum of Solanum nigrum + Microcrystalline cellulose 102

IR Spectra of Solanum nigrum + Pregelantized starch:

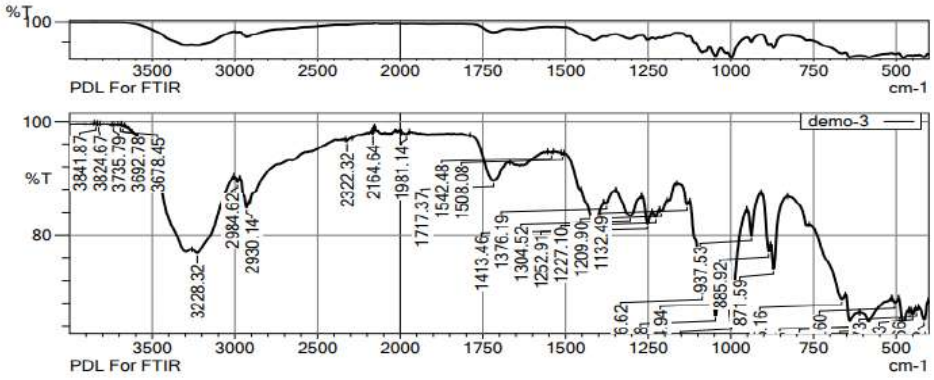


Figure no: 7 FT-IR spectrum of Solanum nigrum + Pregelantized starch

IR Spectra of Solanum nigrum + Stevia

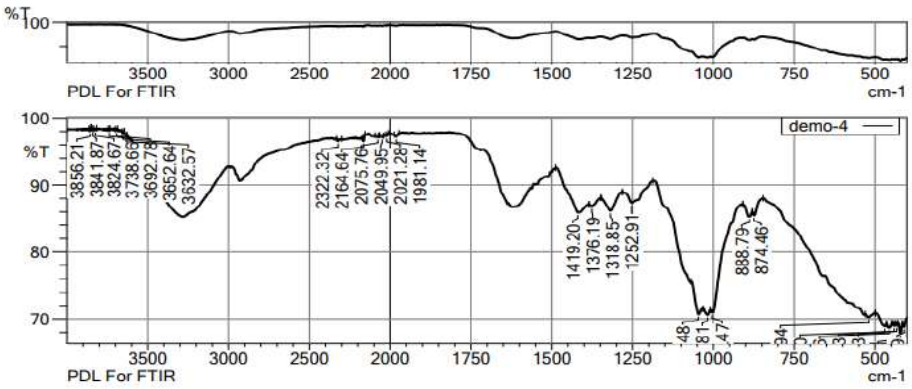


Figure no: 8 FT-IR spectrum of Solanum nigrum + Stevia

IR Spectra of Solanum nigrum + Sorbitol:

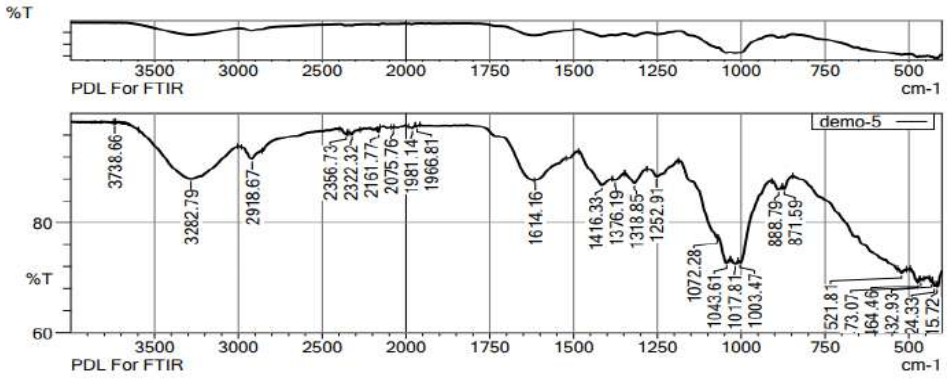


Figure no: 9 FT-IR spectrum of Solanum nigrum + Sorbitol

IR Spectra of Solanum nigrum + Citric acid monohydrate:

