**Original Research Article**

**DEVELOPMENT AND EVALUATION OF POLYHERBAL DISPERSIBLE TABLETS USING AQUEOUS LEAF EXTRACTS**

**ABSTRACT**

The increasing demand for natural and herbal medicines has prompted the exploration of polyherbal formulations as viable therapeutic options. Dispersible tablets offer advantages such as ease of administration and rapid onset of action. The objective of this study was to develop and evaluate polyherbal dispersible tablets incorporating aqueous leaf extracts of *Camellia sinensis*, turmeric, grape seed, oregano, and *Salvia officinalis*. Polyherbal dispersible tablets were formulated and evaluated for their physicochemical properties, disintegration, and stability. Various extracts, including those from *Camellia sinensis*, turmeric, grape seed, oregano, and *Salvia officinalis*, were used. Micromeritic properties, such as angle of repose, bulk density, and Hausner ratio, were assessed. The results revealed that the prepared polyhedral dispersible tablets were non-sticky and looked high-quality. The maximum weight variation obtained was 2.50%, which falls within the acceptable weight variation range, i.e., ±5%, hence passing the weight variation test. The hardness of prepared tablets was in the range of 2.94 to 3.02 kg/cm2, which falls within the limit of not < 3.0 kg/cm2. All the tablets showed a friability value at most 0.90%, which is less than the ideal limit, i.e., 1%. Formulation AP4 exhibited superior characteristics, with rapid disintegration time and stable drug release profile. Stability studies further validated the formulation's consistency under varying storage conditions. Preliminary phytochemical screening of the individual drugs and polyherbal formulation confirmed the presence of phytoconstituents such as flavonoids, alkaloids, carbohydrates, gums & mucilage, fats & fixed oils, steroids, glycosides, phenols, saponins but no volatile oils. The findings underscore the potential of polyherbal dispersible tablets as efficient delivery systems for medicinal herbs. Carr's index and Hauser’s ratio showed that the powder mixtures possess good flow properties. AP1 to AP9 were determined for the uniformity in weight, hardness, drug content and friability, which complied with the official requirements and the official limits mentioned in IP 2010.

**Keywords**: Polyherbal formulation, dispersible tablets, micromeritic properties, stability studies, drug release profile

**1. INTRODUCTION**

“At present, most of the present-day medicines have plant origin, as it has been implicated that modern medicine has evolved from folk medicine and traditional systems on the basis of pharmaceutical and chemical screenings carried out. Polyherbal plant extracts, which usually comprise of two or more plant parts, often contain a wide array of key phytoactive constituents relevant in attaining greater therapeutic efficacy” (Idu et al., 2021). “The increasing demand for natural and herbal medicines has prompted the exploration of polyherbal formulations as viable therapeutic options. Dispersible tablets offer advantages such as ease of administration and rapid onset of action” (Sharma & Leel, 2022). The objective of this study was to develop and evaluate polyherbal dispersible tablets incorporating aqueous leaf extracts of *Camellia sinensis*, turmeric, grape seed, oregano, and *Salvia officinalis*. “The study focused on optimizing tablet formulations and assessing their physicochemical properties, disintegration, and stability. The identification of structures with unique biodynamic effects can also lead to an innovative chemical entity trail for drug development” (Parasuraman et al., 2014). “The scope of Reverse Pharmacology is to understand the mechanisms of action at diverse stages of biological organization and to make optimal safety, effectiveness and acceptability of the leads in natural products, based on relevant science. There are two discrete forms of research on medicinal plants. In the first segment, the choice of plant is mainly based on their genuine use and reputation in the Indian traditional system of medicine, although in second stage, more extensive base, in which screening of a large number of natural products for biological activity is commenced, irrespective of the circumstance whether these plants are being used by the traditional system of medicine or not. Herbal medicines include herbs, herbal materials, herbal formulations and finished herbal products” (Saggar et al., 2022). Herbal medicine has perpetually represented a crucial element of primary healthcare. Approximately 80% of the global population is estimated to use herbal medicinal products for their therapeutic benefits (Balkrishna et al., 2024). “Herbs include crude plant material, such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered. Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In several countries, these materials may be treated by various local processes, such as steaming, roasting or stir-baking with honey, alcoholic beverages or other materials” (Garg et al., 2012). “Herbal preparations are the basis for finished herbal products and may comprise powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials” (Qadir & Raja, 2021). They are formed by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations prepared by steeping or heating herbal ingredients in alcoholic beverages and/or honey or in other materials. Finished herbal products consist of herbal preparations made from one or more herbs. If more than one herb is used, the term ―mixture herbal product can likewise be applied. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients.

