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COMPARATIVE IN-VITRO QUALITY ASSESSMENT OF COMMERCIALLY AVAILABLE ISOSORBIDE DINITRATE 10 MG TABLET FORMULATIONS

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ABSTRACT

Isosorbide dinitrate (ISDN) is a well-known organic nitrate that is frequently used to treat heart failure and angina pectoris because of its potent vasodilatory activity. The pharmacological profile, mechanisms of action, therapeutic uses, and new developments in formulation techniques are the main topics of this review article's thorough assessment of ISDN. The medication's effects on nitric oxide pathway modulation, myocardial oxygen supply-demand balance, and preload and afterload reduction in cardiovascular diseases are highlighted. The article also discusses safety concerns and limitations such as tolerance development, and clinical evidence for its effectiveness. In order to improve therapeutic results, novel therapeutic strategies including combination regimens and medication administration are also covered. Overall, this review highlights the ongoing importance of ISDN in cardiovascular medication and suggests possible avenues for further study and therapeutic application.

Keywords: *Isosorbide dinitrate, angina pectoris, nitric oxide, vasodilation, cardiovascular therapy, drug delivery.*

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INTRODUCTION

An imbalance between the oxygen supply and demand in the heart causes myocardial ischemia, which manifests clinically as angina pectoris. Because they can produce vascular smooth muscle relaxation by activating guanylate cyclase through nitric oxide, organic nitrates continue to be one of the most commonly used anti-anginal medications. Therefore, in order to prove pharmacological equivalency and guarantee therapeutic dependability, a comparative assessment of marketed formulations is required. The goal of the current study was to evaluate and contrast a few quality control metrics of commercially available 10 mg isosorbide dinitrate tablets sold in India [1].

Clinically significant anti-anginal agent widely employed to treat acute heart failure and coronary artery disease is isosorbide dinitrate (ISDN). However, the drug's lipophilic properties and substantial first-pass hepatic metabolism frequently compromise therapeutic efficacy of traditional 10 mg oral tablets. Despite having a well-established pharmacological mechanism, clinical outcomes remain substantially governed by the physicochemical properties and in vitro dissolution profiles of various commercial formulations [2].

The aqueous solubility of ISDN is primarily governed by its physiochemical properties, including crystalline habit, particle size, and melting point can be attributed to variations in manufacturing procedures, different excipient matrices and different compression forces between different brand-name and generic formulations. Rapid dissolution is a critical quality attribute necessary to attain the minimum therapeutic plasma concentration before the drug is cleared according to regulatory requirements, like those set out by the FDA Drug Database [3,4].

DRUG PROFILE

Isosorbide Dinitrate

Description: A pharmacological agent indicated for the relief of angina pectoris which is treated with a vasodilator. Although it acts more slowly, its effects are comparable to those of nitro-glycerine [5].

Structure

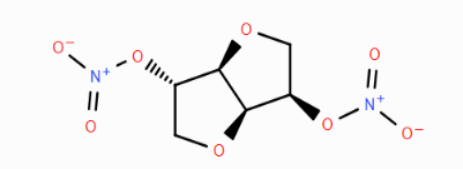


Figure 01: Structure of Isosorbide Dinitrate

Chemical Formula: $C_6H_8N_2O_8$

IUPAC Name:[(3S,3aS,6R,6aS)-3-nitrooxy-2,3,3a,5,6,6a-hexahydrofuro[3,2-b]furan-6-yl] nitrate

Molecular Weight: 236.14 g/mol

Category: Antianginal Agent, Organic Nitrate, Vasodilator.

Solubility: 550mg/L (at 25°C)

Melting point: 70°C.

Pharmacology

Indications: For the prevention of angina pectoris due to coronary artery disease.

Mechanism of Action

Isosorbide dinitrate undergoes biotransformation to nitric oxide, which activate guanylate cyclase. When Guanylate cyclase is activated levels of cyclic guanosine 3',5'-monophosphate (cGMP) elevate. CGMP then activates protein kinases, which induce dephosphorylation of myosin light chains. Finally, when calcium ions are released, results in vasodilation and smooth muscle relaxation [6,7].

Pharmacodynamics

Isosorbide dinitrate, an organic nitrate that stays in the body for a moderate to long time is used to treat and prevent angina pectoris. Induces arterial and venous dilation via relaxation of vascular smooth muscle. When veins widen, resulting in reduced venous return and increased peripheral venous pooling; this reduces left end-diastolic pressure and also lowers pulmonary capillary wedge pressure, which is also called preload. The widening of arteries lowers systolic and mean arterial pressure and reduces systemic vascular resistance [8].