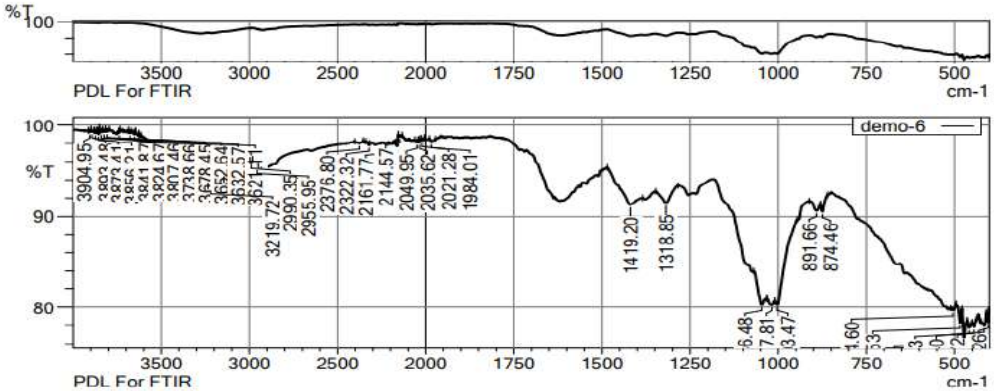


Figure no: 10 FT-IR spectrum of Solanum nigrum + Citric acid monohydrate

IR Spectra of Solanum nigrum + Peppermint oil encapsulated flavour:

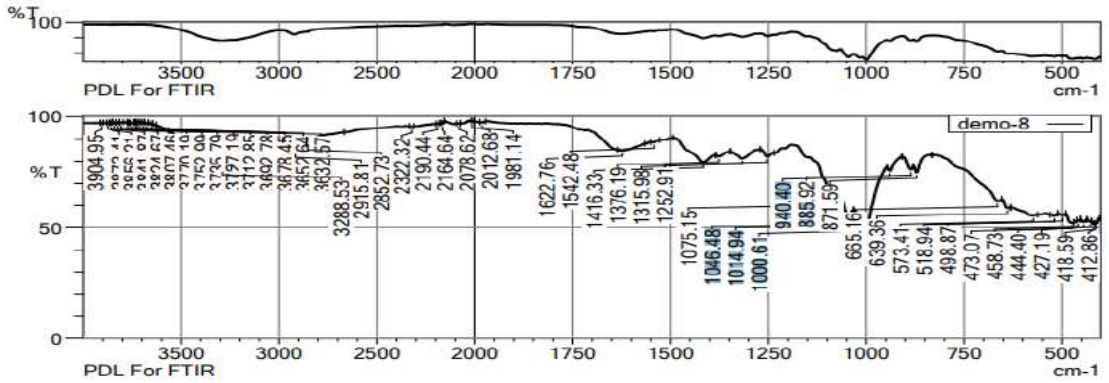


Figure no: 11 FT-IR spectrum of Solanum nigrum + Peppermint oil encapsulated flavour

IR Spectra of Solanum nigrum + Banana Spray dried powder flavour:

