Comparative Study of Quality of Marketed Product of Branded And Generic Ranax Tablet

Dr.Kapil Malviya[1], Dr. Sandhya Godi[2]
[1]Corporate institute of pharmacy Bhopal MP
[2]Kydsctsakegaon college of pharmacy Bhusawal MS

Abstract- *This study provides a comparative evaluation of branded and generic ranolazine tablets, (Ranax) specifically focusing on Ranozex 500 mg, available in the Indian market for managing chronic angina linked to ischemic heart disease (IHD). Ranolazine, the active ingredient in these tablets plays a significant role in controlling angina symptoms by reducing myocardial oxygen Demand and stabilizing heart function, enhancing the quality of life for patients with chronic angina. This activity highlights Ranlazine's clinical relevance as a long-term treatment for angina, focusing on its mechanism, therapeutic benefits, and integration within a comprehensive care plan alongside other cardiovascular medications. A detailed comparison between branded and generic versions, including their pharmacokinetics, cost-effectiveness, patient accessibility, and safety profiles, is presented to guide healthcare providers in optimal treatment selection. The study underscores, the advantages of generic options, like Renulaz, in broadening access to essential medications while meeting regulatory standards for efficacy and safety. In the present study, an attempt was made to evaluate the quality and pharmaceutical equivalence of branded and generic Ranolazine tablet sample easily available in market in India. Ranolazine was selected for the present study because it mostly prescribed tablet for the management of angina (heart-related chest pain).The study was performed using in-vitro methods as per Indian Pharmacopoeia 2018. Both samples were assessed through both official and non-official tests like hardness, friability, weight variation, disintegration time, dissolution profile, assay and impurity testing Both samples met the prescribed limit and found to be of good quality, safe and effective.*

Keywords- *Ranax, Ranazoline ,Generic, Branded*

I. INTRODUCTION

Ranozex 500mg (Ranolazine)

Ranolazine was approved by the US FDA in January 2006 for the treatment of chronic stable angina in patients who have had an inadequate response to traditional anti-anginals. It differs from traditional anti-anginal drug therapies in that its anti-ischemic effects are independent of a hemodynamic effect (e.g. heart rate and/or blood pressure). The presently preferred route of administration for Ranolazine is oral. A typical oral dosage form is a compressed tablet, a hard gelatin capsule filled with a powder mix or granulates, or a soft gelatin capsule (soft gel) filled with a solution or suspension.

Chronic angina is a relatively common cardiovascular disorder that affects millions of patients worldwide, causing significant disability and inhibiting activities of daily living.Ranolazine was FDA-approved in 2006 for the treatment of chronic stable angina.

Chronic stable angina affects more than 7 million people in America and Is one of the major causes of significant morbidity in these patients.

Stable angina is treated to reduce the symptoms and occurrence of ischemia and to prevent myocardial infarction and mortality.[5] Standard therapy includes aspirin, beta-blockers, P2Y12 inhibitors, angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers, statins, calcium channel blockers, and nitrates. Ranolazine may be used in combination with these agents to treat angina.

The mechanism of ranolazine's anti-anginal and anti-ischemic effects is not entirely understood. Ranolazine is known to inhibit the late phase of inward sodium channels in ischemic cardiac myocytes, reducing the intracellular sodium concentration and thus reducing intracellular calcium influx via the Na-Ca channel. Decreased intracellular calcium reduces ventricular wall tension and thus reduces oxygen consumption; it does not affect blood pressure or heart rate. The Monotherapy Assessment of Ranolazine in Stable Angina (MARISA) trial randomized 191 patients with activity-limiting angina to 500 mg, 1000 mg, or 1500 mg twice daily or placebo for a week. Ranolazine significantly increased exercise duration compared to placebo and had negligible effects on heart rate and blood pressure.

Dosage Forms

Ranolazine is available as 500 mg and 1000 mg extended-release tablets.