Pharmacokinetics

Absorption: After oral administration, isosorbide dinitrate is almost entirely absorbed; nevertheless, bioavailability varies greatly (10% to 90%), with significant first-pass metabolism occurring in the liver. Isosorbide dinitrate has an average bioavailability of roughly 25%[9].

Volume of distribution: 2 to 4 L/kg

Protein binding: Very low.

Metabolism: Metabolised in liver.

Half-life: The plasma half-life is 1 hour.

Route of elimination: Renal route.

Drug interactions:

- **Potentiated by:** Alcohol, antihypertensives
- **Contraindicated with:** PDE-5 inhibitors (e.g., Viagra)

Food-drug interactions: Take with or without food. Food decreases drug absorption.

Human overdose experience

- Confusion, vertigo, Seizures, paralysis and visual disturbances.
- Bradycardia, heart block, and palpitations.
- Nausea, vomiting, possibly with colic or bloody diarrhoea.

Precautions

- **Monitor blood pressure**: Risk of **severe hypotension**, especially in elderly or volume-depleted patients.
- **Do NOT use with PDE-5 inhibitors** (e.g., sildenafil, tadalafil, vardenafil): May cause life-threatening hypotension.
- May cause **orthostatic hypotension** and **syncope**.
- May cause **dizziness** or **blurred vision**.
- Use with caution due to altered metabolism and excretion.

Warnings

Warnings associated with Isosorbide dinitrate are;

- Severe Hypotension
- Nitrate Tolerance

Table 01: Major Drug Classes in Angina Pectoris

Class	Examples	Mechanism of Action	Clinical Use	References
Nitrates	Nitroglycerin, Isosorbide dinitrate,	Release nitric oxide → ↑ cGMP → vasodilation (↓ preload, ↓ afterload, ↑ coronary blood flow)	Acute angina attacks, prophylaxis, variant angina	[10]
Beta-blockers	Metoprolol, Atenolol, Propranolol	Block β1 receptors → ↓ HR, ↓ contractility, ↓ BP → ↓ oxygen demand	Chronic stable angina, post-MI angina (not useful in variant angina)	[11]
Calcium Channel Blockers (CCBs)	Dihydropyridines: Amlodipine, Nifedipine	Inhibit L-type Ca^{2+} channels → vasodilation, ↓ cardiac workload	Stable angina, variant angina; Verapamil/Diltiazem also control HR	[12]
Potassium Channel Openers	Nicorandil	Opens ATP-sensitive K^+ channels → arterial vasodilation + nitrate-like effect	Chronic stable angina	[13]
Metabolic Modulators	Ranolazine, Trimetazidine	Ranolazine: inhibits late Na^+ current → ↓ Ca^{2+} overload; Trimetazidine: shifts metabolism to glucose oxidation	Chronic angina unresponsive to other drugs	[14]
Sinus Node Inhibitors	Ivabradine	Inhibits If current → ↓ HR without affecting contractility or BP	Stable angina with high HR, especially when β-blockers not tolerated	[15]
Antiplatelet Agents	Aspirin, Clopidogrel	Prevent platelet aggregation → ↓ risk of thrombus formation	Unstable angina, post-MI prophylaxis	[16]
Statins	Atorvastatin, Rosuvastatin	Inhibit HMG-CoA reductase → ↓ LDL cholesterol, stabilize plaques	Long-term prevention of coronary events	[17]

METHODOLOGY

Evaluation Parameters

1. Weight variation test

AIM:

To ensure that each tablet contains a consistent and accurate amount of active pharmaceutical ingredients (API) and excipients.

Apparatus required:

Weighing balance, Butterpaper, Desiccator.

Procedure:

The weight variation test looks at dosage units to see how their weight spreads in a batch.

The detailed procedure may vary depending on the drug and dosage form but it generally involves the following steps:

1. Sample selection – In step one sample selection I take the drug from brands of Isosorbide dinitrate.

2.Weighing – In step two weighing each tablet strip is weighed carefully up to twenty tablets.

3. Calculation of weight – In step three calculation of weight I add all the weights together and divide by the number of dosage units.

4. Determination of acceptance criteria– In step four determination of acceptance criteria the regulatory authorities such as the United States Pharmacopeia (USP) or the European Pharmacopeia (EP) set the limits, for weight variation. These limits ensure that the medication meets required quality standards.

