ejpmr, 2024, 11(3), 195-202

SJIF Impact Factor 7.065

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

DETERMINATION AND EVALUATION OF PRAZOSIN HYDROCHLORIDE SUSTAINED RELEASE TABLETS AT DIFFERENT PH BY RP-HPLC METHOD

Komathi A.[1], Bakyalakshmi M.[2]*, Gokulan P. D.[3] and Senthilkumar K. L.[4]

[1]M. Pharm Student, Sri Vijay Vidyalaya College of Pharmacy, Dharmapuri, Tamilnadu, India.
[2]Associate Professor, Department of Pharmaceutical Chemistry, Sri Vijay Vidyalaya College of Pharmacy, Dharmapuri, Tamilnadu, India.
[3]Professor cum Head, Department of Pharmaceutical Analysis, Sri Vijay Vidyalaya College of Pharmacy, Dharmapuri, Tamilnadu, India.
[4]Principal, Sri Vijay Vidyalaya College of Pharmacy, Dharmapuri, Tamilnadu, India.

***Corresponding Author: Bakyalakshmi M.**

Associate Professor, Department of Pharmaceutical Chemistry, Sri Vijay Vidyalaya College of Pharmacy, Dharmapuri, Tamilnadu, India.

Article Received on 08/01/2024 **Article Revised on 29/01/2024** **Article Accepted on 19/02/2024**

ABSTRACT

The aim of this study was to provide comparative evaluation of multimedia dissolution profile studies conducted for the "Prazosin SR Tablets 5 mg" Generic and Branded Product. Generic drugs are equivalent to the Branded products if they have same active substance, the same pharmaceutical form, the same Therapeutic Indications and a similar Bioequivalence with respect to the Reference Medical product. A simple, sensitive and accurate In-vitro dissolution method was used according to USP dissolution testing methodologies with different media's to ensure that manufactured generic product maintains its drug release as per the reference lead drug product by using RP-HPLC method. The In-vitro dissolution profile was obtained using 900ml of four different media like 0.1N Hcl, Acetate Buffer 4.5, Phosphate Buffer 6.8 and 0.1N Hcl with 2% of SLS as Dissolution Medium at 37ºC ± 0.5ºC and USP I (Basket) with 100 rpm. The samples are collected at particular time interval and the % In-vitro drug Release was Determined. The drug release was evaluated by RP-HPLC method with Chromatographic Conditions of a stainless steel column (10cm x4.6cm, 5µm) Using methanol and buffer at 50:50 volumes as Mobile phase at Flow rate 1.0 ml/min with detection wavelength 254 nm. Based on the obtained test results, the results meets the acceptance criteria, Among different dissolution medium's The drug substance is less soluble in pH 4.5 acetate Buffer medium and pH 6.8 Phosphate Buffer medium Then 0.1 N hydrochloric Acid medium and 0.1 N hydrochloric Acid with 2% SLS medium and The dissolution profile for the test product Of Prazosin SR Tablets 5 mg (Generic Product) compared against the Reference sample (Prazopill XL 5) is found satisfactory Which is Compared in terms of difference factor (f1) and similarity factor (f2). In conclusion, the study focused on the sustained-release formulation of Prazosin 5 mg tablets has successfully demonstrated the appropriateness of drug release characteristics when compared to the reference product. Through testing and analysis, we have established that the sustained-release mechanism in the generic formulation aligns closely with the reference product, ensuring the intended release profile of the active ingredient. This finding holds significance not only in terms of meeting regulatory standards but also in assuring healthcare practitioners, patients, and regulatory bodies of the therapeutic consistency and efficacy of the generic formulation compared to the reference product.

KEYWORDS: Prazosin Hydrochloride 5mg Sustained release tablet (Generic and Reference Product), Comparative evaluation of In-vitro drug release, % of drug release, RP-HPLC method.

INTRODUCTION

A tablet is like a solid medicine that you take by swallowing. It's made by mixing the main medicine with other stuff, usually in powder form. Then, this mixture gets pressed or squeezed to create a solid dose, which is the tablet. Tablets can be made in different ways, like by molding or squeezing. To make the tablet work well, they add other things like diluents, binders, glidants, and lubricants. These are like helpers that make sure the tablet is made properly. There's also something called a disintegrant, which helps the tablet break up inside your body. Sometimes, they add sweeteners, flavors, or pigments to make the tablet taste better or look nice. And, to make it easier to swallow or control how the medicine comes out, they might put a special coating on the tablet. This coating can also help the tablet last longer or stay good for a more extended time. So, in simple

words, a tablet is a solid medicine that's made with a mix of things and can have a coating for different reasons.[1,2]

TYPES OF TABLETS[3]

Tablets are classified according to their route of administration or function.

