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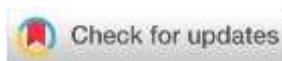
Screening of Marketed Formulations of Shatavari Tablets to Establish Pharmaceutical Equivalence

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Abstract

Using an in vitro dissolving research, compare the pharmacological equivalent of three brands of *Shatavari* tablets sold in India. According to IP rules, the dissolution was performed using apparatus I (the paddle device). According to the Indian Pharmacopoeia, evaluation of physicochemical characteristics including weight variation test, content uniformity test, hardness test, friability test, disintegration test, and dissolution test was conducted. For weight fluctuation, content homogeneity, hardness, friability, disintegration time, and dissolving study, all brands complied with official specifications. Two out of the three brands of *Shatavari* tablets achieved more than 75% dissolve in just 60 minutes, according to the dissolution profile. Out of three brands of *Shatavari* tablets, the results indicated that two of them had satisfactory quality and had passed all of the pharmacopoeia's tests.

Keywords: *Asparagus racemosus*, pharmaceutical equivalence, in vitro dissolution.

1. INTRODUCTION

The ability of the dosage form to transport the medication to its site of action at a rate and amount sufficient to elicit the intended pharmacological response determines a drug's therapeutic effectiveness. [1] Equivalence of medications This phrase denotes that two or more drug products are equal in terms of strength, quality, purity, content, uniformity, disintegration, and dissolution; they may, however, vary in terms of including various excipients.[] If a new product is intended to be used as a pharmaceutical equal or alternative to an approved medicinal medication, the equivalence with this product should be demonstrated or justified. The rate and degree of drug absorption from the site of administration to the systemic circulation determines a drug's therapeutic effectiveness. Poorly water soluble drugs' rate of dissolution is sometimes a rate-limiting stage in their absorption from the GI Tract. Drugs that are poorly soluble have a low oral bioavailability and may have substantial intra- and inter-subject variability. To ensure the quality of the medicine, government manufacturers and independent research groups must continuously monitor the drugs that are marketed but are not very water soluble. [4-9]

Long employed as an ayurvedic remedy for women's health, *Shatavari* (Asparagus racemosus) has little empirical support for its efficacy. Steroids and saponins are widely believed to be the main bioactive components of *Shatavari* root. *Shatavari*

root has other noteworthy chemical components, such as racemosides, racemosol, and asparagomine A. These saponins are known as shatavarins I–IV and are glycosides of sarsaspogenin. they all have antioxidant action. According to the scant literature, *Shatavari* also includes phytoestrogenic substances that can bind to estradiol receptors (E2R). [10-13]

2. MATERIAL AND METHODS

1. **Drugs and Chemicals:** A local shop sold 250 mg of powdered *Shatavari* root. Additionally, three different kinds of 250mg *Shatavari* tablets are bought from a neighborhood pharmacy in Pune, India. The samples' batch numbers, production dates, manufacturing licence numbers, and expiration dates were all appropriately examined. The laboratory makes use of chemicals.

2. **Preparation of *Shatavari* extract:** Heat the mixture after adding 20 ml of ethanol, 80 ml of distilled water, and 15 g of *Shatavari*. Utilise a cotton cloth to filter. Utilise a hot plate instrument to filter evaporated or concentrated material. The extract is kept in an amber-colored bottle after it has been made.

3. **Preparation of stock solutions and calibration curve of *Shatavari* tablets:** *Shatavari* extract, 10 mg, was dissolved in 10 ml of distilled water, 1000 g/ml, to create a stock solution.10ml of distilled water is added to 1 ml of solution to dilute it to 100g/ml from 1000g/ml. Using the same

solvent (distilled water), multiple concentration solutions of 0.2, 0.4, 0.6, 0.8, and 1.0 g/ml were created from this stock. Each solution's absorbance was measured at 273 nm with a UV visible spectrophotometer (UV- Shimdazu Model). The regression equation was generated from a plot of the absorbance against concentration of the *Shatavari* extract.

The obtained r^2 value is 0.9557.

- Weight variation test
- Disintegration test
- Friability test
- Dissolution test
- Hardness test
- Content uniformity test

Weight variation test: Twenty tablets from each brand were individually weighed using an analytical balance. For each brand, the average weights and the percentage departure from the mean value were computed. [2]

Disintegration test: Using an automatic disintegration tester with plastic discs, six tablets of each brand were used for the test, which was conducted in pure water at 37 degrees Celsius. The point at which there were no more particles in the tester's basket was considered the disintegration time. [2]

Friability test: A friability tester machine rotated ten tablets of each brand at a rate of 25 revolutions per minute for four minutes. The tablets should be taken out of the drum, cleaned of any loose dust, and then precisely weighed using an analytical balance. For the majority of tablets, a maximum weight loss of not more than 1.0 percent (from a single test or from the mean of the three tests) is allowed. [2]

$$\text{Friability test (\%)} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \times 100$$

Dissolution test: For each brand, six replicates of the dissolution test were performed using a dissolution tester in accordance with IP requirements. The dissolution medium, 900 ml of 0.1N HCl kept at $37.0 + 0.5°C$, was used. At 5, 10, 15, 30, 45, and 60 minutes in each experiment, 5 ml of the dissolution sample was removed and replaced with a volume of the same size to maintain the sink condition. Samples were analysed using a Shimadzu UV-visible spectrophotometer at 273 nm. From a calibration curve created using *Shatavari* standard samples, the concentration at each sample was calculated. It was calculated the % dissolution. [2]

Hardness Test: An automatic tablet hardness tester was used to gauge the hardness.