5. Evaluation of the results – In step five evaluation of the results I compare each weight to the average weight and measure the variations. The results are then compared against the acceptance criteria to decide if the batch passes or fails the test.

Every unit that was tested fell within ± [a given percentage, such as 5% or 10%] of the average weight. As a result, the batch satisfies pharmacopeial standards for weight homogeneity.

2. Hardness test:

AIM:

To measure the mechanical strength and durability of the tablet under pressure.

Apparatus required:

Monsanto hardness tester, tablets.

Procedure

1. Preparation:

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● Make sure the monsanto hardness tester is calibrated and functioning properly. Check the tester for any parts and keep the device clean and free from debris.
● Adjust the scale of zero indicator if necessary to ensure readings.
2. Select tablets for testing:
● Make sure the tablets are free from cracks, chipping or other visible defects.
The hardness of isosorbide dinitrate tablets typically ranges from 3.00 – 6.00 Kg/cm2, indicating acceptable mechanical strength for handling and administration [18].

3. Position the tablet:

● Place the tablet in the holder of the monsanto hardness tester. Align the tablet with the plunger so that the test force is applied evenly across the tablet's surface.

4. Apply the force:

● Activate the tester to apply pressure to the tablet. The monsanto hardness tester pushes down on the tablet through a plunger. As the force increases the tablet will. Fracture.

5. Read the measurement:

● The force required to break or fracture the tablet will be displayed on the scale. This is the tablet's hardness, typically measured in kilograms (Kg) or pounds (lb).
● Record the hardness value for the tablet.

6. Average hardness calculation:

● Calculate the hardness, from the results of the individual tablets to ensure uniformity and consistency.
The hardness of isosorbide dinitrate tablets typically ranges from 3.00 – 6.00 Kg/cm2, indicating acceptable mechanical strength for handling and administration.(18)

3. Friability test

1. **Sample Placement**

A set of pre-weighed tablets is placed in the plastic chamber. Ensure that the tablets are uniform in size and weight and have been stored under the same conditions to minimize variability.

2. **Rotating Drum or Friability Setup**

Test the tablets in the friability testing apparatus (rotating drum or friability) and ensure that the drum is level and rotating smoothly. The USP recommends a rotating speed of 25 revolutions per minute (rpm) for the Friabilator

3. Test Duration and Rotations

Test the tablets for a specified duration or number of rotations. The USP recommends a minimum of 4 minutes (100 revolutions) for most tablets, but this may vary based on the product's intended use and formulation

4. **Weight Loss Calculation [19].**

The tablets are weighed before and after the test to determine any weight loss due to mechanical stress. The weight loss is calculated as a percentage with friability test formula such as below:

Friability (% loss) = weight before test (w_1)-weight after test (w_2) × 100

Weight before test (w_1)

Friability tests conducted on different brands of isosorbide dinitrate tablets have shown a friability of 0.6% - 2%, indicating excellent mechanical strength and resistance to abrasion during handling [19].

4. Dissolution Test:

Aim: To evaluate the rate and extent at which the active pharmaceutical ingredient (API) in a drug dissolve in a specific solvent, usually water or a buffer solution, under controlled conditions.

Apparatus required:

Rotating basket method.

Procedure:

1. Apparatus setup:

- **Assembly:** Ensure that the basket is securely attached to the rotating shaft and that the apparatus is properly assembled according to the manufacturer's specifications.
- **Calibration:** verify that the apparatus meets the mechanical calibration tolerances as outlined in the United States pharmacopeia (USP) guidelines to ensure accurate and reproducible results.

2. Preparation of Dissolution medium:

- **Selection:** Choose an appropriate dissolution medium, typically water or a water-based solution with a pH range of 5-7, based on the solubility characteristics of the API.
- **Degassing:** Degas the medium (e.g., by sonication) to remove dissolved gases that could affect the test's accuracy.
- **Volume:** Fill each dissolution vessel with the specified volume of medium, ensuring consistency across all vessels.
- **Temperature:** Heat the medium to 37°C ± 0.5°C, maintaining this temperature throughout the test to simulate human physiological conditions.

3. Test conditions:

- **Rotation speed:** Set the basket rotation speed to the specified rpm, typically 100 rpm, to ensure adequate agitation without causing excessive turbulence.
- **Apparatus suitability test:** Perform the Apparatus Suitability Test by individually testing one tablet each of the USP Dissolution Calibrator, Disintegrating Type, and USP Dissolution Calibrator, non-disintegrating Type, according to the operating conditions specified. The apparatus is deemed suitable if the results fall within the acceptable ranges stated in the calibrator certificates.