The following are the 4 main classification groups

1. Tablets ingested orally

a) Compressed tablets.
b) Multiple compressed tablets.
c) Multi layered tablets.
d) Sustained action tablets.
e) Enteric coated tablets.
f) Sugar coated tablets.
g) Film coated tablets.
h) Chewable tablets.

2. Tablets used in the oral cavity, Buccal tablets

a) Sublingual tablets.
b) Lozenge tablets and troches.
c) Dental cones.

3. Tablets administered by other routes

a) Implantation tablets.
b) Vaginal tablets.

4. Tablets used to prepare solutions

a) Effervescent tablets, Molded tablets or tablet triturates(TT)
b) Dispersible tablets(DT)
c) Hypodermic tablets(HT)

SUSTAINED RELEASE

A sustained release dosage form is a special kind of medicine that is carefully made and can control how the medicine is released in the body. This means it's designed to let the medicine out at a specific rate so that the right amount stays in the blood or at the target place in the body. In the last twenty years, more and more people have become interested in this kind of medicine. There are a few reasons for this. First, making new medicines can be very expensive, so finding ways to use existing ones more efficiently is important. Also, as some patents for medicines have expired, it has opened up opportunities to explore sustained release options. Additionally, new materials have been discovered that can help the medicine last longer in the body. This technology isn't just for people – it's also being used for animals. These sustained release systems let the medicine out slowly over a longer time, and they can control when and where the medicine is released in the body. In simple terms, these systems help keep a steady level of medicine where it's needed in the body for a longer time, making treatments more effective and safe.

Advantages of sustained drug delivery system

- Total amount of dose decreases.
- Improved patient compliance.
- Increased safety of drugs.
- Obtain less potentiation or reduction in drug activity with chronic use.
- Minimize drug accumulation with chronic dosing.
- Improve efficiency in treatment.
- Cure or control condition more promptly.
- Reduction in fluctuation of blood drug level.
- Improve bioavailability of some drugs.
- Make use of special effects, e.g. sustained-release aspirin for morning relief of arthritis by dosing before bedtime.
- SR drug delivery system aims at optimized therapy constant blood levels.
- Constant blood levels achieved with desired effect and this effect is maintained for an intended period of time.
- Drugs susceptible to enzymatic inactivation or by bacterial decomposition can be protected by encapsulation in polymer system suitable for SR.

Disadvantages of sustained drug delivery system

- Chances of dose dumping.
- Dose retrieval is difficult.
- High cost of formulation.
- Need for additional patient education.
- Reduced potential for accurate dose adjustment

The performance of a drug presented as a controlled/sustained release system depends upon its

1. Release from the formulation.
2. Movement within the body during its passage to the site of Action[4]

HPLC

In High-performance liquid chromatography (HPLC), there's a competition between the moving and standing parts to sort out the different bits of a sample. HPLC relies on two methods for separation: adsorption and partition. Adsorption chromatography uses tiny particles with a lot of surface area that stick to the molecules in the sample. Usually, a solid like silica gel, alumina, or porous glass beads is used, and it's combined with a liquid that moves, called the mobile phase – like heptanes, octane, or chloroform. Partition chromatography is another method where the solid part is coated with a liquid. The way the sample parts move between these two liquids decides how they get separated. The coating on the solid part can be either polar or non-polar. If it's non-polar, it's called normal phase partition chromatography, and if it's the opposite, it's called reversed-phase partition chromatography. In the normal phase, the polar parts of the sample stick more to the solid part and take longer to move, while in the reverse phase, it's the opposite. This helps scientists separate and analyze different components in a sample using HPLC.

TYPES OF HPLC TECHNIQUES

1. Based on modes of chromatography

a) Normal phase chromatography
b) Reverse phase chromatography

2. Based on principle of separation
a) Adsorption chromatography
b) Ion exchange chromatography
c) Size exclusion chromatography
d) Affinity chromatography

3. Based on elution technique
a) Isocratic separation
b) Gradient separation

4. Based on the scale of operation
a) Analytical HPLC
b) Preparative HPLC

REVERSE PHASE CHROMATOGRAPHY

In the 1960s, scientists made changes to how chromatography works. They wanted to make a material called silica less attracted to water, so they chemically mixed it with other substances. This way, they could use liquids that dissolve in water to separate things that also dissolve in water. When they did this, the nature of silica changed, and they named this type of chromatography "Reverse-phase chromatography." In this method, the parts that move the fastest are the ones that are not very attracted to water. When the liquid that helps the separation becomes more water-like, the time it takes for the parts to move decreases. This method is excellent for separating things that have a charge or are attracted to water. The liquids used in this process are common ones like Methanol, Acetonitrile, and Isopropanol. So, scientists use Reverse-phase chromatography to sort out and study substances that dissolve in water, making it a helpful tool in the world of chemistry.[5]

