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Extraction, Formulation and Evaluation of Panax Ginseng Extract Tablet

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Abstract
The objective of the present study was to formulate sustained-release matrix tablets of Panax ginseng extract, for Helps in managing stress. The matrix tablets were prepared by direct compression method using various synthetic polymers in various concentrations. The powder showed satisfactory flow properties and compressibility. All the formulations showed acceptable pharmacopoeia standards. The result of formulation F4. Successful formulation was found stable after evaluation for physicochemical parameters when kept for 90 days at 40^0C ±20C, 75% ± 5% RH for 3 months. It concluded that sustained release matrix tablets of Panax ginseng extract containing Ethyl cellulose provide a better option for the Sustained release of the drug.

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1. Introduction

Panax ginseng C.A. Meyer, belonging to the family Araliaceae, is one of the most extensively studied and widely used medicinal plants in traditional Chinese, Korean, and Asian medicine. It is commonly referred to as "ginseng" and is renowned for its adaptogenic, immunomodulatory, antioxidant, anti-inflammatory, antidiabetic, and neuroprotective properties. [1] Extraction is a critical step in the development of herbal formulations, as it directly influences the yield, quality, and concentration of active constituents. [2] Selection of an appropriate extraction technique and solvent system is essential to obtain a reproducible and pharmacologically potent extract. Moreover, transforming herbal extracts into solid oral dosage forms such as tablets offers several advantages, including accurate dosing, improved stability, ease of administration, patient compliance, and convenience in handling and transportation. [3] However, formulation of herbal extract tablets presents unique challenges due to the complex nature of plant extracts, which may affect flow properties, compressibility, and tablet integrity. [4] Therefore, systematic formulation development and evaluation are necessary to ensure the production of tablets with acceptable physicochemical and mechanical characteristics. Evaluation parameters such as pre-compression flow properties, post-compression tablet characteristics, disintegration time, dissolution behavior, and stability play a crucial role in determining the quality and performance of the final dosage form. [5] Standardization and quality control of herbal tablets are essential to bridge the gap between traditional herbal medicine and modern pharmaceutical practice. [6] The present research work is aimed at the extraction of Panax ginseng, formulation of the extract into tablet dosage form, and comprehensive evaluation of the prepared tablets to ensure their quality, safety, and suitability for oral administration. [7] The study seeks to contribute to the development of a standardized and pharmaceutically acceptable Panax ginseng tablet that can enhance therapeutic efficacy and patient compliance.

Materials

Panax ginseng extractwere collected from the Tirupati. HPMC and Ethyl cellulosewere obtained from Synpharma Research Labs, Hyderabad. Other chemicalsand the reagents used were of analytical grade.

Methodology

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR spectroscopy Panax ginseng extract discs were created by compressing the Panax ginseng extract with KBr and the spectra was scanned in the range between 4000 to 400 cm-1. Perfect operational conditions were maintained. The absorption maxima which is denoted as max in spectrum obtained with the drug substance is compared with the intensity to those of reference spectrum. [8]

Extraction Process [9]

Preparation of Sample:

- Dry Panax ginseng roots under shade and grind to a coarse powder (40–60 mesh).
- Weigh about 20–30 g of the dried powder.
- Setup of Soxhlet Apparatus:
- Place the weighed powder into a thimble made of filter paper.
- Insert the thimble into the Soxhlet extractor.

Solvent Addition:

- Fill the round-bottom flask with 200–300 mL of ethanol
- Attach the Soxhlet extractor and condenser properly.

Heating:

- Heat the solvent gently using a heating mantle
- The solvent will evaporate, condense in the condenser, and drip into the thimble.
- The solvent repeatedly extracts the phytochemicals from the powder over 6–8 hours or until the solvent in the siphon becomes clear.

Collection:

- After extraction, allow the setup to cool.
- Transfer the extract-containing solvent from the flask to a separate container.

Concentration of Extract:

- Concentrate the extract using a rotary evaporator or by evaporation on a water bath at ~40–50°C.

Drying and Storage:

- Dry the concentrated extract in a desiccator
- Store in an airtight container in a cool, dark place.