Ischemic heart disease (IHD): Ischemic heart disease (IHD), also known as coronary artery disease, is a heart-related chest pain condition resulting from reduced blood flow to the heart muscle due to narrowing or blockage in the coronary arteries. This restricted blood flow limits the oxygen supply to the heart, especially during periods of increased demand, such as physical activity or stress. The reduced oxygen triggers a characteristic chest pain known as angina, which is one of the primary symptoms of IHD. Angina often feels like pressure, heaviness, squeezing, or tightness in the chest and may radiate to the shoulders, arms, neck, or jaw. This recurring pain reflects the heart's struggle to maintain adequate oxygen levels due to compromised blood flow, impacting a person's quality of life and potentially leading to more severe complications, such as heart attacks, if left untreatedThese symptoms and effects highlight the serious consequences of ischemic heart disease if left untreated, emphasizing the importance of timely diagnosis and management.

Angina (Chest Pain):
Shortness of Breath:.
Fatigue:
Dizziness or Lightheadedness:
Nausea and Sweating:.
Heart Failure:.
Arrhythmias:
Increased Risk of Myocardial Infarction (Heart Attack):!

Feature	Branded Drug	Generic Drug
Definition	Original drug developed and patented by a pharmaceutic al company	Copy of a branded drug with the same active ingredients.
Name	Has a unique brand name chosen by the original company.	Uses the generic name, typically the chemical name.
Cost	Generally more expensive due to development and marketing costs.	More affordable, as it bypasses initial development expenses
Patent	Protected by a patent, granting exclusive rights to sell.	Can only be produced after the branded patent expires.
Approval Process	Undergoes rigorous clinical trials to prove safety and efficacy.	Must prove bioequivalenc e (same effect as the branded drug).
Appearance	Often uniquely designed with specific colors and packaging.	May look different (shape, color) but contains the same active ingredient.
Availability	Usually launched first and can be patented for up to 20 years.	Becomes available after the patent on the branded drug expires

Renulaz: A Generic Option for Ischemic Heart Disease (IHD) Treatment

Renulaz is a generic formulation used in the management of Ischemic Heart Disease (IHD), specifically for treating chronic angina. As a generic drug, Renulaz contains the same active ingredient, ranolazine, as its branded counterpart, but it offers a more cost-effective alternative. This bioequivalence ensures that Renulaz provides comparable safety and effectiveness to the original branded version, meeting the therapeutic needs of IHD patients.

The introduction of Renulaz highlights the importance of generic drugs in healthcare, as it allows for broader access to essential medications due to its affordability. By providing similar symptom relief to branded drugs, Renulaz enables patients with IHD to manage their condition more sustainably over the long term, especially when frequent, prolonged treatment is required. The availability of Renulaz demonstrates how generics enhance healthcare access, offering effective alternatives without compromising on quality or safety.

Renulaz: A Generic Drug Administration Guide

Renulaz, a generic form of ranolazine, is prescribed for managing chronic angina in ischemic heart disease (IHD) patients. Effective administration involves tailored dosing, attention to potential interactions, and close patient monitoring.

Administration Guidelines

- Starting Dose: Typically 500 mg twice daily, which may be increased to 1000 mg twice daily if tolerated and required for symptom control.
- Swallow Whole: Tablets should not be crushed or chewed; they can be taken with or without food.

Key Considerations

- Monitor QT Interval: Regular ECGs may be required due to the risk of QT prolongation.
- Kidney and Liver Health: Avoid in patients with severe liver issues (e.g., cirrhosis) and monitor those with kidney conditions.
- Drug Interactions: Avoid CYP3A4 inducers; adjust dose with moderate CYP3A4 inhibitors.
- Diabetic Patients: If taken with metformin, monitor blood glucose, as ranolazine can increase metformin levels.

Educating patients on potential side effects (e.g., dizziness, nausea) and advising on when to report symptoms ensures safe and effective use of Renulaz as a generic IHD treatment.