**2. MATERIALS AND METHODS**

**2.1 Materials**

Fresh leaves of *Camellia sinensis*, turmeric rhizomes, grape seeds, oregano leaves, and *Salvia officinalis* were sourced and authenticated. All reagents and chemicals used were of analytical grade.

**2.2 Extraction Procedure**

The plant materials were dried at 37° C for six days, powdered, and extracted with methanol for 48 hours. Extracts were concentrated using a vacuum evaporator at 50° C, yielding viscous masses stored at 4° C.

**2.3 Preparation of Polyherbal Dispersible Tablets**

### Formulations AP1 to AP9 were prepared using direct compression. Ingredients included polyherbal extracts (250 mg), β-cyclodextrin, microcrystalline cellulose, sodium saccharin, magnesium stearate, and talc. Powdered ingredients were mixed via geometric dilution, sieved through a 120-mesh sieve, and compressed using a rotary tablet compression machine. Formulation and characterization of tablets Polyherbal dispersible tablets were compressed each of 550 mg weight on a 10-station Mini Press-I rotary tablet compression machine fitted with a 12 mm punch size. No tablet manufacturing defects like capping, lamination, and chipping were observed.

### Table 1. Preparation of Polyherbal Dispersible Tablets

|  |  |
| --- | --- |
| Ingredients | **Formulation Code** |
| AP1 | AP2 | AP3 | AP4 | AP5 | AP6 | AP7 | AP8 | AP9 |
| AEP (in mg) | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 |
| Β Cyclodextrin | 215 | 220 | 225 | 230 | 235 | 210 | 200 | 200 | 200 |
| MCC | 65 | 60 | 55 | 50 | 45 | 60 | 65 | 60 | 65 |
| Sod. Saccharin | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Mg. Stearate | 05 | 05 | 05 | 05 | 05 | 15 | 20 | 25 | 20 |
| Talc | 05 | 05 | 05 | 05 | 05 | 05 | 05 | 05 | 05 |
| **Total** | 550 | 550 | 550 | 550 | 550 | 550 | 550 | 550 | 550 |

## **Procedure:**

1. A mixture of powdered herbs of each 250 mg, weighted separately to tablets.
2. After weighing, the powder herbs were pulverized properly using a mortar pestle.
3. After uniform mixing of all the particles, sieving was performed by using sieve No. 85.
4. After that, the powder material was taken for compression. By an automatic tablet compression machine, 25 tablets were compressed. This is how poly-herbal tablets were prepared.
5. All formulations (AP1-AP9) were subjected to evaluation of characteristic parameters like size, shape, colour, and appearance. The colour and shape of all formulations were observed organ optically and found to be similar.

**2.4 Evaluation Parameters**

**Micromeritic Properties**:

* Bulk density
* Tapped density
* Compressibility (Carr’s Index)
* Hausner ratio
* Angle of repose

**Tablet Evaluation**:

* Weight variation
* Hardness
* Friability
* Disintegration time
* In vitro dispersion time

**Stability Studies**: Formulations were subjected to accelerated stability testing under varying temperature and humidity conditions for three months, as per ICH guidelines.

**Dissolution Studies**: In vitro drug release was evaluated using a USP dissolution apparatus. Absorbance was measured at 221 nm to calculate cumulative drug release.

**3. RESULTS AND DISCUSSION**

Characterization of powder the primary characterization of powder and micrometric properties of formulations containing Polyherbal aqueous leaf extracts powder used are mentioned in Table 1.

