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A comparative analysis of in-process quality control test of generic vs. brand Enalapril maleate tablets

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Abstract

This study compares a generic drug (Eopril-5) and a brand drug (Envas-5) to evaluate the quality control parameters of Enalapril Maleate 5 mg tablets. Enalapril maleate is an angiotensin-converting enzyme (ACE) inhibitor that is frequently administered to treat heart failure and hypertension. Comprehensive physicochemical quality control testing is essential to verifying treatment efficacy and patient safety. The formulations are evaluated in this study using both official and unofficial quality control procedures, including FTIR spectroscopy, weight variation, hardness, friability, disintegration, and dissolution. Unofficial tests were also conducted to evaluate properties like thickness, hardness in order to gather further information on the formulation's quality. General appearance evaluation showed that both formulations had acceptable visual uniformity in color, shape, and surface texture. The generic formulation showed a little increase in weight variance and friability, suggesting possible areas for production process improvement. Dissolution testing confirmed that both formulations released at least 80% of the drug within 30 minutes, satisfying USP criteria, and dissolution profile comparison demonstrated comparable drug release behavior. Disintegration times for both products were well within the 15-minute limit, ensuring rapid breakdown for absorption. FTIR spectra confirmed the chemical integrity of the formulations and showed that the active component is present in both products in the correct molecular form. The study highlights the importance of comprehensive quality control testing to ensure clinical comparability between brand-name and generic pharmaceutical medications.

Keywords: Enalapril Maleate; Generic vs. Brand; Quality Control Testing; Dissolution; Disintegration; IR Spectroscopy.

1. Introduction

Enalapril maleate is a prodrug that belongs to the class of angiotensin-converting enzyme (ACE) inhibitors. It is metabolized in the liver to its active metabolite, enalaprilat, which inhibits ACE and restricts the conversion of angiotensin I to angiotensin II. This reduction causes vasodilation, decreased blood pressure, and increased cardiac output in heart failure patients.

The availability of generic enalapril maleate makes treatment alternatives more affordable. Generic products must have similar quality, safety, and efficacy to the original brand (Envas-5). To ensure that both brand and generic formulations meet specified requirements for performance, purity, strength, and consistency, regulatory organizations such as the United States Pharmacopoeia (USP) and the Indian Pharmacopoeia (IP) demand stringent quality control testing.

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Physicochemical quality control studies are necessary to ensure that tablets have the characteristics that patients desire. These tests include:

- Use weight variation in order to ensure consistent dose.
- Hardness Testing is used to determine mechanical strength.

Testing for friability determines how durable tablets are under handling conditions. The breakdown Testing to determine how long it takes for drugs to disintegrate. Dissolution testing is used to assess the pace and degree of drug release under biologically realistic conditions[7].

Additionally, FTIR spectroscopy is used to confirm the chemical identity of enalapril maleate in both formulations and ensure that no degradation or polymorphic conversion has occurred. This study provides a comprehensive comparison of generic and brand-name Enalapril Maleate 5 mg tablets, highlighting potential differences in quality attributes that could ultimately affect therapeutic efficacy[21,22].

2. Materials and Methods

Tablet formulations were evaluated for both Enalapril Maleate commercially available formulations from the local market. The parameters assessed included appearance, weight variation, hardness, friability, content uniformity, disintegration time, and in vitro dissolution performance and FTIR spectroscopy[1,2,3,4,22].

2.1. Sample Collection

2.1.1. Drug Products Tested

- Envas-5 (Brand Tablet) – Enalapril Maleate 5 mg Tablets (Manufactured by: Cadila Pharmaceuticals Ltd., India)
- Eopril-5 (Generic Tablet) – Enalapril Maleate 5 mg Tablets (Manufactured by: Biochem Pharmaceuticals Industries Ltd., India)

2.1.2. Chemicals and Reagents

Purified Water as per IP and USP <1231> standards (used for dissolution and disintegration tests). Phosphate Buffer pH 6.8 made under IP dissolving media specifications and USP. Methanol (HPLC Grade) by IP standards, if used for UV calibration or cleaning.

2.1.3. Instruments and Equipment

Analytical balance: sensitivity of 0.1 mg (USP General Chapter <41>, IP Monograph), Monsanto Hardness Tester (for crushing strength test) is the hardness tester, Roche Friabilator, USP Disintegration Apparatus (Basket Assembly) (per USP <701> and IP) is the disintegration test apparatus, USP Type II (Paddle Apparatus) is the dissolution test apparatus (per USP <711> and IP recommendations), UV-Visible Spectrophotometer For FTIR investigation of dissolving samples at 215 nm, IR Spectrometer For comparing and identifying functional groups (per IP and USP monographs). Vernier Caliper For determining the thickness of tablets[9,10].