4. Sample introduction:

- **Loading: C**arefully place one dosage unit (tablet or capsule) into each vessel, ensuring no air bubbles adhere to the dosage form's surface.
- **Initiation:** Start the apparatus immediately after introducing the samples to maintain consistent testing conditions.

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5. Sampling and Analysis [20, 21].

Sampling: At predetermined time intervals, withdraw samples of the dissolution medium without disrupting the system's hydrodynamics.

- **Analysis:** Analyze the samples using appropriate analytical methods, such as High-Performance Liquid Chromatography (HPLC) or Ultraviolet-Visible (UV-Vis) spectroscopy, to determine the concentration of the dissolved API.
  All four brands showed drug release values ranging from 95% to 98.9%, which are within the pharmacopeial limits for delayed-release formulations of Isosorbide Dinitrate. This indicates that the active pharmaceutical ingredient is released adequately and consistently across the tested brands.(20,21)

5. Disintegration Test

Aim: To evaluate how quickly and effectively a solid oral dosage form, such as a tablet or capsule, breaks down into smaller particles when placed in a liquid medium.

Apparatus required:

Disintegration tester, liquid medium.

Procedure:

1. **Apparatus setup:**

- **Disintegration Tester:** Utilize a disintegration tester equipped with a basket-rack assembly, a 1000 mL beaker, and a temperature control system
- **Immersion Fluid:** Prepare the appropriate immersion fluid, typically water at 37°C ± 1°C, unless otherwise specified in the product monograph.

2. Sample Preparation:

- **Selection:** Randomly select six dosage units (tablets or capsules) from the batch to be tested.
- **Identification:** Ensure that the samples are correctly identified and labeled to prevent mix-up during testing.

3. Test Procedure:

- **Placement:** Place each dosage unit into a separate tube of the basket-rack assembly.
- **Immersion:** Suspend the basket-rack assembly in the beaker containing the immersion fluid, ensuring that the wire mesh remains at least 15 mm below the surface of the fluid at the highest point of the upward stroke.
- **Operation:** Operate the apparatus at a frequency of 29 to 32 cycles per minute, with a stroke distance of 53 to 57 mm, to simulate physiological conditions.
- **Temperature Maintenance:** Monitor and maintain the immersion fluid temperature at 37°C ± 1°C throughout the test.

RESULT & DISCUSSION

Table 02: Experimental Data

Test	IP Standard	Anzidin 10 mg	Isordil	Sorbicap 10 mg	Sorbitrate 10 mg
Weight Variation	±5% for tablets >250 mg	Within limits (±2.3%)	Within limits (±1.8%)	Within limits (±2.5%)	Within limits (±2.1%)
Hardness	3–6 kg/cm² typical	3.8–4.2 kg/cm²	4.5–5.2 kg/cm²	4.0–4.5 kg/cm²	3.5–4.0 kg/cm²
Friability	Not morethan 1%	0.52%	0.35%	0.48%	0.45%
Disintegration Time	Not morethan 15 mins	3.5–5.0 min	6.5–8.0 min	5.5–7.0 min	3.2–4.5 min
Dissolution (30 min)	≥80% drug release	86–90%	82–86%	82–85%	88–92%

