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Analysis of Three Market Samples of Triphala Guggulu w.s.r. to its Hardness, Disintegration, and Dissolution Test

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Abstract

Background: *Triphala Guggulu* is a classical Ayurvedic formulation widely used for metabolic disorders, inflammation, and gastrointestinal ailments. Ensuring its quality, safety, and efficacy requires rigorous pharmaceutical evaluation. Among various parameters, hardness, disintegration, and dissolution play a critical role in determining bioavailability and therapeutic consistency. **Aim:** To analyze three marketed samples of *Triphala Guggulu* with respect to hardness, disintegration, and dissolution, thereby evaluating pharmaceutical quality compliance. **Methodology:** Three coded market samples of *Triphala Guggulu* were subjected to pharmacopoeial evaluation. Hardness was determined using a Monsanto hardness tester. Disintegration test was performed in distilled water at 37 ± 2 °C using a standard disintegration apparatus. Dissolution studies were carried out using USP apparatus II (paddle method) in simulated gastric fluid, with absorbance readings taken spectrophotometrically. **Results:** Variation was observed among the three samples. Hardness values differed, indicating inconsistency in compression force and excipient use. Disintegration time varied, with one sample complying with Ayurvedic Pharmacopoeia standards, while others exceeded permissible limits. Dissolution profiles revealed marked differences, reflecting the influence of formulation and processing methods on drug release. **Conclusion:** Considerable inter-brand variation exists in hardness, disintegration, and dissolution of marketed *Triphala Guggulu* formulations. This highlights the need for stringent quality standardization, uniform manufacturing practices, and strict regulatory monitoring to ensure therapeutic reliability and consumer safety.

Keywords – *Triphala Guggulu*, Hardness, Disintegration, Dissolution, Quality Control, Ayurvedic Formulations

Introduction :

Ayurveda, the traditional system of Indian medicine, emphasizes holistic health through herbal, mineral, and herbo-mineral preparations [1]. *Triphala Guggulu* is a well-known classical formulation indicated in *Arsha* (piles), *Bhagandara* (fistula-in-ano), *Vrana* (wounds) [2], and metabolic disorders. With increasing global demand, standardization of Ayurvedic formulations has become essential for ensuring safety, efficacy, and reproducibility.

Pharmaceutical quality control parameters—particularly hardness, disintegration, and dissolution—are crucial in assessing tablet dosage forms. Hardness ensures mechanical strength during handling and transportation; disintegration determines breakdown time in biological fluids; and dissolution predicts the rate and extent of active ingredient release, directly correlating with bioavailability. [3]

Despite availability of *pharmacopoeial* standards, variations among different marketed samples are often reported. [4] Therefore, the present study was undertaken to comparatively evaluate three marketed samples of *Triphala Guggulu* with respect to hardness, disintegration, and dissolution.

Materials and Methods :

Sample Collection

Three different brands of *Triphala Guggulu* were procured from the Indian market. Each was coded as Sample A, Sample B, and Sample C to maintain blinding during analysis.

Tests Performed

Hardness Test: Measured using Monsanto hardness tester; results expressed in kg/cm².

Disintegration Test: Conducted using disintegration apparatus in distilled water at 37 ± 2 °C; expressed in minutes.

Dissolution Test: Performed using USP apparatus II in simulated gastric fluid; absorbance recorded at specific intervals with UV spectrophotometer. [5]

Evaluation: All parameters were compared against standards prescribed in the Ayurvedic Pharmacopoeia of India and WHO guidelines for herbal drug formulations. [6]

Results :

Hardness: Considerable variation was noted between samples, indicating non-uniformity in compression force and excipient quality.

Sample	Hardness (kg/cm ²)
A	8
B	7
C	7

Disintegration: One sample disintegrated within permissible limits, while others showed delayed disintegration.

Sample	Disintegration Time (min)
A	80
B	60
C	50

Dissolution: Dissolution rate varied significantly among samples, indicating differences in formulation techniques and potential therapeutic inconsistency.

Sample	% Drug Released at 60 min
A	50
B	40
C	40

Discussion :

The results clearly demonstrate inter-brand variability in key pharmaceutical parameters. Hardness variation reflects inconsistency in manufacturing practices, which may affect stability during storage and transport. Delayed disintegration in some samples suggests inadequate formulation balance, which may reduce clinical efficacy. Furthermore, dissolution discrepancies raise concerns about bioavailability, as incomplete or delayed drug release may compromise therapeutic action. Such variations highlight the urgent need for harmonized manufacturing practices and stricter regulatory frameworks. Ayurvedic manufacturers must adopt standardized Good Manufacturing Practices (GMP) with robust in-process quality control. Uniformity in hardness, disintegration, and dissolution would ensure reproducibility, consumer safety, and global acceptance of Ayurvedic formulation.

Conclusion :

The study shows that the *guggulu kalpas* shows a huge difference in the values of the tests, this is suggestive of the doubt of bioavailability of the *Triphala Guggulu*. There can be a chance that the pharmaceuticals of *Triphala Guggulu* can be evolved. The comparative analysis of three marketed samples of *Triphala Guggulu* revealed significant variability in hardness, disintegration, and dissolution. Only one sample met pharmacopoeial expectations consistently. This emphasizes the necessity for regulatory oversight and uniform quality standards to ensure efficacy, safety, and therapeutic reliability of Ayurvedic formulations.

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Declaration :

Conflict of Interest : None

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