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Development of Herbal Tablet Formulation: Systematic Approach

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Abstract

In order to develop, any herbal formulations (tablet, capsules, paste etc), the formulation expert must be having sound knowledge of work flow, which is to be adopted while formulating. The factors including traditional claim of plant based drug, its process to develop formulations, its other active ingredients and additional excipients (if needed), are generally referred from traditional books like Ayurveda Sar Samhita, Charak Samhita, Bhaisaj Ratnawali etc. The present attempt is one of the systematic approaches depicting on development of herbal tablet formulations. This review will assist in knowing the process and work protocol while developing herbal tablet.

Keywords: Herbal formulations; Herbs decoction; Ayurvedic pharmacopoeia; Active ingredients

Introduction

Herbs are derived products in different forms as extract, decoction etc and are used to aid the healing of wounds and various illness [1]. The herbs act as tool to prevent from sickness as well as to maintain normal human health. The trends towards herbal therapy are increasing day by day [2,3]. In present time, the dependency on herbal formulations and herb derived products is more. The beauty of herbal product is that it is used to treat various ailments including fever, allergy, anxiety, cognitive and nervous system disorders with least or nil side effects. These herbal products are efficient in causing balance of biochemicals available in body. The biochemical which are affected by herbal products are Serotonin, GABA, 5HT etc. When these herbs are processed to form dosage form, these are termed as Herbal Products such as capsules, syrups, powders, ointments, creams, soap. The formula and other details are generally referred from standard books like the British Pharmacopoeia, Pharmaceutical compounding books, as well as the Herbal Pharmacopoeias. The Ayurvedic Formulary and Herbal Formulary is the key book in the development of a good Herbal/Ayurvedic product. In general, the main components of any

herbal formula are basically two. First is active constituents and another is excipients [4]. Active constituents are responsible for therapeutic actions to alleviate symptoms, and treat/manage disease conditions. Active constituents in pharmaceuticals/herbs are isolated and then processed with different additional ingredients (Tables 1 and 2) [5-7]. We can use other binders also, but natural and inert binders are preferred.

SI. No	Ingredients (mg)	Α	В	С	D
1	Mixture of powdered herbs	450	450	450	450
2	Lactose	-	10	20	30
3	Starch paste (binder)	40	30	20	10
4	Mg stearate	5	5	5	5
5	Talc (mg)	5	5	5	5
Tablet we	Tablet weight 500 mg				

 Table 1: Active constituents in pharmaceuticals/herbs with different ingredients.

SI. No	Ingredients (mg)	Α	В	С	D	E	F
1	Mixture of powdered herbs	450	450	450	450	450	450
2	Lactose	10	20	30	10	20	30
3	Starch (binder)	30	20	10	-	-	-
4	Acacia gum	-	-	-	30	20	10
5	Mg stearate	5	5	5	5	5	5
6	Talc (mg)	5	5	5	5	5	5
Tablet weight 500 mg							

Table 2: Active constituents in pharmaceuticals/herbs with natural and inert binders.

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Guidelines

Followings are some general guidelines and step by step procedures which are to be followed while working on development of herbal tablet formulations [8-14].

- The selected herbs for the formulation must have a traditional claim for their pharmacological activities. The selected herb should be mentioned in the traditional literature like Charak samhita, Bhaisajya Ratnavali, Sushruta Samhita and Dravyguna vigyan etc. or in Ayurvedic Pharmacopoeia.
- The herbs preferably should be collected from their habitat. The phyto-constituents are available rich in quantity if the herbs are collected from their natural habitat.
- The herbs should be authenticated by a Botanist on the basis of characteristics symptoms available in standard text book. There should be a reference number for the herbarium, which will be used at the any time of any reference.
- The herbal material should be cleaned, dried in shade and stored in a well closed container.
- The herbs should be standardized as per Ayurvedic Pharmacopoeia. Following parameters are evaluated while standardization.
- Macroscopy
- Microscopy
- Foreign matter
- Total Ash
- Acid-insoluble ash
- Alcohol-soluble extractive
- Water-soluble extractive

In some cases Thin Layer Chromatography (TLC) is also performed (Table 3). The values obtained must be within the standard limits given in Pharmacopoeia. In case, if the herb is not mentioned in Ayurvedic Pharmacopoeia, the values given in some standard publication should be considered as the limit. The standard methods for these parameters are available in the annexure section of Ayurvedic Pharmacopoeia or other treatises.

- The batch of herbs passed in standardization should only be considered for the further use.
- 2. The dried herbs should be powdered separately.
- The dose of each herb should be decided before formulations. 3. This should be done on the basis of literature available.
- A simple tablet can be formulated by either direct compression or wet granulation. Generally wet granulation is preferred because it gives enough strength to the tablets.

The prepared batches of granules should be dried and following flow properties must be evaluated.

Flow Properties	AR (O)	CI (%)	HR
Excellent	25-30	≤ 10	1.00-1.11
Good	31-35	11-15	1.12-1.18
Fair (aid not needed)	36-40	16-20	1.19-1.25
Passable (many hang up)	41-45	21-25	1.26-1.34
Poor (must agitate, vibrate)	46-55	26-31	1.35-1.45

Very poor	56-65	32-37	1.46-1.59
Very, very poor	≥ 66	≥ 38	≥ 1.60

Table 3: Thin layer chromatography was performed for the prepared batches of granules.

- Bulk density
- Tapped density
- Angle of repose (AR)
- Carr Index (CI)
- Hausners ratio (HR)

If the values are above than passable limit, we can proceed for tablet punching. If it is below the passable limit, we have to improve the flow property of granules. Addition of SiO2, Mg stearate and talc improves the flow property. The formulation table can modified as per need.

- After this, different batches of granules should be punched separately. The formulated tablets should be evaluated on following parameters:
- Appearance
- Size and shape
- Organoleptic properties
- Uniformity of thickness
- Hardness
- Friability
- Weight variation test
- Wetting time
- Water absorption ratio
- *In vitro* disintegration test
- In vitro dissolution studies: For this one marker compound should be identified. The pure marker compound must be procured. The analytical technique must be chosen on the basis of the nature of marker compound. In the case of UV/Visible spectroscopy, a standard curve must be plotted. During dissolution study, the absorbance of elute should be checked and the concentration can be calculated with the help of standard curve.
- The best batch should be selected on the basis of above 1. parameters. Further we can go for more analytical evaluation like finger print development by HPTLC or HPLC or quantitative estimation of marker compounds by HPLC or HPTLC.
- The interaction studies of marker compounds of herbs used in formulation also can be studied by IR spectroscopy.
- 3. Pharmacological studies can be performed.

Conclusion

The herbal formulations especially tablets as Ashwgandha Tablet, Garlic Tablet, Harde Tablet, Neem Leaves Tablet, Karela (Bitter Gourd) Tablet and Triphala Tablets are high in demand. The other formulations like Triphala, Amalaki, and Haritaki tablets are also in high demand. The joint pain, arteriosclerosis, premature aging, arthritis, diabetes, asthma hypertension, laxative and headache are the ailments which can be easily cured by number of herbal tablets.

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