2.1.4. Glassware and Labware

1000 mL Beakers – For dissolution media preparation, Test Tubes – For disintegration testing, Pipettes and Volumetric Flasks – Class A& calibrated, Pestle and Mortar – For powdering tablets during FTIR sample preparation.

2.2. Evaluation Tests

2.2.1. Physical Characteristics

Tablets were visually inspected for uniformity in color, shape, size, and surface texture. Both brand (Envas 5) and generic (Eopril 5) formulations were evaluated.

2.2.2. Thickness Test

To make sure that batches are consistent, the thickness test gauges the tablets' actual sizes. Maintaining a constant thickness guarantees appropriate tablet handling, packaging, and patient acceptance. Despite not being a pharmacopoeial-mandated test (i.e., not included in USP/IP as a stand-alone test), it is frequently carried out as a

component of Good Manufacturing Practice (GMP) and is advised in FDA and WHO guidelines for solid oral dosage forms.

Apparatus: Vernier Caliper

Procedure:

- Randomly select 10 tablets from each formulation.
- Measure the thickness of each tablet at the center using a Vernier Caliper.
- Record individual readings and calculate mean thickness and standard deviation (SD).
- Acceptance Criteria: There are no official USP/IP limits for tablet thickness. Thickness should be consistent within a batch. Large variations could indicate compression problems or inconsistent granulation

2.2.3. Weight Variation Test

The weight variation test ensures that each tablet contains the intended amount of the active ingredient by checking whether tablets have consistent weight. It is Conducted as per Indian Pharmacopoeia (IP) guidelines. Twenty tablets were weighed individually, and average weight was determined. Percent (%) Deviation calculated to assess compliance.[10]

- Number of Tablets Tested: 20 tablets from each formulation.
- Procedure: Each tablet was individually weighed using an analytical balance (sensitivity 0.1 mg).
- Calculation: The average weight and individual tablet weights were recorded.

%Deviation= [(Individual Tablet Weight−Average Weight)/Average Weight] ×100

Acceptance Criteria: [as per IP]

- For tablets weighing ≤80 mg, limit variation: ±10%
- For tablets weighing 80 mg - 250 mg, variation: ±7.5%
- For tablets weighing >250 mg, variation: ±5%

2.3. Friability Test

Friability testing measures a tablet's ability to withstand mechanical stress during handling and transportation. Tablet endurance tested. Comparing friability values between generic and brand Enalapril indicates robustness differences, providing accurate results.

Number of Tablets Tested were 20 tablets

Equipment: Roche Friabilator.

Procedure: Tablets were weighed collectively, placed in the friabilator, and subjected to 100 rotations at 25 rpm (for 4 minutes). After dedusting, the tablets were reweighed.

Calculation:

$$\text{Friability (\%)} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$$

Acceptance Criteria: ≤1.0% weight loss.

2.4. Hardness Test

The hardness test (also known as crushing strength test) measures the force required to break a tablet under compressive pressure. It helps to assess the tablet's mechanical strength to withstand handling, packaging, transportation, and storage without breaking or chipping. Indian Pharmacopoeia (IP) and USP do not specify a strict hardness requirement, but hardness testing is part of Good Manufacturing Practices (GMP) and is recommended for uncoated tablets.

Apparatus: Monsanto Hardness Tester (manual screw type)

Procedure:

- Select 10 tablets randomly from each batch (brand and generic).
- Place the tablet between the plunger and anvil of the hardness tester.
- Apply force gradually until the tablet breaks.
- Record the crushing strength for each tablet.
- Calculate average hardness and standard deviation.
- Acceptance Criteria and Ideal hardness for uncoated tablets is about 3-8 kg/cm^2.

2.5. Disintegration Test

Drug release is impacted by disintegration testing, which evaluates how long it takes for a tablet to dissolve. An important factor in drug degradation. The purpose of the disintegration test is to check if, under the experimental conditions, tablets or capsules dissolve in a liquid medium within the allotted time. The disintegration tester was first put together. Each 1000 ml beaker was filled with 600ml of distilled water. At 37°C, the temperature was kept constant. One tablet was inserted into each of the six tubes. The switch button was pressed, and the duration of time it took for the tablet to break down was recorded. Disintegration is said to have occurred when there are no longer any residues visible on the screen; If there are, they are composed of a mushy mass without a discernibly hard, swollen core; or 45 Merely broken pieces of the shell or coating (tablets) can adhere to the lower surface of the disc[6,7].