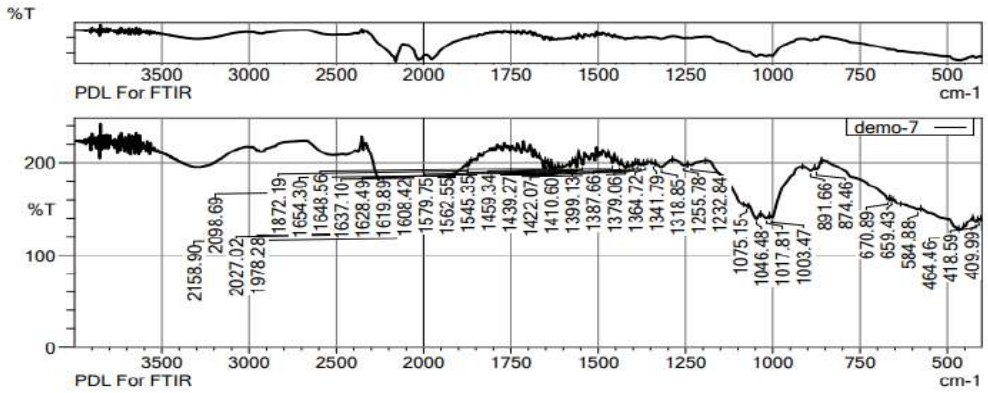


Figure no: 12 FT-IR spectrum of Solanum nigrum + Banana Spray dried powder flavour

IR Spectra of Solanum nigrum + Magnesium Stearate:

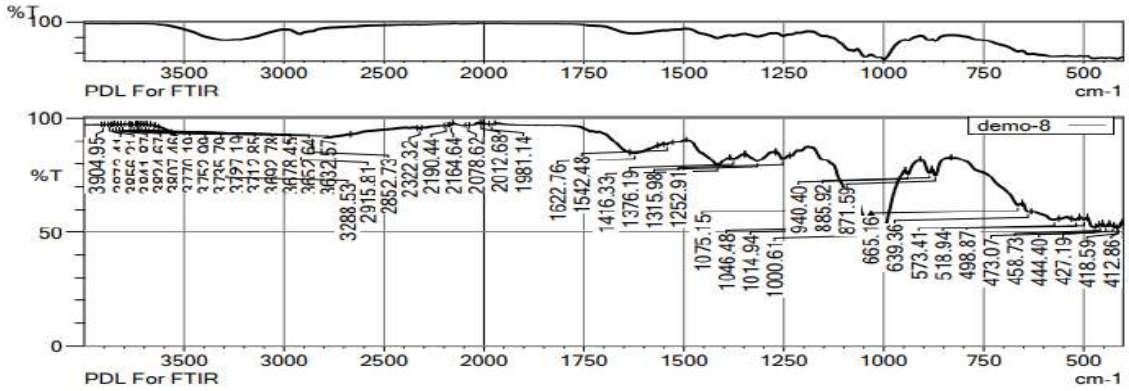


Figure no: 11 FT-IR spectrum of Solanum nigrum + Magnesium Stearate

Comparative of the FT-IR Spectral Data of the plant extract :

Table 14: Comparative of the FT-IR Spectral Data of the plant extract

Compounds	OH	C-H	C=C	C-N	C-O
Solanum nigrum	3362	2921	1617	1241	1028
Solanum nigrum + Microcrystalline cellulose 102	3329	2952	1510	1570	985
Solanum nigrum + Pregelantized starch	3228	2850	1812	1562	1100

Solanum nigrum + Stevia	3632	2672	1713	1372	1002
Solanum nigrum + Sorbitol	3282	2674	1586	1333	975
Solanum nigrum + Citric acid monohydrate	3652	2588	1666	1322	1083
Solanum nigrum + Peppermint oil encapsulated flavor	3735	2547	1685	1431	1072
Solanum nigrum + Banana Spray dried powder flavor	3602	2648	1812	1240	1064
Solanum nigrum + Magnesium Stearate	3602	2765	1718	1350	1082

Discussion:

FT- IR spectral studies indicated that the plant extract is compatible with all the excipients. The FT-IR spectrum of physical mixture showed all the characteristic peaks of the plant extract of solanum nigrum, thus conforming that no interaction of plant extract occurred with the components of formulation.

