



FORMULATION AND EVALUATION OF TABLET CONTAINING UNRIPE FRUIT EXTRACT OF SOLANUM NIGRUM L. IN CHEWABLE FORM

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ABSTRACT

The purpose of this research work is to formulate and evaluate chewable tablets by using Solanum nigrum L. Unripe fruit 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, tapped 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 F2 revealed that the plant extract of Solanum nigrum was stable under accelerated and intermediate stability

conditions for 3 months. Hence, Formula F2, containing the plant extract of *Solanum nigrum* at 650 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.

KEYWORDS: *Solanum nigrum* L. Unripe fruit, Chewable tablet Form, Ethanolic extract, Characterization, FTIR, UV, Stability Studies, Pre-formulation Studies, post- formulation Studies, Stability studies, Glossitis.

INTRODUCTION

Medicines are delivered to the body by a variety of forms. Some medicines are solids, such as tablets and capsules, and others are liquids, such as solutions and suspensions. These varying ways of delivering medicine to the body are called dosage forms.

1. Active ingredient: the part of the medicine designed to treat the patient, also referred to as the 'drug'.
2. Excipients: other ingredients that are added to the drug which, when combined, make the medicine. Excipients include preservatives, coloring agents, and stabilizers (also referred to as 'inactive ingredients', ingredients that do not possess any therapeutic qualities).

According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents. Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration.

Chewable Tablets

Chewable tablets are the tablets that are intended to disintegrate smoothly in the mouth at the modern rate either with or without actual chewing. Characteristically chewable tablets have a smooth structure up to disintegration and are pleasant tasting and unripe fruits not bitter and unpleasant after taste. They are required to be broken and chewed between teeth before ingestion. The purpose of the tablet is to provide unit dosage form of medication that can be easily administered to infants and elderly who may have difficulty in swallowing. Bitter and foul-tasting drugs are not the good candidate for such type of tablet and that intact restrict the use of chewable tablet dosage form.

The Chewable tablets were prepared by using the following methods:

Granulation

Granulation is the process in which primary powder particles are made to adhere to form larger, multi- particles entities called granules. Pharmaceutical granules have size range between 0.2 to 4.0 mm. Granulation is used to improve flow and compressibility of powders and to prevent segregation of the blend components. Granulation is mainly done by using two techniques.

Dry granulation

It is the novel method for semi-automatic production of granules. The method is applicable to any solid dosage pharmaceutical products. Dry granulation method replaces existing solid dosage form development and manufacturing technologies offering more plant extract development and better quality. In this process, the powder mixture is compressed without the use of heat and solvent. Two methods are used for dry granulation. The more widely used is slugging where the powder is recompressed and the resulting tablet are milled to yield the granules.

Wet granulation

Wet granulation is the most commonly used granulation method. This process involves wet massing of powder blend with a granulating liquid, wet sizing and drying. The granulating liquid contains a solvent which must be volatile so that it can be removed by drying and must be non-toxic in nature. Typical liquid include water, ethanol and Isopropyl alcohol. In the traditional wet granulation method the wet mass is forced through a sieve to produce wet granules which are subsequently dried.

Direct Compression

Direct compression is the most popular choice because it provides the shortest, most effective and least complex way to produce tablets. This method is mainly used when a group of ingredients can be blended. This is more suitable for moisture and heat sensitive plant extract's since it eliminates wetting and drying steps and increase the stability of active ingredient by reducing detrimental (harmful) effects.

In this process, plant extract mixed with the excipients and lubricant, followed by compression which makes the product easy to process.

Mechanical Properties and Chewability

The mechanical properties of a tablet are important to ensure tablet durability and low friability after compression, during packaging, shipping, and handling. For chewable tablets, they play a further role as these dosage forms must be readily chewable. Tablets having excessively high mechanical strength may present a risk to teeth, dentures, or mandibular joints. Only a few published studies have investigated the mechanical properties of marketed chewable tablets.

Sensory Factors and Taste-Masking

The organoleptic characteristics of chewable tablets that are important to consider include taste, after-taste, odour, flavour, texture, mouth feel, and visual aesthetics of the product. The oral processing of chewable tablets makes taste-masking a necessity for most formulations. Sweeteners are almost always used and represent the simplest means by which to address taste concerns. Combinations of bulk sweeteners (e.g., sugars or polyols) with high-intensity sweeteners (e.g., aspartame) are common. For example, monoammonium glycyrrhizinate, while having a slow onset, has a prolonged sweetness. Blends of sweeteners may therefore be used to provide synergistic effects.