Apparatus: Disintegration Test Apparatus. (Electro lab)

Procedure: Each tablet was placed in the basket rack assembly and lowered into the water bath.

Acceptance Criteria as per IP for Uncoated tablets must disintegrate within 15 minutes.

2.6. Standard Calibration Curve

First, weigh the tablet and then grind it into powder. The powdered tablets are now placed into a 100 ml volumetric flask, and 0.1 HCl is added to the mark. Now filter the solution and discard the initial few milliliters of the filtrate. Into a 50 ml volumetric flask, take 10 ml of the filtrate and fill with 0.1 N HCl to the mark, then perform a spectrophotometric analysis. The standard calibration curve of the respective drug was used to calculate the concentration of the drug's content (µg/ml).[8]

Drug content is calculated by using the formula

Concentration of the in (µg/ml) × 100 × 50 × 1000

2.7. Dissolution Test

The rate at which enalapril dissolves is determined using dissolution tests. a crucial component of medication release evaluation. In order to replicate in-vivo circumstances, standardized protocols are used. adhering to specific lab protocols to guarantee the accuracy of test results. Differences in release rates between generic and brand-name Enalapril are shown by comparing their dissolution profiles, suggesting possible variances[17].

Performed using USP Type II (Paddle) dissolution apparatus at 50 rpm, in 900 mL phosphate buffer (pH 6.8) at 37 ± 0. 5°C.Drug release (%) measured at 5, 10, 15, 30, and 60 minutes using UV-Visible Spectrophotometry at 240 nm.6 tablets are used in test. Comparison with f2 similarity factor analysis to assess bioequivalence[18].

2.8. Infrared (IR) Spectroscopy

FTIR analysis conducted to confirm the presence of Enalapril Maleate's characteristic functional groups. Spectra compared between brand and generic formulations. It is Referred as per IP (non-official characterization test) and Sample Preparation is Tablets that finely powdered. Instrument used FTIR Spectrometer[1,,2].

3. Results and Discussion

Tablets of the brand and generic varieties of enalapril maleate that are included in the local pharmaceutical index were assessed. Every formulation tablet with a potency of 5 mg was chosen, and the same standard approach was used to test them. According to IP and USP (2008), a number of quality control measures were carried out, including weight variation, hardness, friability, disintegration, and dissolution tests, as well as additional tests such FTIR spectroscopy.

Table 1 Evaluation of different quality control parameters of Enalapril maleate tablets

Sample (Tablet)	Weight variation test limit (%)	Hardness (kg/cm^2)	Friability (%)	Disintegration Time (min/sec)	Enalapril maleate Content (%)
Brand	2.60±0.04	4.43±0.05	0.13±0.02	3.5±0.5	99.8 ± 0.8
Generic	4.00±0.05	4.33±0.34	0.2±0.35	8.2±1.1	96.2±0.5

3.1. Physical Characteristics

Both formulations exhibited acceptable visual appearance, with no significant differences in color, shape, surface texture, or labelling clarity.

Table 2 Physical Parameters

Parameter	Envas 5 mg (Cadila) Brand Drug	Eopril 5 mg (Biochem) Generic Drug
Appearance	Round, flat, beveled edge tablet	Round, flat tablet
Color	White to off-white	White
Shape	Round	Round
Odor	Odorless	Odorless
Size	Approximately 7 mm diameter	Approximately 7 mm diameter
Surface texture	Smooth	Slightly rough
Break line (Scoring)	Present	Present

3.2. Thickness Test

Both formulations showed acceptable consistency within their batches. Slightly greater variability in Eopril-5(3.382mm compare to brand 2.303mm) could suggest variations in granulation flow properties or compression force. No major differences observed that would impact performance.

3.3. Weight Variation

Both Envas-5 and Eopril-5 passed the weight variation test, with all individual tablet weights falling within the ±7.5% tolerance limit specified for tablets in the 80-250 mg weight range. Eopril-5 exhibited slightly higher variability compared to Envas-5, which could be attributed to slight differences in granulation process control or compression uniformity.