ABOUT DRUG

High Blood Pressure, also known as hypertension, is often referred to as the "Silent killer" because it is a widespread, dangerous condition that usually shows little to no symptoms. Many people may not even know they have it until it reaches a severe stage, leading to life-threatening outcomes like a stroke. Due to the lack of specific symptoms, it's recommended for adults to have their blood pressure checked every five years. Blood pressure is the force exerted on the walls of blood vessels as the heart pumps blood through them. An increase in blood pressure puts extra strain on the artery walls, potentially causing complications such as strokes, kidney damage, or heart attacks. The measurement of blood pressure, done with a device called a Sphygmomanometer, is recorded in millimeters of mercury (mm Hg). Blood pressure readings have two numbers. The higher one is called systolic pressure, indicating the blood pressure when the heart beats. The lower one is diastolic pressure, representing the pressure when the heart is at rest between beats. A normal blood pressure level is around 120/80 mm Hg, while a reading above 140/90 mm Hg is considered high. High blood pressure is a common condition and, when left untreated, can lead to severe damage to vital organs such as the brain, heart, blood vessels, kidneys, and more. The consequences may include heart disease, heart attacks, heart failure, strokes, kidney failure, loss of vision, and other health problems. To address hypertension, a variety of medications known as anti-hypertensive drugs are available. These drugs aim to bring blood pressure back to normal levels. Among these medications, alpha-blockers play a crucial role in regulating blood pressure by affecting alpha-adrenergic receptors. These receptors, specifically alpha-1 and alpha-2, play important roles in controlling blood pressure. Alpha-blockers like Doxazosin, Prazosin, and Terazosin are commonly used to lower blood pressure. They work by preventing a hormone called Nor-epinephrine from tightening muscles in smaller arteries and veins, promoting open and relaxed blood vessels, improving blood flow, and ultimately reducing blood pressure. Alpha-blockers are also employed to enhance urine flow in older men with prostate problems. Understanding and managing high blood pressure, along with appropriate medication when necessary, are crucial steps in preventing serious health complications associated with this common and often silent condition. Regular monitoring, healthy lifestyle choices, and effective medical intervention can contribute to maintaining optimal blood pressure levels and overall well-being. Prazosin Hydrochloride, developed in 1965 and introduced for medical use in 1974, is a widely used medication available in generic form. In 2020, it became the most commonly prescribed medication in the United States, with over 2 million prescriptions. This medication, classified as an Alpha-blocker, is known for its versatility. Prazosin hydrochloride is primarily used to treat high blood pressure. Additionally, it is employed alone or in combination with other drugs to manage symptoms related to an enlarged prostate and nightmares associated with Post-traumatic stress disorder (PTSD). Other potential applications include addressing heart failure and Raynaud Syndrome, a condition where fingers and toes change color due to temperature variations.

The mechanism of Prazosin involves dilating blood vessels, making it easier for blood to flow through the body, thus reducing blood pressure. In the case of an enlarged prostate, it helps by relaxing the outflow of the bladder. This makes Prazosin Hydrochloride a valuable medication with various uses, contributing to its widespread prescription and usage in medical practice.[6-10]

Chemical details: All chemicals used in the analysis either AR grade or an equivalent grade and HPLC Grade.
Sample Details: The sample batch numbers and other relevant details of Prazosin SR Tablets 5mg and Reference product specified below.

Test and Reference samples

Name	Manufacturer	B. No	Expiry Date
Prazosin SR Tablets 5 mg	Bal Pharma, Unit-I	PRA/005	11/2025
Prazopill XL 5	Intas Pharmaceuticals Ltd	K2301257	05/2026

METHODOLOGY

DISSOLUTION BY HPLC

Apparatus No II : Basket.
Medium : 0.1N Hydrochloric acid containing 2% Sodium Lauryl Sulphate; 900 ml.
Time : 1st Hour, 2nd Hour, 4th Hour, 6th Hour, 8th Hour, 10th Hour, 12th Hour and 24th Hour.
RPM : 100.
Temperature : 37ºC ± 0.5ºC

PREPARATION OF MEDIUM 1

Preparation of 0.1 N hydrochloric Acid

Prepare required quantity of 0.1 N hydrochloric Acid by diluting 8.5 ml of concentrated hydrochloric acid to 1000 ml of water. (In 7 liters of water dissolved 59.5 ml of hydrochloric Acid and mixed well.)

