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# Comparative Study on Quality Analysis on Marketed Ashwagandha Tablets of Different Pharmaceutical Companies

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**Abstract:-**

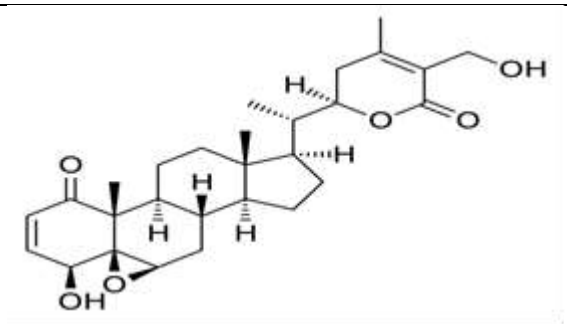
The study of medicine is a science as well as an art. Pharmaceutical oral solid dosage forms have been used widely for decades, mainly due to their ease of administration and suitability for systemic drug delivery. The tablets may be produced directly from powders, granule pellets, or film-coated multiple units. Nowadays, tablets are the most widely used dosage form, making up over 70% of all manufactured ethical pharmaceutical formulations. Ashwagandha is an ayurvedic remedy made from the herb Withania somnifera and is used to treat a variety of conditions including osteoarthritis, type 2 diabetes, anxiety-related issues, and tumor healing abilities. Withaferin-A, Stigmosterol glucoside, and withanolide-D are the three chemical components of ashwagandha. Tablet design and post-formulation quality monitoring require quantitative evaluations and assessments of tablets' chemical, physical and bioavailability properties. The present work reports the comparative study and quality evaluation of tablets formulated by two different pharmaceutical companies. The Ashwagandha tablet of 'X' and 'Y' companies (renamed) was collected for quality analysis and evaluation. The tablets were subjected to various post-production tests such as hardness, friability, and dissolution rate following standard Indian pharmacopeia procedures With the experimental observations recorded.

**Key Words:** Ashwagandha, Disintegration, Tablets, Hardness, Friability, Dissolution rate, Quality evaluation.

## Introduction:

Comparative analysis is carried out to check, compare and evaluate the quality standards of commercially available pharmaceutical brands of tablets. solid oral dosage forms (tablet and capsule) are the preferred class of products of the two forms, the tablet has a number of advantages such as the tablet being an essential tamper-proof dosage form. Standard quality control tests such as diameter, size and shape, uniformity of weight, thickness hardness, friability, percentage of medicament (Assay), rate of disintegration, dissolution, and solubility can be carried out on compressed tablets for their evaluation. In the current work, two different drug tablets from each of the companies X and Y were collected and subjected to the quality control tests hardness, friability, and dissolution rate in order to study the effect of the composition of formulations on drug release rate.

## Drug Profile:

| **Structure:** |  **withaferin** |
|---|---|
| Molecular formula | C28H38O6 |
| Molecular Weight | 470.6 g/mol |
| Family | Solanaceae |
| Uses | Antistress, Depression, Joint pain. |
| Solubility | Soluble in water |
| Appearance | Whitish cream fine powder |

## Materials and methods :

***Materials :***

From each of the companies the following tablets were collected and the quality control tests were carried out.

**Company X:**

Himalaya Ashvagandha - General Wellness Tablets 250 mg

**Company Y:**

Baidyanath Ashvagandha Tablet 250 mg

**Instruments**

Monsanto Hardness tester, Disintegration apparatus B. P. standard Electronic balance.

**Chemicals**
Phosphate buffer solution, 0.1 N Hydrochloric acid, Glacial acetic acid, Ceric Ammonium sulphate, Perchloric acid, Sodium hydroxide, 95% Ethanol.

***Method:***

**Weight Variation:** 20 tablets were taken and weighed using high precision weighing machine. Their average weight was noted down. Then each tablet was weight and their percent deviation from the average weight was determined.

***Hardness Test:***

A tablet was placed vertically on the Monsanto hardness tester. The load was then applied along the radial axis of the tablet. The weight or load required for breaking the tablet was noted down.Similarly, it was done for 10 tablets.

***Friability test:***

A friability test can be performed to evaluate the ability of the tablets to withstand abrasion in packing, handling, and transporting. The Friabulator consists of a plastic chamber divided into two parts and revolves at 25 rpm. A fixed number of tablets are weighed, placed in the tumbling chamber, and rotated for four minutes of 100 revolutions. During each revolution, the tablets fall from a distance of six inches to undergo shock. After 100 revolutions the tablets are again weighed. The loss in weight indicates friability. The acceptable limits of weight loss should not be more than 0.8% t. The friability (f) is given by: f = 100 (1- wo/w), where, wo = initial weight of the sample before friability and w = weight of the samples after friability test10.

Weight of 20 tablets = X

Weight of tablets after test = Y

Loss in weight = x-y

***Thickness:***

The degree of compaction of 20 tablets of each brand is assessed by measuring the thickness of tablets, by using VERNIER CALIPER.