Table 3 Calculations and results of weight variation

Drugs	% wt. of Different Brands		Result
	% upper limit	% Lower Limit	
Brand	2.73	2.60	Pass
Generic	4.06	4.02	Pass

Parameter	Envas-5 (Brand)	Eopril-5 (Generic)
Average Weight (mg)	149.9	123.05
Maximum Deviation (%)	±2.73%	±4.06%
Acceptance Limit (for 80-250 mg tablets) as per IP	±7.5%	±7.5%
Pass/Fail	Pass	Pass

3.4. Friability Test

Brand tablet passed the friability test with 0.13% weight loss (within the IP limit) and Generic drug also passed the test with 0.20% weight loss, indicating lower tablet strength compare to Brand Drug. The difference in friability may be due to variation in excipients, compression force, or binder quality

Table 4 Friability % weight loss

Brand/ Generic	**Initial Weight (g)**	**Final Weight (g)**	**% Weight Loss (Friability)**	**IP Limit (≤ 1.0%)**
Generic Drug	2.475	2.47	0.2%	Pass
Brand Drug	3.036	3.032	0.13%	Pass

3.5. Hardness Test

Both Envas-5 (Brand) and Eopril-5 (Generic) tablets fall within the acceptable hardness range of 3-8 kg/cm^2 for uncoated tablets. Envas-5 shows higher hardness (4.43 kg/cm^2) compared to Eopril-5 (4.33 kg/cm^2), indicating that Envas-5 is more robust, which may result in lower friability and better handling properties. The slightly lower hardness of Eopril-5 may contribute to faster disintegration, which could positively affect dissolution.

Table 5 Hardness Test

Parameter	**Envas-5 (Brand)**	**Eopril-5 (Generic)**
Average Hardness (kg/cm^2)	4.43	4.33
Range (kg/cm^2)	3.5 - 6	2.2 - 6
Recommended Range (Uncoated Tablets)	3 - 8 kg/cm^2	3 - 8 kg/cm^2
Pass/Fail	Pass	Pass

3.6. Disintegration Time

The disintegration time of generic as well as brand drug of Enalapril was found to be satisfactory as compared to uncoated tablet. Brand drug disintegrated in 3.5 min, while generics showed 8.2 minute. All samples complied with pharmacopoeial standards.

Table 6 Disintegration Time of Enalapril Maleate Tablets

Sample	**Disintegration Time (min)**	**Pharmacopoeial Limit (≤15 min)**	**Compliance**
Brand	3.5 ± 0.5	≤ 15 min	Yes
Generic	8.2 ± 1.1	≤ 15 min	Yes

3.7. Standard Calibration Curve of Enalapril Maleate

Calibration Curve of Standard was constructed by plotting Absorbance versus Concentration. The calibration curve is shown in Figure Linearity was observed in the concentration range from 0 – 25µg/ml with a correlation coefficient greater than 0.9986 and 0.9909.

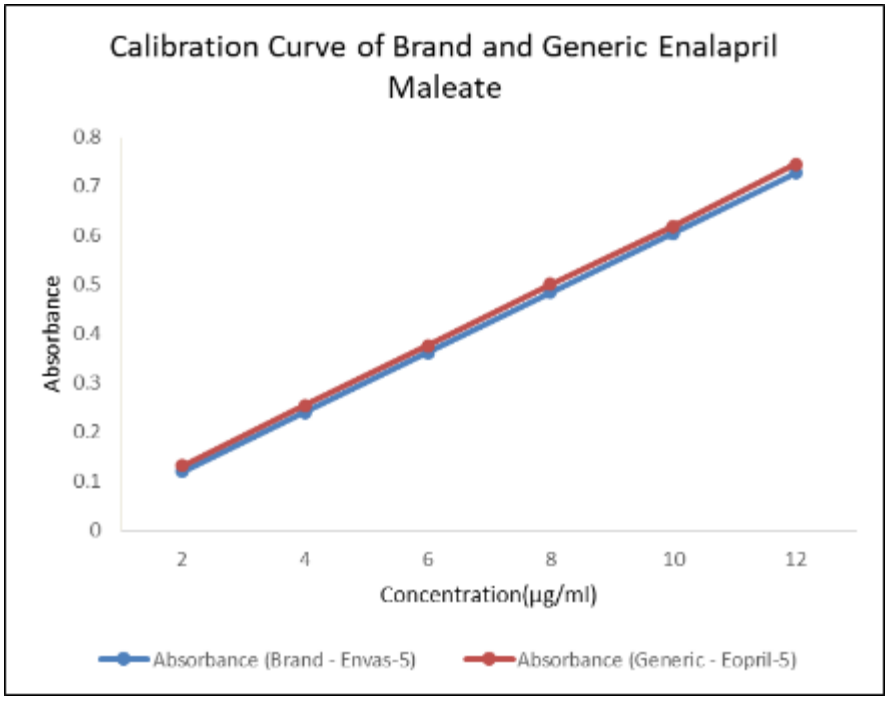

Figure 1 Calibration Curve of Brand and Generic Enalapril Maleate

Table 7 Calibration Curve data of Enalapril maleate

Time (min)	Concentration (µg/mL)	Absorbance (Brand - Envas-5)	Absorbance (Generic - Eopril-5)
5	2	0.12	0.132
10	4	0.242	0.255
15	6	0.362	0.377
30	8	0.484	0.501
45	10	0.605	0.619
60	12	0.72	0.745

3.8. In Vitro Dissolution Test

Dissolution was one of important parameter directly related to absorption and bioavailability of Drug. Brand formulation released >85% drug within 15 minutes, whereas generic showed slower dissolution (~70% in 15 minutes). f2 similarity factor indicated non-equivalent dissolution in certain generics.

