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Comparative standardization studies of marketed Polyherbal tablets

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Abstract
Siddha and Ayurvedha is one of the oldest traditional systems of medicine in the world. There are different formulations which are adequately increase delivery of the drug to our body sites; one of basic formulation is tablet. Tablet is one of the conventional formulations in solid oral dosage form, which are usually used in traditional system of medicines and allopathic medicines. Allopathic formulations like tablets usually maintaining their standards based on the various pharmacopoeia but Ayurvedhic and Siddha proprietary medicines shows lots of troubles in their standardization parameters, why because they consist of multiple herbal crude drugs in one formulation, so it should be prescribed with proper standardization parameters. The present work deals with to evaluation two marketed formulation by performing basic quality control parameters of tablets such as Organoleptic properties, Weight variation, Hardness, Friability, Disintegration of herbal tablets {Alsactil [A] and Alsarex [B]} From the analysis of above parameters, results was observed and all the parameters of both drugs passes the test, within the reference values.

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Introduction

Ayurvedic Medicine, this ancient Vedic knowledge is considered to be one of the oldest healing sciences and has survived until the present generation over many centuries of tradition. Originated in India thousands of years ago, Ayurvedha is known as the "Mother of All Healing" [1]. Ayurvedha is the combination of the Sanskrit words *ayur* (life) and *Veda* (science or knowledge), which means "the science of life," focusing on bringing harmony and balance in all areas of life including mind, body and spirit. The philosophy behind *Ayurvedha* is preventing unnecessary suffering and living a long healthy life. Unlike the allopathic medicines which uses mainly synthetic chemicals designed for specific target receptors and primarily give symptomatic relief. *Ayurveda* is said to be holistic as it aims to integrate and balance body, mind and spirit to prevent illness [2]. Tablets are solid dosage forms containing one or more medicinal substances with or without added pharmaceutical ingredients. Among the pharmaceutical agents used are diluents, disintegrants, colorants, binders, solubilizers, and coatings. Tablets may be coated for appearance, for stability, to mask the bitter taste of the medication, or to provide controlled drug release [3]. Herbal medicines formulations are used to alleviate many types of diseases in the recent world. Because of the similar properties and the combination of the ingredients synergistically increase the efficacy. In market for preparing an herbal product in a suitable solid dosage form preferably tablet [4]. The polyherbal solid, dosage form was formulated by filling the polyherbal powder mixture and granulated into tablet and standardized as per WHO guidelines of quality standardization [5]. Standardization of herbal formulations is essential in order to assess of quality drugs, based on the concentration of their active principle, physical, chemical, physico-chemical standardization and in vitro, in-vivo parameters[6]. The active moieties of herbal medicine are the secondary metabolites of botanical plants [7]. The active phytochemical constituents of individual plants are insufficient to

achieve the desirable therapeutic effects [8].

When combining the multiple herbs in a particular ratio, it will give a better therapeutic effect and reduce the toxicity. The quality assessment of synthetic drugs is comparatively easy compared to polyherbal formulations that possess several herbal extracts with numerous chemical constituents [9]. Tablet design and post-formulation quality monitoring requires qualitative evaluations and assessments of tablet's chemical, physical properties. The standard quality control tests such as diameter, size and shape, uniformity of weight, thickness, hardness, friability, rate of disintegration, dissolution test can be carried out on compressed tablets for their evaluation [10]. Commercially available polyherbal formulations vary widely in quality and in the concentration of their active constituents and this variation could help to explain the variable efficacy of herbal medicines [11].

Materials and Methods

General Appearance

The general appearance of the tablet involves the measurement of a number of attributes such as a tablet's size, shape, color, presence or absence of an odor, taste, surface texture, physical flaws and consistency, and legibility of any identifying markings [12].

Weight Variation Test: (Figure-1)

Weigh individually 20 units selected at random or, for single dose preparations in individual containers, the contents of 20 units, and calculate the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the table and none deviates by more than twice that percentage [13].

Table 1

IP/BP	LIMIT	USP
80 mg or less	±10%	130 mg or less
80-250 mg	±7.5%	130-324 mg
>250 mg	±5%	>324mg

Upper limit = (+) Average weight + (Average weight ×5/ 100)
Lower limit = (-) Average weight - (Average weight ×5/ 100)

Hardness Test: (Figure 2)

Hardness can be defined as the strength of the tablet to withstand the pressure applied. The tablet to be tested was held between a fixed and a moving jaw of Monsanto Hardness Tester. The force applied to the edge of the tablet was gradually increased by moving the screw knob forward until the tablet breaks. The reading was noted from the scale which indicates the pressure required to break the tablet. The hardness of a tablet depends on the weight of the material used, space between the upper and lower punches at the time of compression and pressure applied during compression. The hardness also depends on the nature and quantity of recipients used during formulation. If the finished tablet is too hard, it may not disintegrate in the required period of time and if the tablet is too soft it may not withstand the handing during packing and transporting [10].
LIMIT: Hardness for compressed tablets = 3 to 5 kg/cm^2 [17]

Friablity Test: (Figure 3)

Pre-weighed sample of tablets was placed in the Roche Friabilator tester, which was then operated for 25 rpm and 100 revolutions per minute. Tablets were deducted and reweighed; tablets should not lose more than 1% of their initial weight [14].

Formula

$$\% \text{ Friability} = \frac{\text{Tablet weight before friability} - \text{Tablet weight after friability} \times 100}{\text{Tablet weight after friability}}$$

LIMIT: Less than 1 % [18]

Disntegration Test: (Figure 4)

The disintegration test was performed using Electro lab disintegrating apparatus. One tablet was placed in each of the six tubes of the basket and the apparatus was maintained at 37 ± 0.50°C of the immersion liquid (0.1M HCL and 0.5M HCL). The time required for complete disintegration of tablet was noted [15].