Ten tablets were chosen at random from each brand, and the crushing pressure that each tablet experienced was noted. [2]

Content uniformity test: 100 millilitres of distilled water was mixed with the powdered remnants of each brand of *Shatavari* tablet. Following filtering, the sample was diluted and the absorbance at 270 nm was measured. The amount of *Shatavari* in each tablet was determined using the calibration curve's regression equation and absorption value. [2]

3. RESULTS AND DISCUSSION

Three different brands of *Shatavari* tablets were compared for their in vitro pharmaceutical equivalency. The findings of the weight uniformity, hardness, friability, dissolving study, and disintegration time are displayed.

1. Weight variation is a crucial test for determining whether tablets are up to IP standards because variations in weight lead to variations in content uniformity, which ultimately result in sub therapeutic doses or overdoses of the tablet. In this experiment, all of the tablets from each brand showed weight variation within the acceptable range, and no tablets showed variation outside the acceptable range.

2. The time it took for all the brands to disintegrate was reasonable. While the USP states that both uncoated and film-coated tablets must dissolve within 30 minutes, the BP specifies that uncoated tablets must dissolve in 15 minutes and film-coated tablets must dissolve in 30 minutes. All *Shatavari* tablets were film-coated, and the Brand A highest disintegration time was found to be 21:43 minutes.

3. The IP specification for friability is not greater than 1.0%. All the brands of *Shatavari* comply with the IP specification.

4. A table displaying the dissolution mean values in 0.1 N HCl was created. Brand B, who promoted the Brand A, released more than 75% of the *Shatavari* within one hour. Only Brand C had a one-hour drug release that was less than 75%. The comparatively sluggish rate at which this brand can release the active ingredient raises therapeutic concerns because it may have an adverse effect on the formulation's pharmacokinetic and therapeutic efficacy. [14]

5. Hardness is considered to as a non-compendial test, and according to IP, a tablet's hardness should be between 5-8 kg/cm^2. It can also affect other factors like friability and disintegration.

6. The drug's % potency is crucial to preserving therapeutic efficacy. The drug's potency must be between 85 and 115% in accordance with IP specifications.

There is good correlation in the calibration curve depicted in the picture (r^2 = 0.9557). The outcome shows that every *Shatavari* brand complies with IP requirements.

3.1 Figures

3.1.1 Calibration curve of *Shatavari* for measurement of dissolution profile.

$y = 0.067x + 0.6256$
$R^2 = 0.9557$
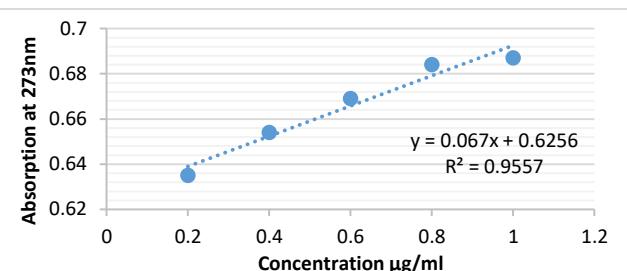
3.1.2 Comparison of dissolution profiles of different brands (A-C) of *Shatavari* tablet.
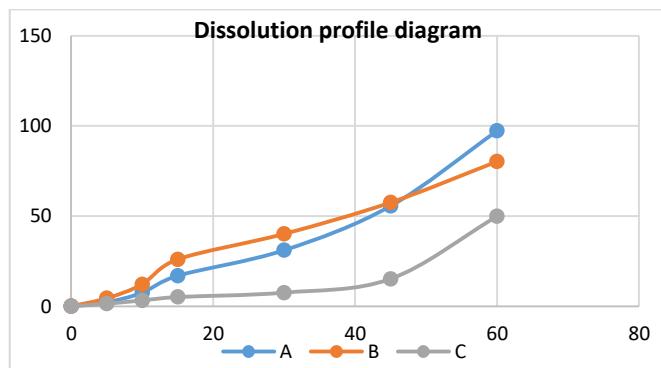
3.2 Tables