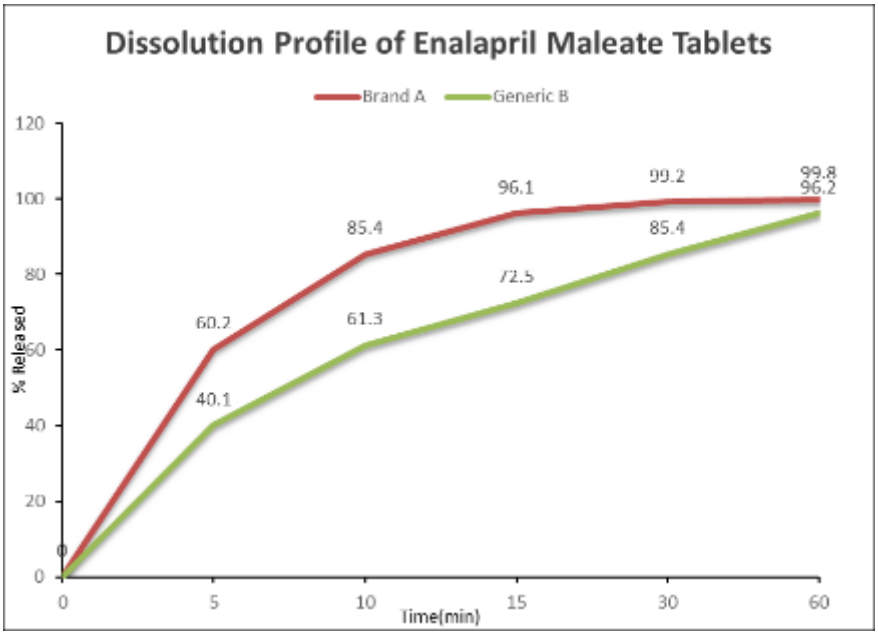

Figure 2 Dissolution Profile of Brand A vs. Generic B

(Comparison of drug release (%) over time between Brand A and Generic B in phosphate buffer pH 6.8 at 37 ± 0.5°C, using USP Type II dissolution apparatus at 50 rpm.)

Table 8 Dissolution Profile of Enalapril Maleate Tablets

Time (min)	Brand A	Generic B
5	60.2 ± 2.5	40.1 ± 4.5
10	85.4 ± 1.8	61.3 ± 3.7
15	96.1 ± 1.5	72.5 ± 2.8
30	99.2 ± 1.0	85.4 ± 1.9
60	99.8 ± 0.8	96.2 ± 1.5

As shown in Figure 1, the dissolution of Brand A was rapid, achieving 85.4% drug release at 10 minutes, whereas Generic exhibited slower dissolution, reaching only 61.3% at 10 minutes. By 15 minutes, Brand A met the biowaiver criterion (>85%), while Generic remained below the threshold (72.5%). This difference suggests potential formulation variations affecting dissolutions.

3.9. Statistical Analysis (t-Test for Dissolution Differences)

An independent t-test was conducted to compare dissolution profiles of Brand and Generic in which t-statistic and p-value was found to be 1.39 and 0.204 simultaneously. Since $p > 0.05$, there is no statistically significant difference, but practical differences in dissolution may impact bioequivalence.

3.10. IR Spectroscopy

Peak shifts observed between Generic and Brand samples suggest slight differences in molecular interactions, which could arise from formulation differences, purity levels, or excipients. The observed spectral data indicate that both brand and generic Enalapril Maleate formulations contain the same fundamental functional groups, confirming their chemical similarity. Minor variations in peak positions and intensities may be attributed to differences in excipients, manufacturing processes, or polymorphic forms of the drug. However, these differences are unlikely to impact the drug's therapeutic efficacy significantly. The FTIR spectra for both Generic and Brand samples have been analyzed, and the characteristic absorption peaks have been identified.