Preparation of Panax ginseng extract tablets:

Table 1: Formulation Table of Panax ginseng extract sustained release tablets

S.NO.	Ingredients	F1	F 2	F 3	F 4	F 5	F 6
1	Panax ginseng extract	100	100	100	100	100	100
2	HPMC	50	100	150	-	-	-
3	Ethyl cellulose	-	-	-	50	100	150
4	Microcrystalline Cellulose	145	95	45	145	95	45
5	Magnesium stearate	3	3	3	3	3	3
6	Talc	2	2	2	2	2	2
7	Total Wt.	300	300	300	300	300	300

Direct compression technique

Sustained release matrix tablets of Panax ginseng extract were prepared by direct compression. All the ingredients were passed through 40-mesh separately. Then the ingredients were weighed and mixed in geometrical order and compressed into tablets of 300 mg using 10mm round flat punches on 8-station rotary tablet machine (Rimek). [10]

Evaluation parameters

Weight variation: Twenty tablets were randomly selected form each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weight deviates from the average weight by more than the percentage. [11]

Thickness: Twenty tablets were randomly selected form each batch and their thickness were measured by using vernier caliper. Thickness of three tablets from each batch was measured and mean was calculated. [12]

Hardness: Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm^2. Three tablets were randomly picked and hardness of the tablets were determined. [13]

Friability: Friability test is performed to assess the effect of friction and shocks, which may often cause tablet to chip, cap or break. Roche friabilator was used for the purpose. This device subjects a number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at distance of 6 inches with each revolution. Twenty tablets were weighed and placed in the Roche friabilator, which was then operated for 25 rpm for 4 min. After revolution Tablets were dedusted and reweighed. Compressed tablets should not lose more than 1% of their weight. [14]

The percentage friability was measured using the formula,

$$\% F = \{1-(Wo/W)\} \times 100$$

Where,

% F = friability in percentage

Wo = Initial weight of tablet

W = weight of tablets after revolution

Content Uniformity:
The drug content directly relates to the pharmacological efficacy, so it is mandatory to do the drug content test. It is an official quality control test. The drug content in all formulations were analyzed by triturating 20 tablets in mortar and pestle, then from the powder 75 mg equivalent of Panax ginseng extract was taken and transferred to 100ml standard volumetric flask. Then the volume was prepared to 50ml with pH 6.8 phosphate buffer. This was shaken for 15 min to mix. Then the volume was prepared to 100ml with phosphate buffer. The solution was strained by using whatmann filter paper and then it is diluted and absorbance was determined by using UV-Visible spectrophotometer at 210 nm using pH 6.8 phosphate buffer as blank. [15]

Disintegration time: The disintegration time of tablets was determined by using Disintegration test apparatus (scientific). Tablets were placed in disintegration test assembly and disc was placed on tablets in each glass tube of assembly. The assembly was dipped in a vessel containing 900 ml distilled water at 37°C. The time for disappearance of tablet residue above mesh was noted as disintegration time. [16]

***In- Vitro* Release study:** *In-Vitro* drug release studies were carried out using Tablet dissolution test apparatus USP II at 100 rpm. The dissolution medium consisted of 900 ml of Standard buffer pH 1.2 for the first 2 hrs, followed by pH 6.8 for remaining period of time. Temperature maintained at 37 ± 5^0.The sample of 5ml was withdrawn at predetermined time intervals and an equivalent amount of fresh dissolution fluid equilibrated at the same temperature was replaced. From that 5 ml sample, 1 ml sample was withdrawn and placed in a 10 ml volumetric flask and make the volume with distilled water. The diluted samples were assayed at 210 nm against reagent blank. [17]

Stability studies: The success of an effective formulation can be evaluated only through stability studies. The purpose of stability testing is to obtain a stable product which assures its safety and efficacy up to the end of shelf life at defined storage conditions and peak profile. The prepared Matrix tablets of Panax ginseng extract were placed on plastic tubes containing desiccant and stored at ambient conditions, such as at room temperature, 40±2ºc and refrigerator 2-8ºc for a period of 90 days. [18]