**Table 2. Micromeritic parameters of polyherbal aqueous root extracts powder (AEP)**

|  |  |
| --- | --- |
| **PARAMETERS** | **EXTRACT(AEP)** |
| BULK DENSITY (GM/ML) | 0.42±0.04 |
| TAPPED DENSITY (GM/ML) | 0.59±0.08 |
| % COMPRESSIBILITY | 20.64 |
| HAUSNER RATIO | 1.39±0.14 |
| ANGLE OF REPOSE ( °) | 26.48±1.02 |

**Table 3. Physical Properties of the tablet**

|  |  |
| --- | --- |
| **Parameter** | **Result** |
| Colour | Dark Buff-Brown |
| Shape | Round, Biconvex |
| Odor | Characteristic odour |
| Taste | Pleasant taste |

The prepared polyhedral dispersible tablets were non-sticky and looked high-quality. The diameter and thickness of tablets was determined using 20 tablets of a single formulation via digital venire scale during the physical study because it permits accurate measurements and provides exact information about variations between tablets of each formulation.

**Table 4. Characterization of polyhedral dispersible tablets**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Formulation Code** | **Average weight****(mg** | **Weight variation****n (%)** | **Content uniformity****ty (%)** | **Hardne ss****(kg/cm)** | **Friability ty (%)** | **Disintegration time (Min)** | **Dispersing time (Min)** |
| AP1 | 560.80±10.2 | 1.93 | 099.85 | 2.94±0.13 | 0.90 | 02.18±0.51 | 2.50±0.6 |
| AP2 | 565.31±8.11 | 2.71 | 103.10 | 3.00±0.12 | 0.86 | 02.00±0.45 | 3.00±0.7 |
| AP3 | 563.28±7.78 | 2.36 | 105.05 | 2.99±0.14 | 0.79 | 01.10±0.10 | 2.00±0.4 |
| AP4 | 562.40±8.01 | 2.30 | 101.25 | 2.91±0.09 | 0.82 | 01.45±0.28 | 2.30±0.6 |
| AP5 | 563.15±9.38 | 2.34 | 102.38 | 2.98±0.13 | 0.90 | 02.08±0.62 | 3.18±0.8 |
| AP6 | 564.13±8.78 | 2.50 | 099.68 | 2.97±0.11 | 0.88 | 01.50±0.58 | 3.00±0.8 |
| **AP7** | 563.18±8.07 | 2.34 | 102.00 | 3.02±0.18 | 0.78 | 02.06±0.70 | 2.55±0.7 |
| **AP8** | 558.34±7.68 | 1.22 | 098.96 | 2.96±0.16 | 0.85 | 02.15±0.55 | 3.25±0.8 |
| **AP9** | 563.63±7.40 | 2.42 | 101.80 | 2.95±0.12 | 0.80 | 01.55±0.60 | 2.24±0.5 |

The maximum weight variation obtained was 2.50%, which falls within the acceptable weight variation range, i.e., ±5%, hence passing the weight variation test. The hardness of prepared tablets was in the range of 2.94 to 3.02 kg/cm2, which falls within the limit of not < 3.0 kg/cm2. All the tablets showed a friability value at most 0.90%, which is less than the ideal limit, i.e., 1%. The disintegration apparatus used for the study was determined using USP (Electro lab-ED2 SAPO). It contains two basket rack assemblies. Each basket rack assembly comprises six glass tubes that are 3 inches long, open at the top and held against ten mesh screens at the bottom. Each tablet was placed in each basket tube, and the basket rack was dipped in a 1-L beaker of distilled water. The dispersion time of polyherbal dispersible tablets was observed by placing two tablets in 100 ml of water in a beaker and gently stirring until dispersed completely. We obtained a smooth dispersion by passing through a sieve screen with a nominal mesh aperture.

***In vitro* dissolution study:**

The dissolution profile of a polyherbal tablet was evaluated by utilizing the USP dissolution equipment II with 900 ml of 0.1 PBS at 37±0.5 degrees Celsius and a stirring rate of 100 revolutions per minute. The absorbance at a wavelength of 221 nm was measured with the assistance of a UV spectrophotometer after various samples totaling 5 ml were removed and replaced with simulated fluid of the same amount at 1, 2, 4, and 8 hours, respectively. The samples were then filtered through Whatman filter paper before the absorbance was measured.