Formulation of Chewable Tablets

Chewable tablets can be prepared in a variety of shapes. Some children's products come in animal shapes to provide aesthetic appeal for this specific population. Because chewable tablets are broken down in the mouth before swallowing, total tablet weights can be higher than those utilized for conventional (swallow) tablets, which are usually less than 1000 mg. Antacid tablets, for example, often exceed one gram in total weight. Due to the tablets being orally reduced into particles, there is less need to use oval or capsule shapes, which are preferred for large conventional tablets.

Tablet hardness: Less than 12kp; higher hardness values may be considered if justified (e.g., tablet extract softens or disintegrates after brief (< 30 seconds) exposure to simulated saliva).

Disintegrations: Typically the same specifications as immediate-release tablets important to determine since some individuals may swallow tablets without chewing.

Dissolution

- Typically the same specifications as immediate-release tablets.
- Does not apply to chewable modified-release products.

Others

- In vitro dissolution testing should be conducted on intact chewable tablets since some individuals may swallow tablets without chewing.
- Specific to the individual product (e.g., tablets with functionally coated particles should not be adversely affected by chewing.
- Tablet size, shape, thickness, friability, palatability

The chewing difficulty index is discussed in the guidance. However limits are not provided.

PLANT AND EXCIPIENT PROFILE

Biological Source: *Solanum nigrum* linn

Taxonomical Classification

Division : Embryophyte

Kingdom : Plantae- Plants

Subkingdom : Racheobionta- Vascular plants

Super division : Spermatophyte- seed plants

Division : Magnoliophyte- Flowering plants

Sub-division : Angiospermae

Class : Magnoliopsida Dicotyledonae

Order : Tubeflorae

Sub-order : Solanales

Family : Solanaceae

Genera : *Solanum*-nightshade

MATERIALS AND METHODOLOGY

The materials used in the present work are as follows,

S.NO	Materials	Source (Gift sample or Purchase)
1.	<i>Solanum nigrum</i> L. (Unripe Fruit)	Collected from Natural source
2.	Natural sweetener	S.D Fine chemicals, Mumbai
3.	Mannitol powder	Kroda Excipients
4.	Spearmint Oil	Bright Labs (Hyderabad)
5.	Magnesium Stearate	Abitec Corporation (USA).
6.	Citric acid	Astra Chemicals
7.	Microcrystalline cellulose	Abitec Corporation (USA).
8.	Pregelantized starch	Panchamrut Chemicals
9.	Sucralose	S.D Fine chemicals, Mumbai

Equipments Used

The equipment used in the present work are as follows,

S.NO	Application/parameter measurement	Instrument/ Equipment
1.	To measure pH of system	PH meter (Elico LI127, INDIA)
2.	To measure the weight of ingredients	Electronic/ digital weighing balance (Sartorius CP124S, India & Swisser Instrument, India)
3.	To measure how quickly and completely a drug releases its active ingredients	Electrolab Tab. Disso.tester USP–TDT– 06P
4.	To measure the resistance of a material to deformation	Monsanto Hardness Tester Cadmach
5.	To transforms powdered or granulated materials into solid tablets of uniform size, shape, and weight	Tablet compression machine ACG Worldwide.
6.	To assess the mechanical strength of tablets	Electrolab Friabilator (USP) – EF-1W
7.	To measure the absorbance and concentration	UV/Visible Spectrophotometer (Shimadzu 1700, Japan)
8.	Generation of IR spectra	FTIR Spectrophotometer
9.	To determine how quickly tablets or capsules break down into smaller particles when exposed to a liquid medium	Disintegration
10.	Solubility of drug in liquid	Sonicator Optics technology
11.	To improve mixing of liquids or improve solubility of solid in liquid	Vortex mixer (Remi elektrotechnik limited)

METHODOLOGY

Plant Collection and Authentication

Solanum nigrum Unripe fruits plant was collected from Gollapalle Village, Eluru District, Andhra Pradesh and India. The process of isolating secondary plant metabolites is initiated with a crucial step – the selection of the plant. This pivotal aspect of the project is guided by ethnobotany, a discipline that delves into the study of plants significant to primitive people. Ethnobotany, often referred to as "people's botany," encompasses an interdisciplinary approach, combining botany with fields such as chemistry, pharmacology, and anthropology. The investigation into medicinal properties of plants has gained prominence globally due to their potent pharmacological activities, low toxicity, and economic viability. Ethnobotany, specifically focused on present-day practices, aids in locating plants with historical significance. The library search provides details of folk medicinal plants used in specific areas, ensuring the availability of plants for collection purposes.