Mechanism of Action:

Renulaz (ranolazine) works by inhibiting the late sodium currents in heart muscle cells. This reduction in sodium levels indirectly decreases calcium overload in the heart, which improves the heart's ability to relax. By minimizing calcium overload, Renulaz reduces the oxygen demand of the heart, helping to prevent episodes of angina (chest pain) associated with IHD.

Ranazex: As a Branded drug Administration in IHD Treatment

Renazex, a branded formulation of the active ingredient ranolazine, is used in the treatment of Ischemic Heart Disease (IHD), specifically for managing chronic angina. As a branded drug, Renazex has undergone extensive clinical testing to confirm its safety and effectiveness, providing a reliable option for patients and healthcare providers.

Ranazex: Branded Drug Administration for Ischemic Heart Disease (IHD)

Ranazex, a branded form of ranolazine, is administered to manage chronic angina in patients with ischemic heart disease (IHD). Proper administration focuses on optimal dosing, minimizing side effects, and addressing potential interactions.

Drug-Drug Interactions:

- Avoid potent CYP3A4 inhibitors (e.g., ketoconazole, ritonavir).

- Limit dose to 500 mg twice daily when using moderate CYP3A4 inhibitors (e.g., diltiazem, verapamil).
- Avoid CYP3A4 inducers (e.g., rifampin) due to reduced efficacy.
- Diabetic Patients: If co-administered with metformin, blood glucose should be monitored closely, as Ranazex can increase metformin levels in the blood.

Patient education on side effects such as dizziness, nausea, and the importance of adherence to dosing helps ensure Ranazex's effective and safe use for managing IHD-related angina.

Mechanism of Action:

Ranazex, a branded formulation of ranolazine, works by inhibiting late sodium currents in the cardiac cells. By reducing sodium and, consequently, calcium overload in the heart muscle, Ranazex decreases the heart's oxygen demand, helping to prevent angina (chest pain).

Dr. Reddy's Laboratories Novartis – Teva Pharmaceuticals –.Cipla Ltd. Torrent Pharmaceuticals

Drug-Drug Interactions:

- Avoid potent CYP3A4 inhibitors (e.g., ketoconazole, ritonavir).
- Limit dose to 500 mg twice daily when using moderate CYP3A4 inhibitors (e.g., diltiazem, verapamil).
- Avoid CYP3A4 inducers (e.g., rifampin) due to reduced efficacy.
- Diabetic Patients: If co-administered with metformin, blood glucose should be monitored closely, as Ranazex can increase metformin levels in the blood.

Patient education on side effects such as dizziness, nausea, and the importance of adherence to dosing helps ensure Ranazex's effective and safe use for managing IHD-related angina.

Mechanism of Action:

Ranazex, a branded formulation of ranolazine, works by inhibiting late sodium currents in the cardiac cells. By reducing sodium and, consequently, calcium overload in the heart muscle, Ranazex decreases the heart's oxygen demand, helping to prevent angina (chest pain).

Dr. Reddy's Laboratories Novartis – Teva Pharmaceuticals –.Cipla Ltd. Torrent Pharmaceuticals

Evaluation of Tablets I.P.

The evaluation of tablets as per the Indian Pharmacopoeia (I.P.) involves several physical, chemical, and performance-related tests. Below is a detailed description of the tests commonly used for tablet evaluation, along with specific parameters:

General Appearance:

The control of the general appearance of a tablet involves the measurement of a number of attributes such as a tablet's size, shape, color, presence or absence of an odor, taste, surface texture, physical flaws and consistency, and legibility of any identifying markings.

Thickness measurement:

The measurement of the diameter and the thickness was done for selected Ranolazine 20 tablets were taken from different brands, the diameter and thickness of the tablets were measured using micrometers to determine the average thickness and diameter. The mean, percentage deviation from the mean and Standard Deviation (SD) were calculated

Weight variation:

Weight variation test was carried out to check that each of the tablet contains the labeled amount of Ranolazine. The test was conducted by weighing twenty tablets using a digital balance. The average weight was calculated in milligrams . Percentage deviation was calculated using the formula.