**Table 5. Dissolution profile of a polyherbal tablet**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **TIME****(MIN)** | **PERCENTAGE RELEASED (%)** | **AP1** | **AP2** | **AP3** | **AP4** | **AP5** | **AP6** | **AP7** | **AP8** | **AP9** |
| 15 | 28 | 24 | 30 | 29 | 35 | 25 | 27 | 31 | 21 |
| 30 | 51 | 48 | 53 | 46 | 49 | 39 | 38 | 47 | 34 |
| 45 | 62 | 56 | 68 | 57 | 61 | 51 | 46 | 53 | 47 |
| 60 | 74 | 65 | 73 | 63 | 73 | 64 | 53 | 62 | 53 |
| 75 | 81 | 71 | 81 | 78 | 84 | 76 | 69 | 78 | 61 |
| 90 | 90 | 83 | 89 | 81 | 88 | 85 | 78 | 87 | 82 |

Series1

Series2

Series3

Series4

Series5

Series6

100

90

80

70

60

50

40

30

20

10

0

90

75

60

45

30

15

90

81

74

62

51

83

89

81

71

73

8718

65

56

48

68

53

63

57

46

884

73

61

49

35

24

85

76

64

51

39

25

78

69

53

46

38

27

87

78

62

82

61

53

28

30

29

47

31

53

47

34

21

Time

(Mins)

AP1

AP2 AP3 AP4 AP5 AP6 AP7 AP8 AP9

**% Drug Release**

**Fig. 1 Drug Release Profile**

## **Table 6. Stability Studies of AP1 Formulation**

|  |
| --- |
| **% Drug content at different storage conditions** |
| Timeduration | 25 °C and 60% RH | 30 °C and 65% RH | 40 °C and75 % RH |
| 30 Days | 98.3 | 98.5 | 99.3 |
| 60 Days | 99.5 | 99.3 | 98.3 |
| 90 Days | 99.2 | 99.1 | 97.2 |

**Macroscopical evaluation**

The macroscopic evaluation was carried out to assess the color, odor, taste, shape, and texture of the individual drugs, and the polyherbal formulation was observed and recorded.

## **Physicochemical Analysis**

Physicochemical analysis of individual ingredients and PHF was studied and represented with standard deviation. In physicochemical evaluation, such as total ash, water-soluble ash, acid insoluble ash, water-soluble extractive value, ethanol-soluble extractive value, loss on drying, and pH were evaluated. The ash values demonstrate the presence of inorganic salts present in the drug. The extractive values (water and ethanol soluble extractive value) were resolved. The data gathered from this evaluation was helpful for standardization and obtaining the quality standards for a crude drug as well as for PHF formulations. Determination of these physiochemical constants was according to systems referred to as per WHO guidelines.

## **Preliminary phytochemical screening**

Preliminary phytochemical screening of the individual drugs and polyherbal formulation confirmed the presence of phytoconstituents such as flavonoids, alkaloids, carbohydrates, gums and mucilage, fats and fixed oils, steroids, glycosides, phenols, saponins but no volatile oils.

**Table 7. Preliminary phytochemical screening**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test of Constituents** | **CS Ext.** | **TUR. Ext.** | **GS. Ext.** | **OR. Ext.** | **SO. Ext.** |
| Flavonoids | √ | # | √ | # | √ |
| Alkaloids | √ | # | # | # | # |
| Carbohydrate | √ | √ | # | √ | # |
| Gum/Mucilate | # | # | √ | √ | √ |
| Protein/ Amino Acid | # | √ | # | √ | # |
| Fats | √ | # | # | # | # |
| Steroids | √ | √ | √ | # | √ |
| Glycosides | √ | # | √ | # | # |
| Phenol | √ | # | √ | √ | √ |
| Saponin | √ | √ | # | # | # |
| Volatile Oil | # | √ | √ | √ | √ |

**√: Present, #: Very little or Absent.**

**4. CONCLUSION**

The results from the angle of repose, Carr's index and Hauser’s ratio showed that the powder mixtures possess good flow properties. AP1 to AP9 were determined for the uniformity in weight, hardness, drug content and friability, which have complied with the official requirements and the official limits mentioned in IP 2010. The AP3 showed suitable disintegration properties and in vitro dispersion time compared to other formulations. The FTIR spectroscopy suggests the absence of any chemical interaction between the polyherbal extract and the excipients used in the dispersible tablet. The stable peaks of the drug remained unchanged in the mixtures, showing characteristic functional groups like the alkynes group, aliphatic amines, alkyl halides, an aromatic group, alkanes, alcohols, and the ester possess various medicinal properties. The AP 3 was kept for stability studies, and observed that it was reproducible even after being stored for three months.

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