Preparation of Dry Powdered Samples

The unripe fruits of *Solanum nigrum* were washed to remove dust and dried under shade for

about 25 days at 30±2°C temperature. 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.

Preparation of Plant Extracts

In this process, 500gm of the Unripe fruits 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 at least nine 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 and also sunlight. Finally dried form of powder was obtained and the dried extract was collected and stored in a desiccators to avoid the moisture absorption.

QUALITATIVE PHYTOCHEMICAL ANALYSIS

Phytochemical evaluation is used to determine the nature of phytoconstituents present in the plant. Therefore a complete investigation is required to characterize the phytoconstituents qualitatively. The chemical tests for various phytoconstituents in the extracts of unripe fruit of *Solanum nigrum* were carried out as described below:

1. Test for carbohydrates

Molisch's Test: Filtrate was treated with 2-3 drops of 1% alcoholic - naphthol solution and 2 ml of Con. Sulphuric acid was added along the sides of the test tube. Appearance of brown ring at the junction of two liquids shows the presence of carbohydrates.

2. Test for Tannins

Ferric chloride test: The filtrate was treated with 5% FeCl₃ solution. A violet precipitate was formed which indicates the presence of phenolic compounds and tannins.

3. Test of Alkaloids

A small portion of the extracts were stirred separately with few drops of dil. HCl and filtered. The filtrate was tested with various reagents for the presence of alkaloids. The reagents are:

Dragendroff's reagent-Reddish brown/orange brown precipitate Mayer's reagent-Creamy white color precipitate Wagner's reagent-Brown color precipitate Hager's reagent -Yellow precipitate.

4. Test for Flavonoids

Alkaline reagent test: The extract was treated with aqueous sodium hydroxide solution - Blue to violet color (anthocyanins) yellow color (flavones), yellow to orange (flavonones).

5. Test for Saponins

Foam test: The extract was diluted with 20ml of distilled water and it was agitated on a graduated cylinder for 15 minutes. The presence of saponins was indicated by formation of layer of foam.

6. Test for Glycosides

Modified Bontrager's test: The aqueous solution of sample is treated with ferric chloride solution and dilute hydrochloric acid. shake well and the solution is added to organic solvent like carbontetra chloride or ether. the organic layer is separated and shaken with dilute ammonia. The ammonical layer shows rose-pink colour, which indicates presence of c-glycosides.

7. Test for Phenols

Lead acetate test: Few ml of filtrate was treated with lead acetate solution, a white precipitate was formed which indicates the presence of phenolic compounds and tannins.

8. Tests for Steroids and Triterpenoids

A small portion of extract was dissolved in 1ml of chloroform and filtered. To the filtrate on ice, 1ml of acetic acid was added and then a few drops of conc. H₂SO₄ were run down the sides of the test tube. The appearance of a pink or pinkish brown ring/colour indicates the presence of terpenoids. The appearance of blue, bluish-green, or a rapid change from pink to blue colour indicates the presence of steroids and a combination of pink and these colour indicates the presence of both steroids and terpenoids.

PRE FORMULATION STUDIES

Preformulation studies like fundamental characterization studies (Organoleptic properties, melting point, and loss on drying, solubility, and pH) and spectroscopic studies (UV and IR)

were performed on drug sample.

CALIBRATION CURVE USING UV- VISIBLE SPECTROSCOPY

The standard stock solution of solanum nigrum.L. Unripe fruit extract was prepared by accurately weighing and transferring 10 mg of the extract to 100 ml of volumetric flask.

- 1) Then 2ml of the solution was added to 10ml volumetric flask and final volume was made up with phosphate buffer(PH 6.2±0.2) to get final standard solution(20µg/ml) Solanum nigrum L. unripe fruit extract.
- 2) Then 4ml of the solution was added to 10ml volumetric flask and final volume was made up with phosphate buffer(PH 6.2±0.2) to get final standard solution(40µg/ml Solanum nigrum L. unripe fruit extract.
- 3) Then 6ml of the solution was added to 10ml volumetric flask and final volume was made up with phosphate buffer(PH 6.2±0.2) to get final standard solution(60µg/ml) Solanum nigrum L. unripe fruit extract. Then 8ml of the solution was added to 10ml volumetric flask and final volume was made up with phosphate buffer(PH 6.2±0.2) to get final standard solution(80µg/ml) Solanum nigrum L. unripe fruit extract.