Results and Discussion

FT-IR Spectrum of Panax Ginseng Extract

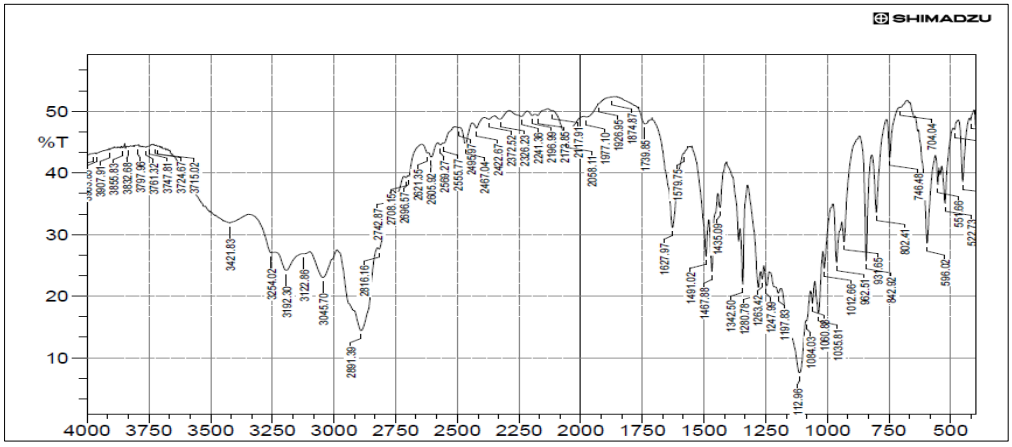

Fig 1: FT-IR Sample for Panax ginseng extract

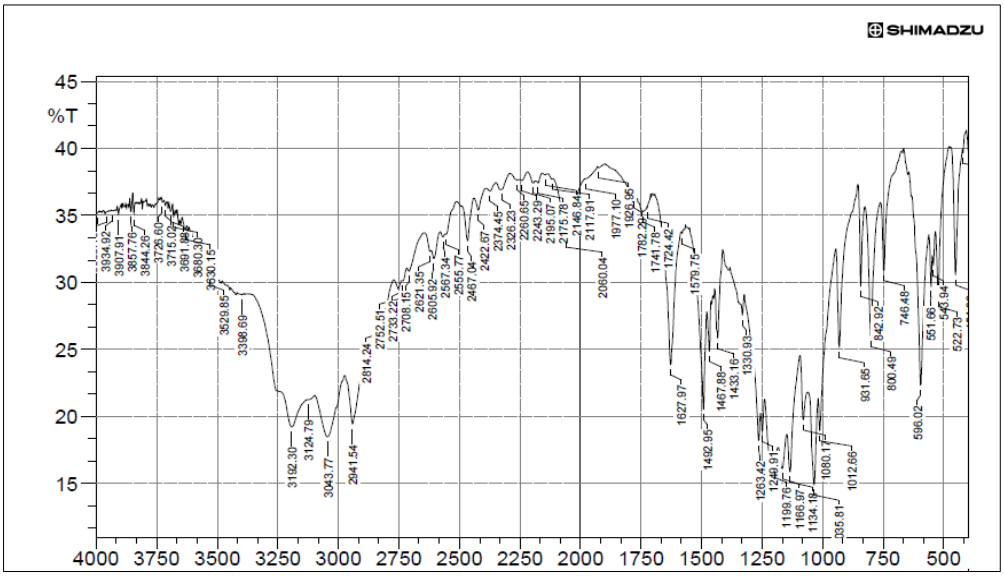

Fig 2: FT-IR Sample for Optimized formulation

Evaluation parameters

Weight variation: All the formulated (F1 to F6) tablets passed weight variation test as the % weight variation was within the pharmacopoeia limits of ±7.5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values.

Thickness: Tablets mean thickness were uniform in F1 to F4 formulations and were found to be in the range of 2.1 mm to 2.7 mm.

Hardness: The measured hardness of tablets of each batch ranged between 3.2 to 3.7 kg/cm^2. This ensures good handling characteristics of all batches.

Friability: The % Friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

Content Uniformity: The percentage of drug content for F1 to F6 was found to be between 81.46% to 89.69% of Panax ginseng extract, it complies with official specifications.

Disintegration Time: In the presented studies, three different types of *in vitro* methods of tablet disintegration were used: those where the only factor leading to the disintegration was water wicking into the matrix of the tablet, the tests with water agitation or stirring, and the methods where direct destructive forces were put on the tested tablet, such as grinding or pressing with additional weight. Therefore, disintegration tests showed great variability in the data measured with different methods.