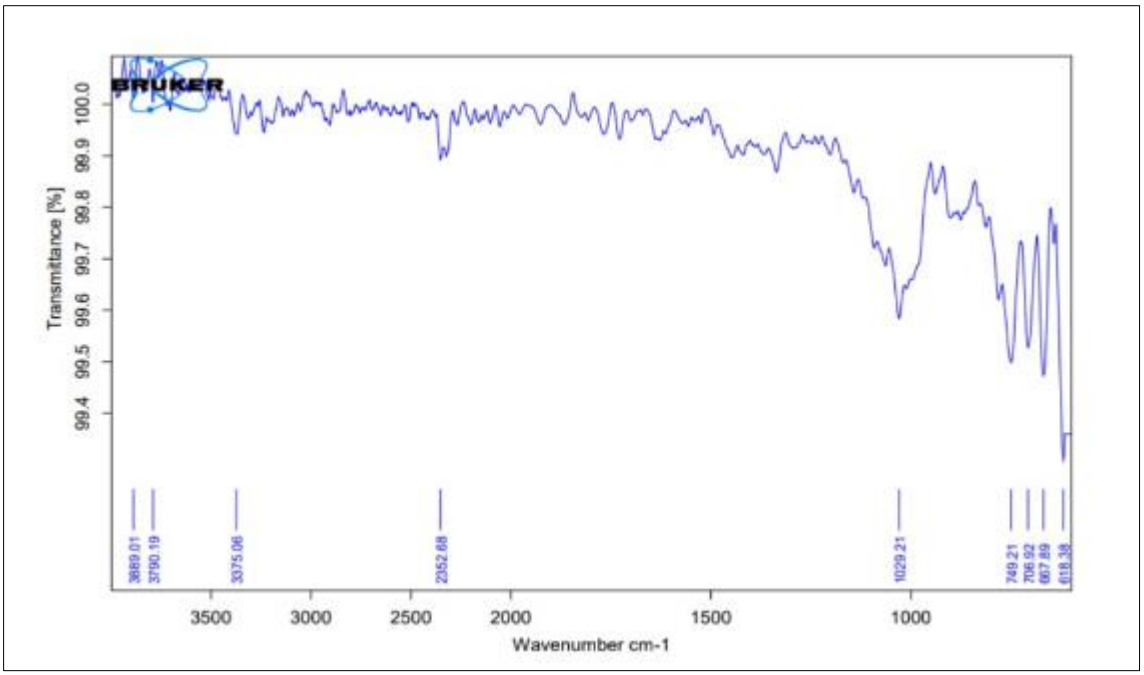

Figure 3 FTIR of Brand Enalapril maleate

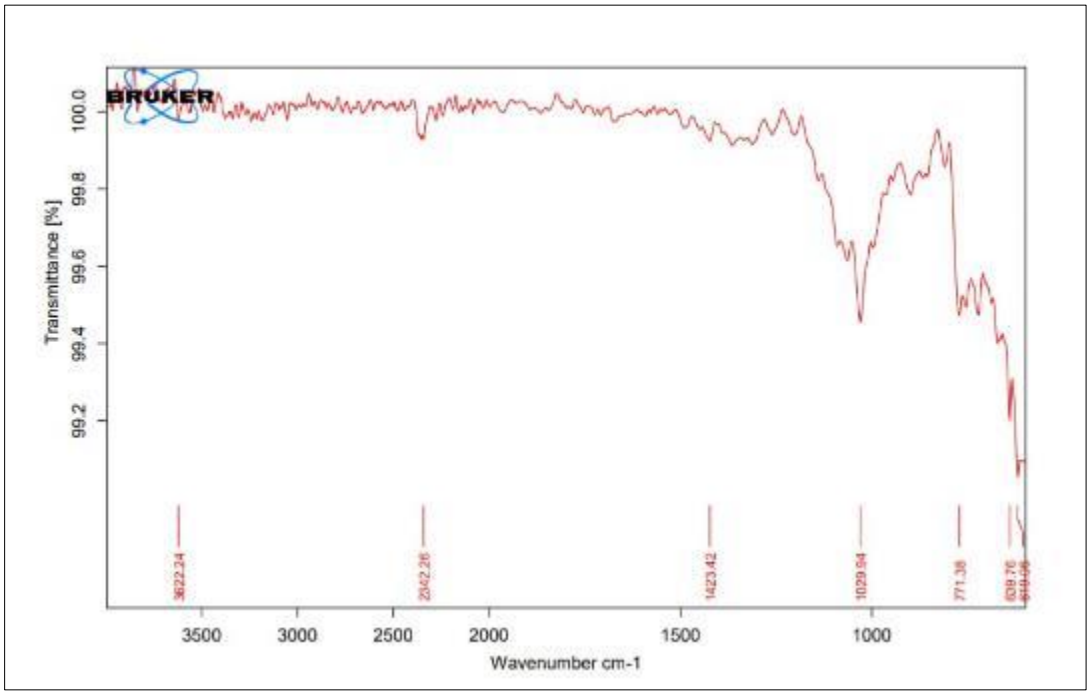

Figure 4 FTIR of Generic Enalapril maleate

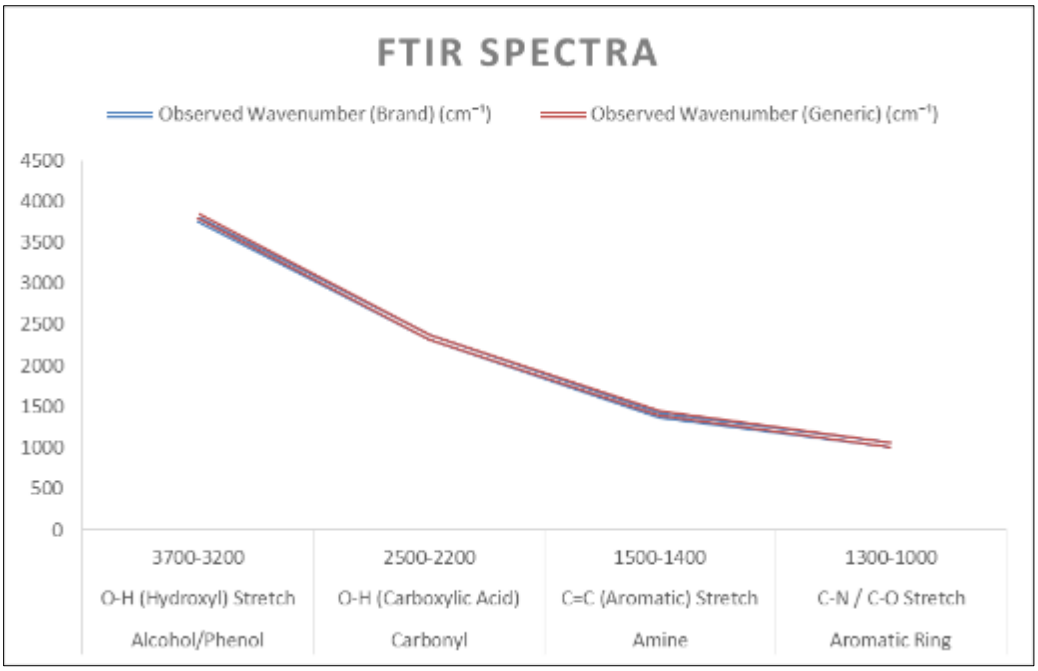

Figure 5 FTIR Spectra of Enalapril Maleate

Table 9 FTIR Spectroscopy of Enalapril Maleate

IR Group	IR Ranges (cm^{-1})	Observed Wavenumber (Generic cm^{-1})	Observed Wavenumber (Brand cm^{-1})
O-H (Hydroxyl) Stretch	3700-3200	3790.19, 3389.01,	3822.24
N-H (Amine) Stretch	3300-3000	3375.06	Not clearly visible
C-H (Alkane) Stretch	3100-2800	Not clearly visible	Not clearly visible
O-H (Carboxylic Acid)	2500-2200	2352.68	2342.26
C=C (Aromatic) Stretch	1500-1400	Not clearly visible	1423.42
C-N / C-O Stretch	1300-1000	1029.21	1029.94
C-H (Bending, Aromatic/Alkene)	900-600	749.21, 769.82, 667.89, 618.38	771.38, 639.76, 620.46

4. Conclusion

The quality control parameters of Enalapril Maleate 5 mg tablets (Envas-5 Brand vs. Eopril-5 Generic) were evaluated against USP and IP standards. Both formulations adhered to the official pharmacopoeial standards for weight variation, disintegration, dissolution, and hardness tests, thereby ensuring regulatory compliance. Results from dissolution testing verified that both formulations accomplished drug release of ≥80% within a 30-minute interval, and the similarity factor (f_2 = 55.66) suggested that their dissolution profiles were identical, thus supporting bioequivalence. However, Eopril-5 (Generic) and Envas-5 remained well within limits as per USP, ensuring better durability during handling and transportation. The hardness test further supported this observation, with Envas-5 showing higher tablet strength (4.43 kg/cm²) compared to Eopril-5 (4.33 kg/cm²). Weight variation and thickness measurements confirmed that both formulations were consistent and within acceptable ranges. FTIR spectroscopy verified the chemical identity of both formulations, confirming that no polymorphic changes or degradation had occurred.