FORMULATION OF CHEWABLE TABLET BY DIRECT COMPARSION METHOD

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 15 min by using poly bag.

Step: 3 Magnesium Stearate is sifted through 40 # added with Step: 2 mixing for 5 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.

Weighing	Done by using analytical balance
Sieving	Raw materials are sifted through Sieve No. (Mesh) 44
Blending	Done by using pharma-grade polyethylene (LDPE)
Lubrication	Magnesium stearate is sifted Sieve No.85
Compression	Compression is done by using caplet punch size- 12 × 5 mm (Standard adult dose)
Optional Coating	NA

Name of ingredients	Quantity of ingredients in mg			
	Formulation-1	Formulation-2	Formulation-3	Formulation-4
Powdered Solanum nigrum (Active drug)	300	300	300	300
Microcrystalline cellulose	25	25	25	25
starch (Pregelatinized)	60	58	61	59
Sucralose	15	14.5	16	14.5
Mannitol	212	220	219	215
Citric acid	30	25	20	28
Spearmint Oil	1	1.5	1	1
Magnesium Stearate	7	6	8	7.5
Total tablet weight	650	650	650	650

RESULTS 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.

Phytochemical screening

S. No	Extract	Physical nature	Colour	Percentage Yield (%w/w)
1.	Ethanolic Extract	Solid Powder in nature	Pista Green to brownish in colour	9.6

S. No	Phytochemical constituents	Results
1	carbohydrates	-
2	Tannins	+
3	Alkaloids	+
4	Flavonoids	+
5	Saponins	-
6	Glycosides	+
7	Phenols	+
8	Steroids and Triterpenoids	-

PRE FORMULATION STUDIES ORGANOLEPTIC PROPERTIES

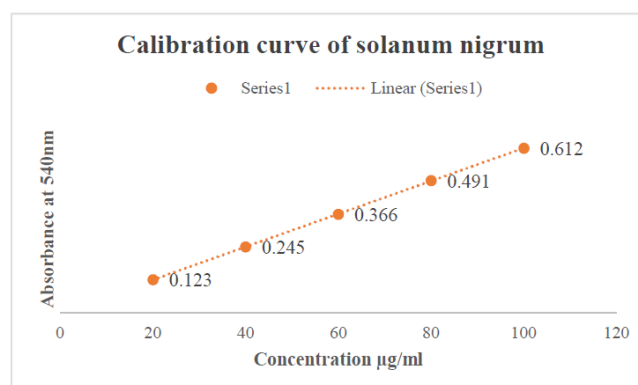
S.NO	ORGANOLEPTIC	PROPERTIES
1.	Appearance	Granular powder
2.	Colour	Sage green to Creamiest white colour
3.	Taste	Spearmint Oil
4.	Odour	Herbal Odour
5.	Melting range	155-157°C

SOLUBILITY TEST

S.NO	SOLVENT	RESULT
1.	Water	+
2.	Methanol	+
3.	Ethanol	+
4.	Petroleum ether	-
5.	Chloroform	-
6.	Dilute Sodium hydroxide	+
7.	Dilute Hydrochloric acid	+
8.	PEG	-

Calibration curve of solanum nigrum

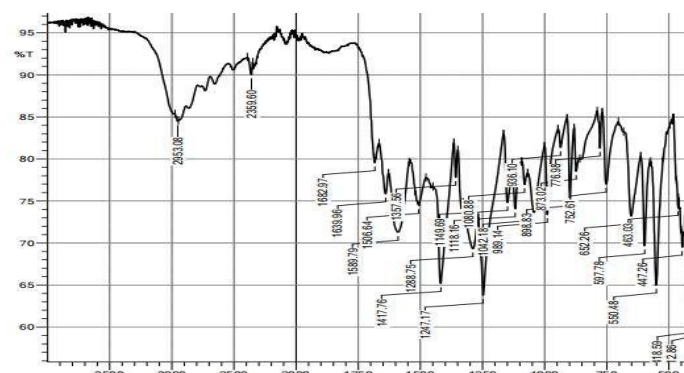
Concentration (µg/ml)	Absorbance at 540 nm
20	0.123
40	0.245
60	0.366
80	0.491
100	0.612