% deviation = Average weight of tablet - Individual tablet weight $\times$ 100

Hardness test :

Tablet hardness testers function on the principle that it yields a definite extent of force to break down a tablet. The hardness of each tablet was determined by selecting six tablets randomly using a hardness tester. Each tablet was placed between two anvils and force was applied to the anvils, and the crushing strength that causes the tablet to break was recorded. Crushing strength of average of six tablets was recorded

- **Friability test:**

The friability test was completed using the Roche friabilator. Twenty tablets were selected randomly from each brand and weighed, then placed together in the friabilator device. All tablets were subjected to the combined effect of abrasion and shocks and it was rotated at 25 revolutions per minute (rpm) for four minutes (100 times). Then, tablets were weighed and were compared with their initial weights and percentage friability was calculated

Disintegration test:

The disintegration test apparatus (Electolab) was used to determine the disintegration time of the selected tablets. Six tablets were placed in a disintegration tester filled with distilled water at $37\pm0.5°C$.The tablets were considered completely disintegrated when all the particles are passed through the wire mesh and time was recorded.

Dissolution test :

Dissolution is essential in determining the bioavailability of a drug. The dissolution test method was developed and validated for Ranolazine tablet dosage from quality control. In the present study, the in vitro dissolution study of Ranolazine tablets was done in simulated gastric fluid pH

1.2 The dissolution of Ranolazine hydrochloride was done using dissolution apparatus type II (paddle apparatus) with the rate of 50 rpm at $37\pm0.5°C$ on six tablets of each brand. The dissolution medium was 900 ml 0.1 N HCl (pH=1.2). 5 ml sample was withdrawn at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12 h and an equivalent amount of fresh dissolution medium, maintained at equal temperature, was replaced. Filtered samples were then appropriately diluted (100-fold dilutions) and absorbance readings were taken with UV/Visible Spectrophotometer at wavelength of 272 nm. Solutions of Ranolazine working standard was also prepared using dissolution medium and absorbance was measured. 0.1 N HCl was used as a blank. The concentration of each sample was determined from calibration curve and the percent of drug release at each time was calculated

These tests are critical for ensuring that the tablets produced meet the pharmacopoeial standards for safety, efficacy, and quality. They are part of the routine quality control process in pharmaceutical manufacturing and are essential to regulatory approval and patient safety.

Material And Methods

The design of study included the sample collection from the nearby community pharmacy and government hospital. All samples were checked for their shelf life and assessed for different tests like hardness, friability,weight variation, disintegration, dissolution profiling, potency test (assay), and impurity testing (related substances). All tests were performed according to Indian Pharmacopoeia 2018

The following equipment were used for the experiment: UV-Visible Spectrophotometer (Double beam Spectrophotometer, shimadzu,1800), analytical balance (Precision electronic balance, UNITED, UN602A) Pfizer hardness tester , friability tester (single drum), disintegration apparatus (Electolab ED-2L), dissolution apparatus (Electolab EDT-08Lx) type 2.

These tests are critical for ensuring that the tablets produced meet the pharmacopoeial standards for safety, efficacy, and quality. They are part of the routine quality control process in pharmaceutical manufacturing and are essential to regulatory approval and patient safety.
.