Limit

Uncoated tablet = not more than 45 mins
Coated tablet= not more than 60 mins [19]

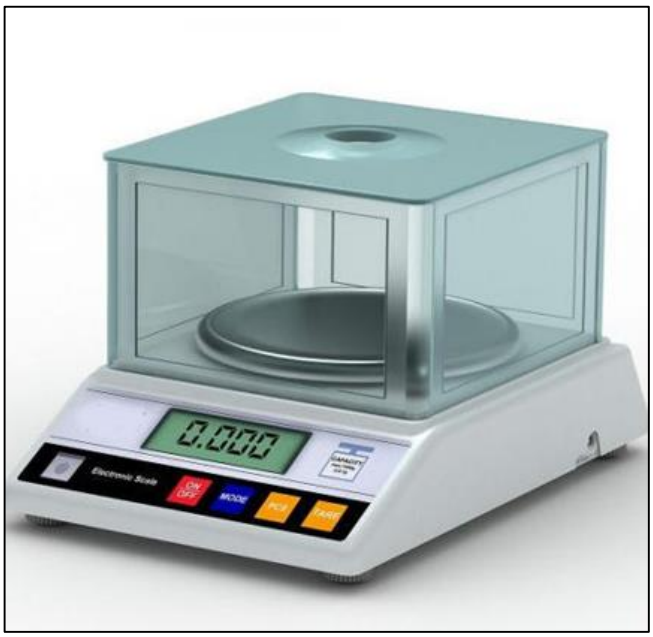

Fig 1: (Weighing balance)

Fig 2: (Monsanto hardness tester)

Fig 3: (Roche friabilator)

Fig 4: (Disintegration)

Results and discussion

- **Organoleptic Properties**

Table 1

Category	Tablet A	Tablet B
Colour	Greenish brown	Greenish brown
Odour	Characteristic	Characteristic
Taste	Bitter	Bitter
Shape	Round	Round

- **Weight variation test**

Table 2

Tablet No	Tablet A	Tablet B
1	0.729 gm	0.542 gm
2	0.718 gm	0.545 gm
3	0.729 gm	0.549 gm
4	0.725 gm	0.552 gm
5	0.717 gm	0.549 gm
6	0.724 gm	0.546 gm
7	o.726 gm	0.542 gm
8	0.723 gm	0.539 gm
9	0.732 gm	0.546 gm
10	0.718 gm	0.553 gm
11	0.724 gm	0.556 gm
12	0.722 gm	0.541 gm
13	0.722 gm	0.546 gm
14	0.721 gm	0.554 gm
15	0.728 gm	0.543 gm
16	0.709 gm	0.549 gm
17	0.723 gm	0.553 gm
18	0.724 gm	0.554 gm
19	0.706 gm	0.546 gm
20	0.695 gm	0.553 gm
Total weight of 20 tablets	**14.443 gm**	**11.002 gm**

Tablet A

Average weight of the 20 tablets = 722.15 mg.

Upper limit =758.25 mg.

Lower limit =686.04 mg.

Deviation occur = ± 5.

Tablet B

Average weight of the 20 tablets = 550mg.

Upper limit = 577.5 mg.

Lower limit = 522.5 mg.

Deviation occur = ± 5

Tablet A and B shows the report within the reference limits.

- **Hardness test**

Table 3

Tablet No	Tablet A	Tablet B
1	3	7
2	5	5.5
3	3	5.5
4	2	8
5	3	6.5
Total Hardness	**3.2kg/cm^2**	**6.5kg/cm^2**

Friability test

Tablet A

Initial weight of 20 tablet (W_1) = 14.443 g.
Final weight of 20 tablet (W_2) = 14.405 g.

$$\% \text{ Loss} = \frac{W_1 - W_2}{W_1} \times 100$$

$$= \frac{14.443 - 14.405}{14.443} \times 100$$

$$= -85.29\% W/W$$

Tablet B

Initial weight of 20 tablet (W_1) = 11.002 g.
Final weight of 20 tablet (W_2) = 11.000 g.

$$\% \text{ Loss} = \frac{W_1 - W_2}{W_1} \times 100$$

$$= \frac{11.002 - 11.000}{11.002} \times 100$$

$$= -88.98\% W/W$$

- **Disintegration test**

Table 4

Tablet No	Concentration	Time in Mins
Tablet A	0.1 M HCL	25 ins
	0.5 M HCL	10 mins
Tablet B	0.1 M HCL	55 ins
	0.5 M HCL	30 mins

The comparative study of standardization parameters of two different marketed Herbal tablets were observed and reported.

- The Weight variation test was performed for tablet A and B.
  - The average weight of the tablet A = 722.15 mg (Upper limit = 758.25 mg and Lower limit = 686.04 mg)
  - The average weight of the tablet B = 550 mg (Upper limit = 577.60 mg and Lower limit = 522.60 mg)
- The Hardness test was performed and the observed values was found to be Tablet A = 3.2 kg /cm^2 and Tablet B = 6.5 kg / cm^2.
- The Friability test was performed and the observed values was found to be Tablet A = -85.29%W/W, Tablet B = -88.98%W/W
- The disintegration test was performed and disintegration time of the tablet was found to be Tablet A = 25 mins in 0.1M HCL & 10 mins in 0.5M HCL and Tablet B = 55 mins in 0.1M HCL & 30 mins in 0.5M HCL.

Conclusion

The present work is an attempt to study the standardization parameters of two marketed herbal tablets. We evaluate weight variation, Hardness, friability, and disintegration test were performed and the resulted values were compared with the Indian pharmacopoeia standards. All the Standardization parameters of both the tablets pass in the IP standard value.

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