IDENTIFICATION OF PLANT EXTRACT OF SOLANUM NIGRUM BY FTIR SPECTROSCOPY

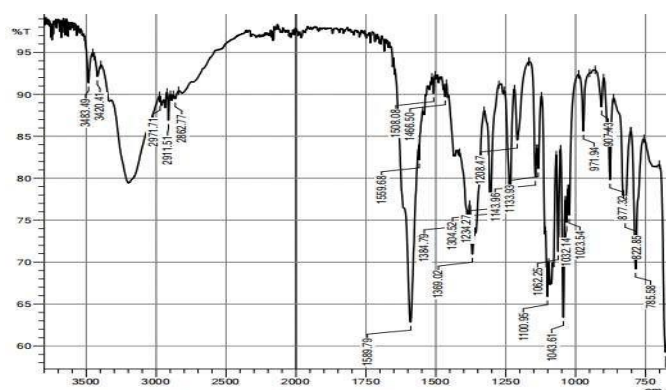
COMPATIBILITY STUDIES USING FTIR SPECTROSCOPY

Powdered Solanum nigrum



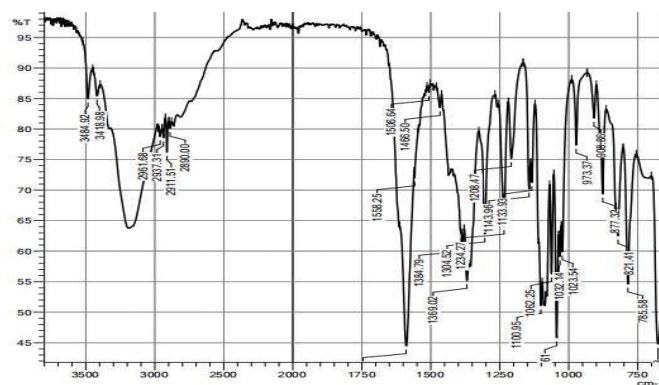
S.No	Interpretation	IR absorption Bands cm^{-1}	
		Characteristic peak	Observed peak
1	O-H Stretch	3200-3600	3355
2	C-H Stretch	2850-2950	2911.51
3	C=C Stretch	1680-1820	1682.97
4	C-N Stretch	1000-1250	1222.45
5	C=O Stretch	1700-1900	1859.23

Powdered Solanum nigrum + Microcrystalline cellulose

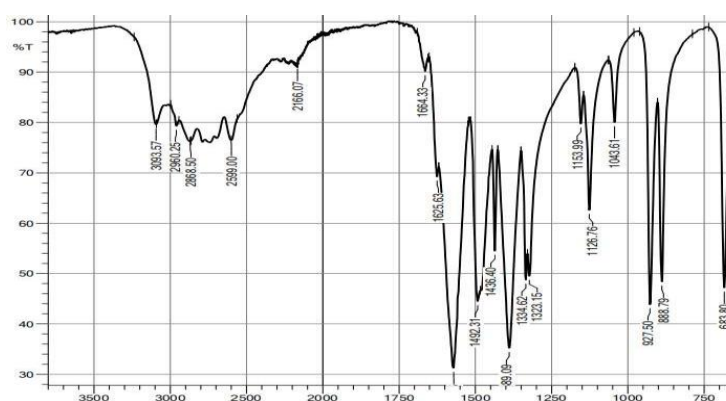


S.No	Interpretation	IR absorption Bands cm^{-1}	
		Characteristic peak	Observed peak
1	O-H Stretch	3200-3600	3346.23
2	C-H Stretch	2850-2950	2857
3	C=C Stretch	1680-1820	1818
4	C-N Stretch	1000-1250	1100.95
5	C=O Stretch	1700-1900	1733