Sample collection

Two samples of Ranolazine tablets with label claim of 500 mg were used. One brands of Ranolazine tablets and another generic Ranolazine tablets were procured from the community pharmacy

Sample code	Company	Sample type	Sample collection Site	Cost (inRs)	Mfg date	Expiry date
A	SunPharma	Branded	Local pharmacy store	184	03/2023	**02/2025**
B	**Maxford Healthcare**	**Generic**	**Local pharmacy store**	**165**	**03/2024**	**02/2026**

Table1

Ranolazine UV –spectroscopy analysis

- Preparation of standard stock solution

Primary stock solution of Ranolazine was prepared by dissolving accurately weighed 100 mg of drug and transferred in to a clean and dry 1000 mL volumetric flask and dissolved in a few mL methanol made the volume up to the

mark using distilled water as a diluent to get 1000 µg/mL drug solution. The standard stock solution 1000 µg/mL was further diluted with distilled water to obtain the concentration of 100 µg/mL.

- Selection of detection wavelength for estimation of Ranolazine

The prepared solution of Ranolazine (100 µg/mL) were scanned in the ultraviolet wavelength region (200-400 nm) to determine the wavelength of maximum absorption (λ). It was observed that the drug showed maximum absorbance at 272 nm.

Observation And Result

Generic drugs by definition are equivalent to branded drugs in terms of bio-equivalence, strength,safety and efficacy. Generic drugs are relatively cheap in comparison with branded drugs. Despitethis being the case many treating physicians hardlyprescribe generic medicine. Reasons whyphysiciansusuallydoesn'tprescribegenericdrugsincludePhysicians'andsometimesevenpatients'perceptionthatthecheaperdrugsmeanslesseffectivedrugs.

General Appearance

Criteria	Sample A	Sample B
Size	18mmx9mmx5mm	19mmx9mmx5mm
Shape	Shallow Convex	Shallow Convex
Colour	Sunset Yellow FCF	Titanium Dioxide
Odour	No odour	No odour
Surface	Smooth surface with clean edges	Smooth surface with extra edges
Any marking	Mid line	Mid line

1. **Thickness test**

Results showed that the both brands were examined had the thickness withinof 5.56 and 5.72mm. Both sample showed acceptable thickness as none of the sample deviated by up to ±5.0 %fromthemeanvalueasstipulatedbythereference.

Sr.No	Sample	Label Claim	Average of 20 tablet	% deviation	Result
1	A (Ranozex)	500mg	0.7030	0.3411	Pass
2	B (Renulaz)	500mg	0.7702	0.2084	Pass

2. **Weight Variation Test**

The weight variation test of the tablet is used to confirm that the prepared tablet has the accurate amount of active drug in which no more than two tablets are outside the percentage limit. The results indicate a weight uniformity in the selected tablets and all tablets within the usual range, and no one exceeds the allowed percent as per percentage specified in Indian Phamacopiea

3. Hardness test:

Sufficient tablet hardness is essential to ensure destruction resistance to endure mechanical shocks during production, packaging, and transportation. In addition, tablets should be able to tolerate reasonable mishandling by the consumer. The mean hardness values of Ranolazine tablets are Tabulated in Table 4

Sr. No	Sample	Hardness	Result
1.	A (Ranozex)	7.8	Pass
2.	B(Renulaz)	9.4	Pass

4. Friability test

Tablets must resist corrosion when subjected to tensions from collision and tablet slip towards one another and other solid bodies, which can result in removing small pieces from the tablet surface. Both samples of Ranolazine have passed the friability test and met the IP specification, which specifies that any brand must not lose more than 1% of its initial weight

5. Disintegration

Table5

Sr. No	Sample	Friability %	Result
1	A (Ranozex)	0.006	Pass
2	B(Renulaz)	0.621	Pass

Disintegration times of the different brands of Ranolazine tablets are shown in Table 6. The results showed that all the brands passed the disintegration test according to USP in 2007, which specifies 120 min for enteric coated and delayed-release tablets

Table 4: Disuntigration of Ranozex tablet

Sr. No	Sample	Disintegration time	Result
1	A (Ranozex)	1hr.15 min	Pass
2	B(Renulaz)	1hr.38 min	Pass

6. Dissolutiontest

According to USP, the amount of Ranolazine released within 12 should not be less than 60 % of the stated amount. From the dissolution test results shown in Table 7