3.2.1 Summary of the quality control test undertaken on different brands of *Shatavari* tablets

Brands	Average weight ± SD (mg)	Weight variation (%)	Content Uniformity (%)	Hardness±SD (kg/cm$^{2)}$	Friability (%)	Disintegration time ± SD (Min)	% drug release
Brand A	251±0.01	1.73	99.23±1.5	13.83±0.5	0.4%	19±3.5	97.27%
Brand B	253±0.03	2.92	98.94±2.12	2.16±0.5	0.2%	14±1.5	80.23%
Brand C	314±0.02	3.71	97.55±4.8	4.83±0.3	0.1%	13±2.5	43.89%

*All above readings are in triplicate and SD taken

3.2.2 Brand A dissolution study

Time	Absorption	Concentration µg/ml	Dilution	Cumulative concentration µg/ml	Concentration 900 µg/ml	Concentration 900mg/ml	%drug release
5	0.1005	0.614	6.14	6.14	5526	5.526	2.21
10	0.1404	0.858	8.58	14.72	13248	18.774	7.50
15	0.1873	1.14	11.4	26.12	23508	42.282	16.91
30	0.2174	1.32	13.2	39.32	35388	77.670	31.068
45	0.4719	2.88	28.8	68.12	61308	138.978	55.59
60	0.7768	4.75	47.5	115.62	104058	243.036	97.21

*All above readings are in triplicate and SD taken

3.2.3 Brand B dissolution study

Time	Absorption	Concentration µg/ml	Dilution	Cumulative concentration µg/ml	Concentration 900 µg/ml	Concentration 900mg/ml	% drug release
5	0.2017	1.233	12.33	12.33	11097	11.097	4.93
10	0.3505	2.143	21.43	33.76	30384	30.384	12.15
15	0.6295	3.850	38.50	72.26	65034	65.034	26.01
30	0.6415	3.923	39.23	111.49	100341	100.341	40.13
45	0.7905	4.834	48.34	159.83	143847	143.847	57.53
60	1.0309	6.305	63.05	222.88	200592	200.592	80.23

*All above readings are in triplicate and SD taken

3.2.4 Brand C dissolution study

Time	Absorption	Concentration µg/ml	Dilution	Cumulative concentration µg/ml	Concentration 900 µg/ml	Concentration 900mg/ml	% drug release
5	0.0643	0.3932	3.932	3.932	3538.8	3.538	1.41
10	0.0838	0.5125	5.125	9.057	8151.3	8.151	3.26
15	0.0841	0.5143	5.143	14.2	12780	12.780	5.11
30	0.1112	0.6801	6.801	21.001	18900.9	18.900	7.56
45	0.3478	2.127	21.27	42.27	37980	37.980	15.19
60	1.3024	7.965	79.65	121.92	109728	109.728	43.89

*All above readings are in triplicate and SD taken

4. CONCLUSION

Pharmaceutical equivalence this phrase denotes that two or more drug products are equal in terms of strength, quality, purity, content, uniformity, disintegration, and dissolution; they may, however, vary in terms of including various excipients.

There were three different brands of *Shatavari* tablets available in Indian shops. Two brands, Brand A and Brand B, complied with all pharmacopoeial requirements for acceptable tablets. In the weight variation and dissolution research, just one brand (Brand C) fails to meet the requirements. But before making any definitive judgements about the caliber of commercially available *Shatavari* brands, an in vivo test could be necessary.

5. SUMMARY

The Brand A, Brand B, and Brand C of *Shatavari* tablets were examined for quality control.

Brand A and Brand B tablets pass the weight variation test, however Brand C does not. A Brand A tablet typically weighs 251 mg, a Brand B tablet typically weighs 253 mg, and a Brand C tablet often weighs 314 mg.

All three tablet brands passed the pharmacopoeia standards for disintegration: The Brand A tablet disintegrates in 19 minutes, the Brand B tablet disintegrates in 14 minutes, and the Brand C tablet disintegrates in 13 minutes.

All tablet brands passed the pharmacopoeia standards in the friability test; the Brand A tablet has a friability of 0.4%, the Brand B tablet has a friability of 0.2%, and the Brand C tablet has a friability of 0.1%.

Both the Brand A and Brand B brands of tablets released more than 75% of the medication in an hour during the disintegration test. In one hour, Brand A tablets release 97% of the medication, while Brand B tablets release 80.25 percent. Less than 50% of the medicine is released by the Brand C tablet in an hour; 43.89% of the drug is released.

The Brand A tablet's hardness test result of 13.83 kg/cm² indicates that it does not exceed pharmacopoeial requirements. The Brand B tablet and the Brand C tablet are 2.16 kg/cm² and 4.83 kg/cm², respectively, in terms of hardness.

The pharmacopoeial standards were met by all brands of tablets in the content uniformity test. The test's findings for content homogeneity are as follows:

Brand C tablet: 97.55%, Brand A tablet: 99.23%, Brand B tablet: 98.94%.

Acknowledgements

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