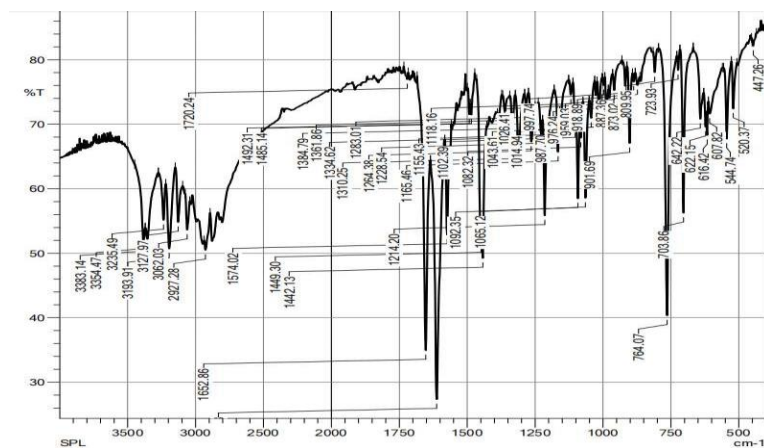
Powdered Solanum nigrum + Starch (Pregelatinized)



S.No	Interpretation	IR absorption Bands cm^{-1}	
		Characteristic peak	Observed peak
1	O-H Stretch	3200-3600	3256
2	C-H Stretch	2850-2950	2890
3	C=C Stretch	1680-1820	1791
4	C-N Stretch	1000-1250	1208.47
5	C=O Stretch	1700-1900	1834

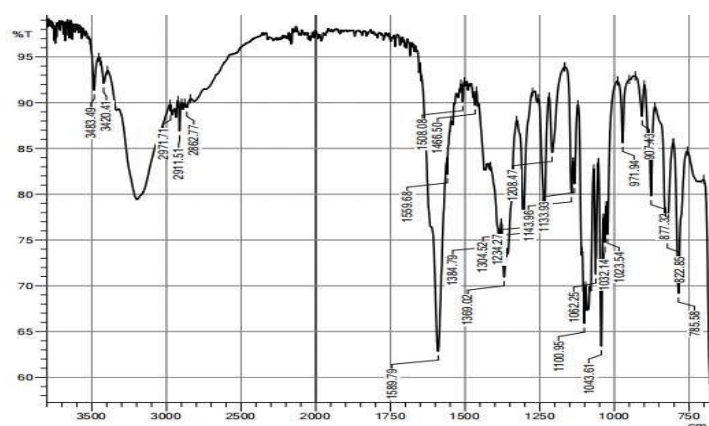
Powdered Solanum nigrum + Sucralose

S.No	Interpretation	IR absorption Bands cm^{-1}	
		Characteristic peak	Observed peak
1	O-H Stretch	3200-3600	3093.57
2	C-H Stretch	2850-2950	2672
3	C=C Stretch	1680-1820	1664.33
4	C-N Stretch	1000-1250	1126.76
5	C=O Stretch	1700-1900	1856

Powdered Solanum nigrum+ Magnesium Stearate

S.No	Interpretation	IR absorption Bands cm^{-1}	
		Characteristic peak	Observed peak
1	O-H Stretch	3200-3600	3354.47
2	C-H Stretch	2850-2950	2927.28
3	C=C Stretch	1680-1820	1720.24
4	C-N Stretch	1000-1250	1065.12
5	C=O Stretch	1700-1900	1848

Powdered Solanum nigrum + Mannitol



S.No	Interpretation	IR absorption Bands cm ⁻¹	
		Characteristic peak	Observed peak
1	O-H Stretch	3200-3600	3282.23
2	C-H Stretch	2850-2950	2862.77
3	C=C Stretch	1680-1820	1688.24
4	C-N Stretch	1000-1250	1043.61
5	C=O Stretch	1700-1900	1862.77

Evaluation of The Plant Extract Parameters for Pre-Compression

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

S.No	Parameters	Formulation-1	Formulation-2	Formulation-3	Formulation-4
1.	Loss on drying	1.11345%	1.56434%	1.36567%	1.26576%
2.	Tapped Density	0.628 gm/ cm ³	0.635 gm/ cm ³	0.630 gm/ cm ³	0.624 gm/ cm ³
3.	Bulk Density	0.521 gm/ cm ³	0.530 gm/ cm ³	0.524 gm/ cm ³	0.529 gm/ cm ³
4.	Hausner Ratio	1.397	1.333	1.367	1.345
5.	Angle Of Repose	29.50 °	28.99 °	30.14 °	34.25 °
6.	Compressibility Index	28.40%	26.86%	20.38%	24.44%

DISCUSSION

The Loss on drying of all formulations was found between 1.1-1.5% which indicates the for all the formulations the % LOD of the all formulations were found to comply within the limits specified and it should not affect the disintegration process of the formulations.