Table.no.7 Dissolution test of Ranozex

Table.no.7

Time (hr)	Sample A(Ranozex)	Sample B(Renulaz)
1	16.71	20.44
2	28.52	31.62
3	38.98	35.47
4	44.10	40.06
5	48.21	43.89
6	51.37	45.32
7	53.06	48.69
8	55.81	52.18
9	57.34	56.20
10	59.50	60.81
11	61.34	62.48
12	62.60	65.98

Graphical study of Ranozex table

Complication during evaluation

Renulaz: A Generic druge valuation complication

Evaluating generic drugs like Renulaz can present several challenges and complications, which are essential to address to ensure they meet standards equivalent to branded drugs, such as Ranazex, in terms of safety and efficacy for treating ischemic heart disease (IHD)-related chest pain. Key complications in evaluating Renulaz might include:

1. Bioequivalence Testing: Generic drugs must demonstrate bioequivalence to the branded version, meaning they should have similar bioavailability (the rate and extent of drug absorption in the bloodstream). Minor variations could impact effectiveness or side effects.
2. Quality Control Standards: The manufacturing process of generic drugs might face more stringent quality checks to ensure that the drug consistently matches the branded version's purity, potency, and stability. Inconsistent manufacturing could lead to variations in the therapeutic effect.
3. Therapeutic Equivalence: While bioequivalence is required, therapeutic equivalence (same clinical outcomes) is also critical but can be more complex to evaluate, especially if minor formulation differences affect the drug's efficacy or safety profile in sensitive populations.
4. Regulatory Compliance: Renulaz, like any generic drug, must comply with stringent regulatory requirements, which differ from country to country. Meeting these

standards can pose logistical and cost challenges that affect the timeline and accessibility of the generic drug.

5. Perception and Acceptance: Patients and healthcare providers may hesitate to adopt generic drugs due to concerns about effectiveness, even if the generic has proven bioequivalence and therapeutic equivalence. This can influence prescribing habits and acceptance rates, complicating its evaluation on a broader scale.

6. Adverse Event Monitoring: Post-marketing surveillance of generic drugs may sometimes reveal unexpected adverse events, especially in real-world usage across diverse patient populations. Monitoring these events is essential but can be challenging and costly.

Ranazex: As a Branded drug evaluation complication

Evaluating a branded drug like Ranazex for treating ischemic heart disease (IHD)-related chest pain can present unique complications. These challenges differ from those associated with generic drugs, given the brand's proprietary nature, innovation standards, and regulatory expectations. Key complications in evaluating Ranazex include:

1. Clinical Trial Standards: Branded drugs undergo rigorous clinical trials to demonstrate safety and efficacy. Designing and conducting these trials, especially for a complex condition like IHD, requires significant time, resources, and stringent adherence to regulatory protocols. Trial results may vary based on patient demographics, which complicates generalized efficacy conclusions.

2. Long-Term Safety and Efficacy: For a new drug, long-term effects on patients with chronic conditions like IHD aren't always fully known at launch. Evaluating long-term safety requires extended post-marketing studies and surveillance, which are both costly and time-consuming.

3. High Cost and Resource Allocation: The development of branded drugs involves high costs for research, testing, and marketing. These costs must be recouped through pricing strategies, which can affect accessibility and lead to concerns over affordability for patients.

4. Regulatory Approval Process: Branded drugs must meet strict regulatory standards, often requiring extensive documentation, trials, and proof of innovation or therapeutic advantage over existing treatments. Any delay or complication in the approval process, such as unexpected side effects during trials, can significantly impact the drug's market entry and profitability.

5. Patent Limitations and Competition: Patents provide a limited period of market exclusivity. Evaluation during this period must justify the investment before generics enter the market. If the branded drug doesn't establish strong evidence of superior efficacy or safety, competition

from generics can reduce its market share after patent expiration.