EVALUATION OF THE PLANT EXTRACT OF SOLANUM NIGRUM CHEWABLE TABLETS

PRE-COMPRESSION PARAMETERS

The powder blends were evaluated for the following parameters such as Angle of repose, Bulk density, Tapped density, Carr's index and Hausner ratio. The results were given below in Table

Table 15: Evaluation of the Pre compression Parameters

Sr. No	PARAMETERS	F1	F2	F3	F4
1.	ANGLE OF REPOSE	31.40±1.24	29.65±1.01	32.64±1.09	33.21±1.62
2.	BULK DENSITY	0.45±0.02	0.44±0.01	0.43±0.01	0.46±0.02
3.	TAPPED DENSITY	0.57±0.01	0.58±0.02	0.59±0.02	0.58±0.02
4.	CARR'S INDEX	21.94±0.12	17.86±0.18	13.88±0.17	21.31±0.11

All the values are expressed as mean ± SD, n=3

Discussion:

The angle of repose of all formulations was found between 29.65-33.64 Ɵ which indicates the flow type of powder blend was passable. The bulk density was found between 0.42-0.46 g/cm3, tapped density was found between 0.56-0.59 g/cm3. Carr's index was found in the range of 13.88 to 21.94 % which indicates the flow type of powder blend was passable. Hausner's ratio ranges between 1.26 to 1.37. The above results in terms of micromeritic properties revealed that the flow property of all formulation was passable and within the acceptable limit.

POST COMPRESSION PARAMETERS

GENERAL APPEARANCE

The general appearance of all formulations (F-1 to F-5) were examined and found as follows,

Colour - Creamiest to off white colour

Shape - Caplet Shape

Surface - Smooth surface

The prepared tablets were evaluated for various post compression parameters. The results are presented in Table

Table 16: Evaluation of the post compression Parameters

Sr. No	PARAMETERS	F1	F2	F3	F4	F5
1.	Thickness (mm)	5.34±0.90	5.16±0.98	5.29±0.90	5.22±112	5.27±1.14
2.	Hardness (kg /cm2)	6.31±1.28	7.12±0.98	6.43±0.52	6.71±1.45	6.45±1.22
3.	Weight Variation (mg)	696±1.23	701±0.84	694±0.76	699±1.08	704±1.06
4.	Friability (%)	0.25±0.10	0.14±0.08	0.24±0.10	0.18±0.16	0.24±0.12

All the values are expressed as mean ± SD, n=3

Discussion:

THICKNESS AND HARDNESS

The thickness of tablets was measured and was found in the range between 5.16 to 5.34 mm. All the formulation possessed uniform thickness. The hardness of the tablets was measured and the values were found in the range between 6.31 to 7.12 kg/cm2.

WEIGHT VARIATION AND FRIABILITY

Test all formulations of tablets passed the weight variation test since the values are within the acceptable variation limit (±20.0%) of the tablet. Similarly, percentage friability values of the prepared chewable tablets showed less than 1% weight loss that is highly within the acceptable limit. Hence all the tablets passed the friability test. Tablets were evaluated for various parameters and the results are given in Table

DRUG CONTENT AND DISINTERGRATION TIME

Table 17: Evaluation of Drug content and Disintegration Test

Sr. No	PARAMETERS	F1	F2	F3	F4	F5
1.	ASSAY (DRUG CONTENT)	99.82±1.00	100.54±2.52	100.27±1.64	99.28±1.25	100.85±1.36
2.	DISINTEGRATION TIME (min)	3 min 23 sec	3 min 40 sec	3 min 15 sec	2 min 56 sec	3 min 24 sec

All the values are expressed as mean ± SD, n=3

Discussion:

The content of the chewable tablets was found in the range between 99.00 -101.00%. The results revealed that the content of Solanum Nigrum L extract was within the acceptable limits in all the formulations. Disintegration time of Solanum Nigrum L extract chewable tablets were found between 2.50±0.01 to 3.45±0.015 minutes. Specification limit of disintegration time for uncoated tablet from I.P is NMT 5 minutes. Disintegration time of all formulations were found within the time as specified in the I.P and passed the disintegration test. The disintegration time of formulation III containing showed plant extract disintegration (3.15 ±0.01 min) compared with other formulations.