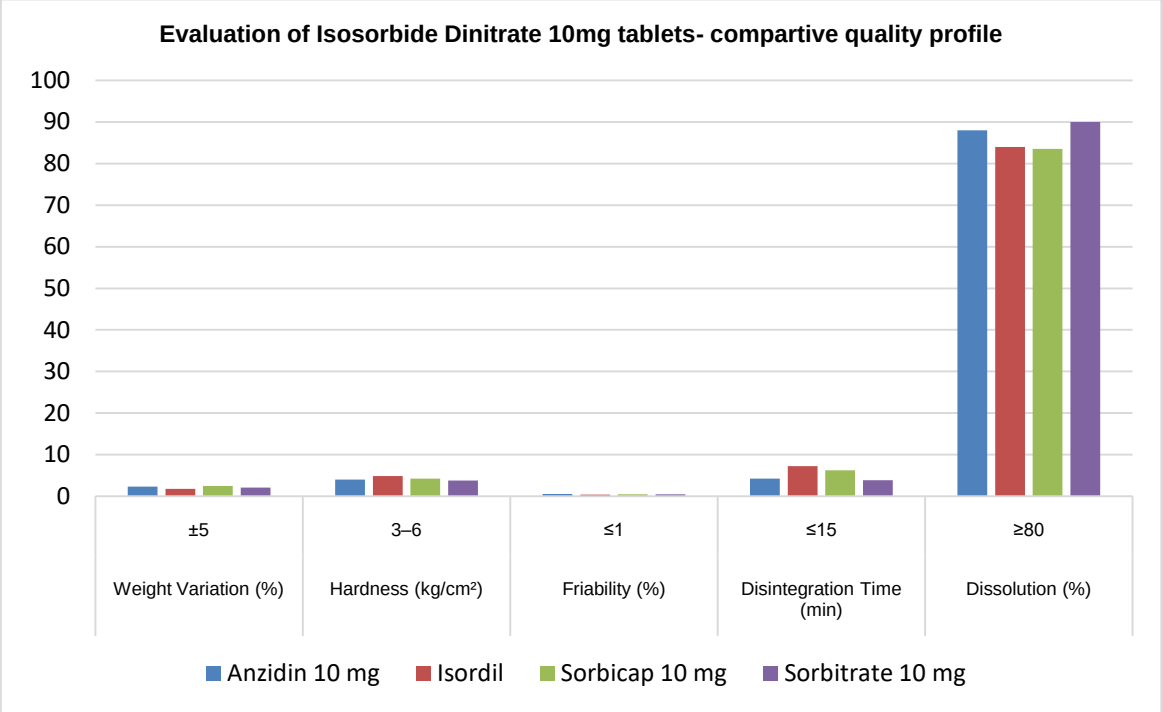


Figure 01: Graphical representation of isosorbide dinitrate 10mg tablets

1. **Weight Variation** All four brands complied with pharmacopeial limits (±5% for tablets >250 mg). Minor differences (±1.8% to ±2.5%) suggest uniform die filling and good manufacturing practices. This confirms dosage accuracy and minimizes risks of under- or overdosing.
2. **Hardness** values ranged between 3.5–5.2 kg/cm². Isordil exhibited the highest hardness, indicating stronger compaction, while Sorbitrate showed the lowest, favouring faster disintegration. These variations reflect differences in excipient composition and compression force, which can influence dissolution behavior.
3. **Friability** All brands demonstrated friability below 1%, confirming adequate mechanical strength for handling and transport. Isordil (0.35%) was the most resistant to abrasion, while Anzidin (0.52%) was slightly more friable but still within acceptable limits.
4. **Disintegration Time** Sorbitrate disintegrated fastest (3.2–4.5 min), while Isordil required longer (6.5–8.0 min). Faster disintegration correlates with quicker onset of action, making Sorbitrate more suitable for acute relief. Longer disintegration may delay drug release but can support sustained therapeutic effect.
5. **Dissolution Profile** All brands exceeded the pharmacopeial requirement of ≥80% drug release within 30 minutes. Sorbitrate showed the highest release (88–92%), while Sorbicap and Isordil released slightly less (82–86%). These differences, though minor, highlight formulation variability that could influence bioavailability.
6. **Comparative Performance**
   a. **Sorbitrate**: Rapid disintegration and high dissolution → best suited for acute angina relief.
   b. **Isordil**: Strong hardness and slower disintegration → potentially more sustained release.
   c. **Anzidin & Sorbicap**: Balanced profiles, meeting all quality standards with moderate release rates

CONCLUSION

The comparative in-vitro evaluation of Anzidin, Isordil, Sorbicap, and Sorbitrate (10 mg Isosorbide Dinitrate tablets) demonstrated that all four tested brands complied with the Indian Pharmacopoeia (IP) standards for weight variation, hardness, friability, disintegration, and dissolution. The weight variation results were within acceptable limits, indicating uniformity of dosage units. Hardness and friability tests showed that the tablets possessed adequate mechanical strength, with Isordil exhibiting the highest hardness and lowest friability. Disintegration times varied among the brands, with Sorbitrate showing the fastest disintegration, whereas Isordil required a comparatively longer time, indicating differences in formulation characteristics. The dissolution studies revealed that all four brands exhibited drug release values exceeding the specified requirement of 80% within 30 minutes, indicating satisfactory in-vitro drug release performance. Overall, the study demonstrated that although minor variations were observed in the physical properties and disintegration behaviour of the different brands, all four formulations met the specified quality control requirements. These findings emphasize the

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importance of routine pharmaceutical quality control testing in ensuring the quality, consistency, and reliability of marketed Isosorbide Dinitrate tablets for the effective management of angina pectoris.

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AUTHOR CONTRIBUTIONS
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CONFLICT OF INTEREST
The authors declare no conflict of interest.

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