Table 2: Evaluation parameters of Panax ginseng extract SR tablets

F. No.	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Drug content (%)	Disintegration time (min)
F1	300	2.3	3.5	0.26	83.49	16
F2	299	2.5	3.2	0.29	82.40	17
F3	301	2.1	3.4	0.27	86.37	14
F4	300	2.6	3.3	0.22	89.69	12
F5	300	2.7	3.5	0.28	88.52	16
F6	299	2.5	3.7	0.32	81.46	15

Dissolution studies

All the 6 formulation of Panax ginseng extract tablets were subjected to *in vitro* release studies these studies were carried out using dissolution apparatus. The dissolution medium consisted of 900 ml of Standard buffer pH 6.8 for period of time.

Table 3: Drug release studies of all formulations

Time	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	17.59	18.13	16.89	15.49	17.36	18.12
2	27.86	26.97	27.10	26.38	28.13	27.46
3	37.49	35.10	34.69	35.46	36.91	35.20
4	54.23	55.10	57.48	55.49	56.68	52.34
5	65.78	66.78	67.90	65.42	64.92	65.50
6	74.18	72.19	71.16	73.20	75.15	76.34
7	86.10	85.62	84.28	85.16	84.62	85.19
8	94.68	95.16	93.56	97.15	93.64	95.46

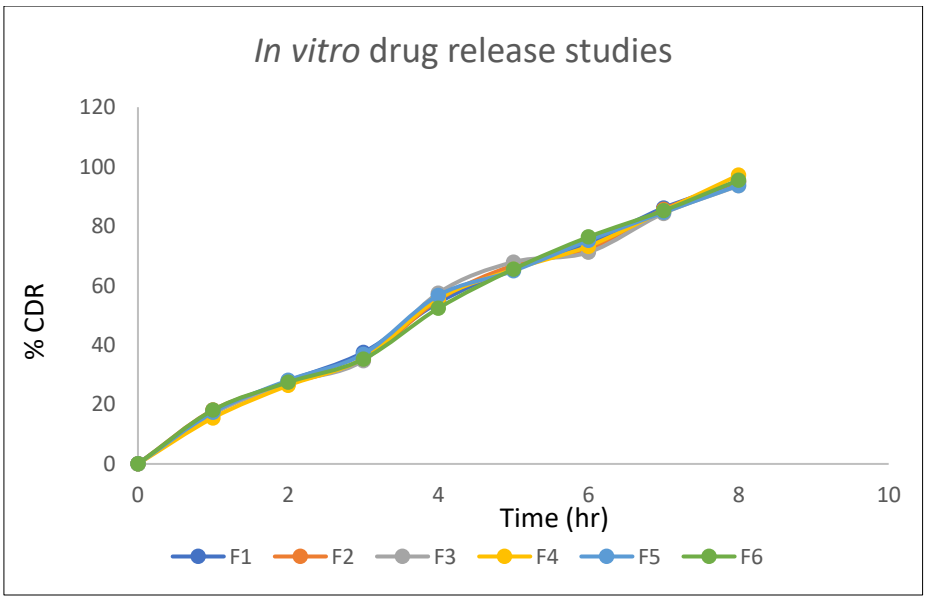

Fig 3: Dissolution Profile of F1 to F6 formulations

Cumulative Drug release of F4 formulation shows 97.15% within 8 hr. better drug release when compared with other formulations.

Stability Study

There was no significant change in physical and chemical properties of the tablets of formulation F-4 after 90 days. Parameters quantified at various time intervals were shown.

Table 4: Stability studies of all formulations

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-4	25^0C/60%RH % Release	97.15	96.39	95.67	94.63	Not less than 85%
F-4	30^0C/75% RH % Release	97.15	96.20	95.28	94.51	Not less than 85%
F-4	40^0C/75% RH % Release	97.15	96.42	95.14	94.25	Not less than 85%

Conclusion

From the above experimental results, it can be concluded that sustained-release tablets of Panax ginseng can be prepared by using different proportions & combination of Excipients and we selected F4 as the best formulation based on dissolution profile and physical characteristics. Formulation (F4) showed total drug release in 8 hr. and showed fair flow properties when compared to other formulations.

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