6. Post-Market Surveillance and Liability: Even after approval, branded drugs like Ranazex are subject to stringent monitoring for adverse effects. High standards of accountability mean that any safety issue can lead to costly recalls or legal action, affecting both the brand's reputation and financial stability.

These factors make evaluating a branded drug like Ranazex challenging, as thorough assessments of efficacy, safety, cost-effectiveness, and long-term outcomes are necessary to justify its use over generic alternatives. effects. This would allow optimized dosing for those more prone to QT prolongation or other side effects.

1. Innovations in Drug Delivery: Exploring novel delivery methods, such as transdermal patches or oral dissolving tablets, could improve patient compliance and broaden options for those with swallowing difficulties or absorption issues.

2. AI and Predictive Analytics: Using AI to track real-world outcomes and patient responses could help identify trends in effectiveness, detect rare side effects sooner, and refine treatment recommendations for different patient demographics.

The continuous evaluation, risk prevention, and innovative approaches in formulation and delivery will allow Ranazex to maintain its efficacy and safety standards while adapting to evolving patient needs

II. CONCLUSION

Generic drugs by definition are equivalent to branded drugs in terms of bio-equivalence, strength, safety and efficacy. Generic drugs are relatively cheap in comparison with branded drugs. Patients needs to be understand about the meaning of generic drugs.

The results of this study showed that all brands of Ranolazine 500 mg (Ranozex, Renulaz) oral tablets conformed to the official specification of standard pharmacopeia. Both tablets disintegrated within a time limit of less than 120minutes. An in vitro release study of the drug in

1.1 N HCl (pH 1.2) exceeded 65% after 12 h. According to the outcomes of this study, there were no deviations from pharmacopeial standards.

REFERENCES

[1] StatPearis (internet). Ranolazine: Mirembe Reed; Connor C. Kerndt, Shwetha Gopalt: Mark V. Pellegrini, Diala Nicolas.

[2] Gunda, R.K., Manchineni, P.R., Duraiswamy, D., Gan, K.R. (2022): Design, development, optimization and evaluation of ranolazine extended release tablets.

[3] Ja, S.K., Khanabhi, S. (2019): Development and Doppa, D.V.S, Konidala, S.K., Khanabhi, S. validation of UV spectroscopic method for the determination of ranolazine in bulk and formulation.

[4] Kumari, M.V., Reddy, P.V., Sudhakar, M. (2012): Formulation and evaluation of sustained release matrix tablets of ranolezine. International Journal of Pharmacy 2(1): 224-229

[5] Priya, M.R. Natarajan, R, Rajendran, N.N. (2011): Design and in vitro evaluation of sustained release tablets of ranolazine. International Journal of Pharmaceutical Sciences and Research 2(4): 922-928

[6] Ugale, J.B. Mulgund, S.V. (2015) Development and Validation of UV Spectrophotometric Area under cure method for Quantitative Estimation of Ranolazine in API and Tablet Formulation World Journal of Pharmaceutical Research 4(5): 2665- 2672

[7] Vambhurkar, G. B., Jagtap, A.M., Gavade, A.S., Rajput, M.D., Kambale, H.V, Kengar, M.D. (2018). Evaluation of five Different Marketed Brands of Paracetamol Tablets using Quality Control Tests - Asian Journal of

[8] Pharmacy and Technology (4): 227-230 PHARMACY Leon Lachman, Herbert A. Lieberman Joseph L. Kanig's Book of "The Theory and Practice of Industrial Pharmacy", Third Edition.

[9] Rayner-Hartley E, Sedlak T. Ranolazine: A Contemporary Review. J Am Heart Assoc. 2016 Mar 15;5(3):e003196. [PMC free article] [PubMed]

[10].Mezincescu A, Karthikeyan VJ, Nadar SK. Ranolazine: A true pluripotent cardiovascular drug or jack of all trades, master of none? Sultan Qaboos Univ Med J. 2018 Feb;18(1):e13-e23. [PMC free article] [PubMed]