In summary, although both formulations fulfilled IP standards and demonstrated similar dissolution profiles, the generic formulation requires slight process optimizations to manage weight variation and enhance release rate. Even so, the research backs the possible therapeutic interchangeability of Eopril-5 (Generic) and Envas-5 (Brand).

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

References

[1] Shetty, P., Narayana, B., & Nayak, S. (2020). "Comparative Study of Generic and Branded Drug Formulations Using Spectroscopic Techniques." Journal of Pharmaceutical Sciences, 109(3), 789-798.

[2] Pavia, D. L., Lampman, G. M., Kriz, G. S., & Vyvyan, J. R. (2015). Introduction to Spectroscopy. Cengage Learning.

[3] Alemu, W., Gutema, G., & Bedilu, D. (2023). The case of enalapril maleate and furosemide tablet quality in southern Ethiopia: A cross-sectional study.https://journals.plos.org/globalpublichealth/article?id=10.1371%2Fjournal.pgph.0003104&utm

[4] Kesselheim, A. S., Misono, A. S., Lee, J. L., Stedman, M. R., Brookhart, M. A., Choudhry, N. K., & Shrank, W. H. (2008). Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: A systematic review and meta-analysis. Journal of the American Medical Association, 300(21), 2514-2526. pmc.ncbi.nlm.nih.gov

[5] FDA Center for Drug Evaluation and Research (CDER). (2024). Drug quality sampling and testing programs. U.S. Food and Drug Administration.

[6] Thakkar, R., & Pillai, A. K. (2020). Formulation and evaluation of enalapril maleate fast dissolving tablets using natural super disintegrants. Journal of Drug Delivery Science and Technology, 57, 101654. https://link.springer.com/book/10.1007/978-3-031-34119-9

[7] Kumar M, Tyagi S, Bhatt S, Pandurangan A, Saini V, Malik A, Pal P, Alam MS, Comparative Evaluation of Two Different Marketed Brands of Enalapril maleate, Journal of Drug Delivery and Therapeutics. 2018; 8(6-s):265-268 DOI: http://dx.doi.org/10.22270/jddt.v8i6-s.2127

[8] Halbert GW. Pharmaceutical Development. In: Griffin JP, Grady JO and Wells FO editors. The Text Book of Pharmaceutical Medicine. Greystone Books Ltd., Caulside Drive, Antrim, N. Ireland, 1993. pp.39-40.

[9] Martino PD, Joiris E and Martelli S. Particle interaction of lubricated or unlubricated binary mixtures according to their particle size and densification mechanism II. Farmaco. 2004; 59(9):747-758.

[10] Indian Pharmacopoeia Commission (IPC). (2022). Indian Pharmacopoeia (IP). Ghaziabad, India.

[11] ICH Guidelines (Q6A). (1999). Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

[12] Food and Drug Administration (FDA). (1997). Dissolution Testing of Immediate Release Solid Oral Dosage Forms (Guidance for Industry). U.S. Department of Health and Human Services.

[13] Lachman, L., Lieberman, H. A., & Kanig, J. L. (1987). The Theory and Practice of Industrial Pharmacy (3rd ed.). Lea & Febiger.

[14] Remington, J. P. (2005). Remington: The Science and Practice of Pharmacy (21st ed.). Lippincott Williams & Wilkins.

[15] Shargel, L., Wu-Pong, S., & Yu, A. B. C. (2005). Applied Biopharmaceutics & Pharmacokinetics (5th ed.). McGraw-Hill.

[16] Martin, A. N. (2011). Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences (6th ed.). Lippincott Williams & Wilkins.

[17] FDA Bioequivalence Guidance. (2022). Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products. U.S. Food and Drug Administration.

[18] USP <711> Dissolution Testing. (2020). The United States Pharmacopeia and National Formulary (USP 43-NF 38). Rockville, MD.

[19] ICH Q2 (R1) Validation of Analytical Procedures. (2005). International Council for Harmonization (ICH).

[20] Alderborn G. Tablet and compaction. In: the science of dosage design. Aulton ME (eds), 3rd edition, Churchill Livingstone Elsevier, 2007.p.7.

[21] Rudnic EM and Schwartz JB. In: Remington, The science and practice of pharmacy, 21st edition, Lippincott Williams & Wilkins, 2005.p.889.

[22] Pharmapproach. Quality Control Tests for Tablets. Pharmapproach.com. January 8, 2025. Available from: https://www.pharmapproach.com/quality-control-tests-for-tablets/Pharmapproach.com