***Tablet Dissolution:***

For this test U.S.P. Type- 1 (Basket) Apparatus was used. Phosphate buffer (pH 5.8) as Dissolution Medium: The tablets were immersed into 900 ml. of Dissolution medium, and the temperature of the dissolution medium was maintained at 37 ± 0.20C. The basket was rotated at a speed of 50 rpm. At 5, 10, and 20 minutes 1 ml. of the medium was pipette out and replaced with fresh medium (Phosphate buffer pH 5.8). This was continued all along for 1 hour. The pipetted-out samples were then diluted to 10 ml. with fresh dissolution medium and were then filtered.

***Tablet Disintegration:***

It was performed using a USP disintegration device. 6 tablets were placed in the Disintegration test apparatus. It was maintained at 37 ± 0.20C containing distilled water. The time taken for a tablet to disintegrate was noted down.

## Results and Discussion:

***Uniformity of weight test:***

**Company X**

| Tablet no | Weight(gm.) | Inference |
|---|---|---|
| 1 | 0.42 | Pass |
| 2 | 0.41 | Pass |
| 3 | 0.41 | Pass |
| 4 | 0.41 | Pass |
| 5 | 0.41 | Pass |
| 6 | 0.41 | Pass |
| 7 | 0.41 | Pass |
| 8 | 0.41 | Pass |
| 9 | 0.41 | Pass |
| 10 | 0.43 | Pass |
| 11 | 0.41 | Pass |
| 312 | 0.41 | Pass |
| 13 | 0.41 | Pass |
| 14 | 0.41 | Pass |
| 15 | 0.41 | Pass |
| 16 | 0.42 | Pass |
| 17 | 0.41 | Pass |
| 18 | 0.41 | Pass |
| 19 | 0.41 | Pass |
| 20 | 0.41 | Pass |

***Company Y***

| Tablet no | Weight (gm) | Inference |
|---|---|---|
| 1 | 0.56 | Pass |
| 2 | 0.56 | Pass |
| 3 | 0.56 | Pass |
| 4 | 0.57 | Pass |
| 5 | 0.56 | Pass |
| 6 | 0.57 | Pass |
| 7 | 0.56 | Pass |
| 8 | 0.56 | Pass |
| 9 | 0.56 | Pass |
| 10 | 0.57 | Pass |
| 11 | 0.57 | Pass |
| 12 | 0.56 | Pass |
| 13 | 0.56 | Pass |
| 14 | 0.56 | Pass |
| 15 | 0.56 | Pass |
| 16 | 0.57 | Pass |
| 17 | 0.58 | Pass |
| 18 | 0.56 | Pass |
| 19 | 0.57 | Pass |
| 20 | 0.56 | Pass |

***Company X:***

Average weight = weight of total tablet/ No.of tablet

8.24/20= 0.412

Limits : Lower limit = 0.41 gm

Upper limit = 0.43 gm

Results: The given tablet passes the test for uniformity of weight.

***Company Y :***

Average weight = weight of total tablet/ No.of tablet

11.28/20= 0.564

Limits : Lower limit = 0.56 gm

Upper limit = 0.58 gm

Results: The given tablet passes the test for uniformity of weight.

***Dimensions:***

**Company X**

| | |
|---|---|
| Width | 7.4 mm |
| Height | 16 mm |
| Thickness | 5.2 mm |

**Company Y**

| | |
|---|---|
| Diameter | 10 mm |
| Thickness | 06 mm |

***Friability Test:***

**Company X**

Weight of 20 tablets (a) – 8.24

Weight of tablet after a test (b) – 8.22 gm

Loss in weight a-b –0.02 gm

Percentage loss in weight = a – b / a * 100

=8.24 – 8.22/8.240 * 100

=0.24 %

**Company Y**

Weight of 20 tablets (a) – 11.28 gm

Weight of tablet after a test (b) – 11.20

Loss in weight a-b – 0.08

Percentage loss in weight = a – b / a * 100

=11.28-11.20/11.28*100

=0.7%

Limit: It should be less than 1%w/w

***Hardness Test:***

**Company X**

| **No. of Tablet** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| **Hardness in Kg/cm$^2$** | **11** | **11** | **13** | **13** | **12** |

**Company Y**

| **No. of Tablet** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| **Hardness in Kg/cm$^2$** | **8.5** | **9** | **8.7** | **8.9** | **9** |

## Dissolution:

Dissolution was another studied important quality control parameter directly related to the absorption and bioavailability of a drug. The study revealed that at different time intervals drug release rate was better. After 5 minutes, the release rate of both tablet brands of Ashwagandha was 49% to 55.2%. Finally after 15 minutes, 72.5% to 83% drug release was observed.

***Disintegration Time:-***

**Company X**

16

**Company Y**

15

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