The angle of repose of all formulations was found between 28.99-34.25° which indicates the flow type of powder blend was passable.

The flow properties of all the formulations are in the increasing order of: Formulation-2 <

Formulation-1 < Formulation-3 < Formulation-4

The bulk density was found between 0.521-0.530 g/cm³, tapped density was found between 0.624-0.635 g/cm³.

Carr's index was found in the range of 20.38% to 28.40 % which indicates the for all the formulations the compressibility index of the formulations was found to comply within the limits specified and shown good compressibility index.

Hausner's ratio ranges between 1.333 to 1.397. The above results in terms of micromeritic properties revealed that the flow property of all formulation was passable and within the acceptable limit.

Parameters for Post-Compression Description

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

Colour - Sage green to Creamiest white colour

Shape - Caplet Shape

Surface - Smooth surface

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

S.No	Parameters	Formulation-1	Formulation-2	Formulation-3	Formulation-4
1.	Hardness (kg /cm ²)	5.99	6.82	6.23	6.34
2.	Thickness (mm)	6.00	5.99	5.87	5.96
3.	Friability (%)	0.17	0.19	0.29	0.20
4.	Weight Variation (mg)	647	651	646	648

DISCUSSION

Thickness and Hardness

The hardness of the tablets was measured and the values were found in the range between 5.99 to 6.82 kg/cm².

The thickness of tablets was measured and was found in the range between 5.87 to 6.00 mm. All the formulation possessed uniform thickness.

Weight Variation and Friability

Test all formulations of tablets passed the weight variation test since the values are within the acceptable variation limit ($\pm 20.0\%$) 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.

Assay and Disintegration Time

Assay were determined by using ultra-violet Spectrophotometer with the wavelength of 540nm.

S.No	Parameters	Formulation-1	Formulation-2	Formulation-3	Formulation-4
1.	Disintegration Time (Min)	2 min 44 sec	2 min 59 sec	2 min 45 sec	2 min 57 sec
2.	Assay (%)	100.11	100.21	100.32	100.06

DISCUSSION

The content of the chewable tablets were found in the range between 98.00 -102.00%. 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 2.00 to 3.00 minutes. Specification limit of disintegration time for uncoated tablet from I.P is NMT 10 minutes.

STABILITY STUDIES

The stability study was carried out for 3 months. In this study contains the sample was stored at $25\pm 2^{\circ}\text{C}/60\%\pm 5\%\text{RH}$ and $40\pm 2^{\circ}\text{C}/75\%\pm 5\%\text{RH}$ 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.

Storage condition at $25\pm 2^{\circ}\text{C}/60\%\pm 5\%\text{RH}$ -(Room Temperature)-Long Term stability condition

S. No.	Storage Conditions: $25\pm 2^{\circ}\text{C}/60\%\pm 5\%\text{RH}$				
	PATRAMETER	INITAL PERIOD	1 ST MONTH	2 ND MONTH	3 RD MONTH
1	Physical appearance	Sage green to Creamiest white colour	Sage green to Creamiest white colour	Sage green to Creamiest white colour	Sage green to Creamiest white colour
2	Weight variation test (mg)	651	652	651	650
3	Thickness (mm)	5.99	5.97	5.98	5.97
4	Hardness (Kg/cm^2)	6.82	6.81	6.79	6.79
5	Friability (%)	0.19	0.20	0.19	0.18
6	Disintegration time	2 min 59 sec	2 min 40 sec	2 min 38 sec	2 min 35 sec

	(min.)				
7	Drug content	100.21	100.11	100.05	99.88

Storage condition at 40±2°C/75%±5%RH- Accelerated Term stability condition

S. No	Storage Conditions: 40±2°C/75%±5%RH				
	PATRAMETER	INITAL PERIOD	1 ST MONTH	2 ND MONTH	3 RD MONTH
1	Physical appearance	Sage green To Creamiest white colour	Sage green to Creamiest white colour	Sage green to Creamiest white colour	Sage green to Creamiest white colour
2	Weight variation test (mg)	651	649	648	647
3	Thickness (mm)	5.99	5.97	5.96	5.95
4	Hardness (Kg/cm ²)	6.82	6.80	6.78	6.78
5	Friability (%)	0.19	0.18	0.19	0.18
6	Disintegration time (min.)	2 min 59 sec	2 min 43 sec	2 min 36 sec	2 min 37 sec
7	Drug content	100.21	100.02	99.91	99.85

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.

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