STABILITY STUDIES

The optimized formulation (F-3) was selected for the stability study and stored at 25±2°C/60%±5%RH and 40±2°C/75%±5%RH for a period of three months. The tablets were evaluated for various parameters like physical appearance, weight variation, thickness, hardness, friability, disintegration time and drug content at every month interval.

The results are presented in Table

Table 18: Stability Data of Optimized Formulation (F-3) Stored at 25±2°C/60%±5%RH

Sr. No	Storage Conditions: 25±2°C/60%±5%RH				
	PARAMETER	INITAL PERIOD	1ST MONTH	2ND MONTH	3RD MONTH
1	Physical appearance	Creamiest to off white colour	Creamiest to off white colour	Creamiest to off white colour	Creamiest to off white colour
2	Weight variation test (mg)	694 ±0.98	692±1.42	690±1.24	691±1.03
3	Thickness (mm)	5.29±0.19	5.12±0.28	5.17±0.45	5.22±0.52
4	Hardness (Kg/cm^2)	6.43±0.54	6.52±0.48	6.45±0.13	6.25±0.21
5	Friability (%)	0.24±0.01	0.42±0.02	0.36±0.02	0.52±0.02
6	Disintegration time (min.)	3 min 15 sec	3 min 10 sec	3 min 05 sec	2 min 50 sec
7	Drug content	100.27±1.24	99.82±1.20	99.34±1.00	99.25±1.42

All the values are expressed as mean ± SD, n=3

Table 19: Stability Data of Optimized Formulation (F-3) Stored at 40±2°C/75%±5%RH

Sr. No	Storage Conditions: 40±2°C/75%±5%RH				
	PARAMETER	INITAL PERIOD	1ST MONTH	2ND MONTH	3RD MONTH
1	Physical appearance	Creamiest to off white colour	Creamiest to off white colour	Creamiest to off white colour	Creamiest to off white colour
2	Weight variation test (mg)	694 ±1.54	690±1.24	686±2.78	683±1.65
3	Thickness (mm)	5.29±0.21	5.21±0.27	5.14±0.17	5.20±0.62
4	Hardness (Kg/cm^2)	6.43±0.40	6.23±0.24	6.15±0.21	6.05±0.18
5	Friability (%)	0.24±0.01	0.42±0.01	0.36±0.02	0.52±0.01
6	Disintegration time (min.)	3 min 15 sec	3 min 16 sec	2 min 57 sec	3 min 00 sec
7	Drug content	100.27±1.54	100.10±1.79	99.45±0.52	99.62±1.28

All the values are expressed as mean ± SD, n=3

Discussion:

Stability results revealed that there were no significant changes found in physical appearance, weight, thickness, hardness, friability, disintegration time, drug content a during the period of 3 months even after stored at 25±2°C/60%±5%RH and 40±2°C/75%±5%RH. The results revealed that the drug was stable even after stored at 25±2°C/60%±5%RH and 40±2°C/75%±5%RH for three months.

CONCLUSION

- The chewable tablets of taste masked the plant extract of solanum nigrum L were successfully prepared by direct compression method.
- 5 batches using various additives were prepared and evaluated with an aim of presenting the plant extract of Solanum Nigrum L taste masked by the chewable tablet.
- Drug excipients compatibility study was performed by FTIR.
- The physicochemical evaluation results for the powdered blend of all trials pass the official limits in the angle of repose, compressibility index, Bulk density, Tapped density, Hausner's ratio.
- After the compression of the chewable tablet to evaluate the Appearance, Thickness, Hardness test, Friability test, weight variation test and Disintegration test all the trials within the limits.
- So, the plant extract of solanum nigrum was stability study of Formulation F3 revealed that the drug was stable under accelerated and long-term ability conditions for 3 months. Hence the Formula F3 containing the plant extract of Solanum Nigrum 700 mg has been formulated as a chewable tablet by direct compression method, which satisfied all the criteria for chewable tablets.
- Hence it may be summarized that the tablets prepared by direct compression method might be a perfect and effective formulation to prevent the treatment of glossitis.

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