PREPARATION OF MEDIUM 2

Weigh accurately about 140.0 g of sodium lauryl sulphate and to this add about 5000 ml of 0.1 N hydrochloric Acid solution and stir contentiously until it dissolves. Then make up the volume up to 7000 ml with 0.1 N hydrochloric Acid solution.

PREPARATION OF MEDIUM 3

Acetate buffer (pH: 4.5)

Prepare required quantity of Acetate buffer by dissolving 2.99 g of sodium Acetate trihydrate in 1000 ml of water. (For 7 liters of buffer dissolved 20.93 g of sodium Acetate trihydrate in 7000 ml of water) and pH is adjusted to 4.5 with glacial acetic acid.

PREPARATION OF MEDIUM 4

Phosphate buffer (pH: 6.8)

Prepare required quantity of phosphate buffer by dissolving 6.8 g of Potassium dihydrogen ortho phosphate in 1000 ml of water. (For 7 liters of buffer dissolved 47.681 g of Potassium dihydrogen ortho phosphate in 7000 ml of water) and pH is adjusted to 6.8 with sodium hydroxide solution.

CHROMATOGRAPHIC SYSTEM

Column : A stainless steel column (10cm x4.6cm, 5µm)
Packing L1 : 1.0 ml/minute.
Flow rate : 254 nm.
Wavelength : 60µl.
Injection : 40ºC
Column Temperature : NLT 2 times the retention of Prazosin.
Run time

BUFFER PREPARATION: Weigh 3.4 g/L of sodium dihydrogen phosphate adjust with 10% sodium hydroxide solution to a pH of 7.5.

MOBILE PHASE PREPARATION: Take a mixture of 50 volumes of methanol and 50 volumes of buffer.

STANDARD SOLUTION

- Accurately weigh and transfer 12.0 mg of Prazosin Hydrochloride WS/RS to volumetric flask dissolve and make up to volume with medium and mix.
- Further transfer 5 ml of above standard solution to a 50 ml volumetric flask, and make up to volume with medium and mix.
- Further transfer 5 ml of above standard solution to a 100 ml volumetric flask, and make to volume with medium and mix.

SAMPLE SOLUTION

- Keep 6 bowls in dissolution apparatus; add 900 ml of dissolution medium in each bowl.
- After obtaining the requirement temperature, place one tablet to each basket.
- Stop the basket rotation after temperature of media reached 37ºC ± 0.5ºC and basket containing tablet.
- Bring down the basket assembly and start rotation. After specified time withdraw (1st Hour, 2nd Hour, 4th Hour, 6th Hour, 8th Hour, 10th Hour, 12th Hour and 24th Hour) sufficient volume (10 ml) of medium from each bowl.
- Filter the sample solution through suitable filter (whatman filter paper No. 41.) Discard the first few ml of filtrate and use the resulting solution.
- After each withdrawal of sample replace with 10 ml of dissolution medium Inject standard and sample solution.

SYSTEM SUITABILITY: Tailing factor: NMT- 2.0; Relative standard deviation is NMT – 3.0%.

RESULTS AND DISCUSSION

DISSOLUTION TEST

Table 1: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) ((Hydrochloric acid (0.1N), pH 1.2).

Dissolution Medium	Hydrochloric Acid (0.1 N)															
Sample	Dissolution Profile (%)															
	B. No: PRA/005								B. No : K2301257							
	Prazosin SR Tablets 5 mg								Prazopill XL 5							
	1 Hr	2 Hrs	4 Hrs	6 Hrs	8 Hrs	10 Hrs	12 Hrs	24 Hrs	1 Hr	2 Hrs	4 Hrs	6 Hrs	8 Hrs	10Hrs	12Hrs	24 hrs
Unit-1	3	6	15	24	33	43	53	94	2	2	4	9	16	25	38	92
Unit-2	2	4	10	17	22	34	43	86	2	1	4	12	19	28	38	94
Unit-3	2	5	12	22	32	43	54	95	3	5	16	30	43	60	74	95
Unit-4	2	6	15	24	32	42	53	95	2	2	8	19	29	44	60	100
Unit-5	2	6	15	25	34	41	51	96	2	4	12	25	38	50	64	97
Unit-6	2	4	11	19	28	39	48	93	2	2	7	18	28	39	53	94
Min (%)	2	4	10	17	22	34	43	86	2	1	4	9	16	25	38	92
Max (%)	3	6	15	25	34	43	54	96	3	5	16	30	43	60	74	100
Average (%)	2	5	13	22	30	40	50	93	2	3	8	19	29	41	55	95
Similarity Factor(f_2)	75															
Difference Factor(f_1)	8															

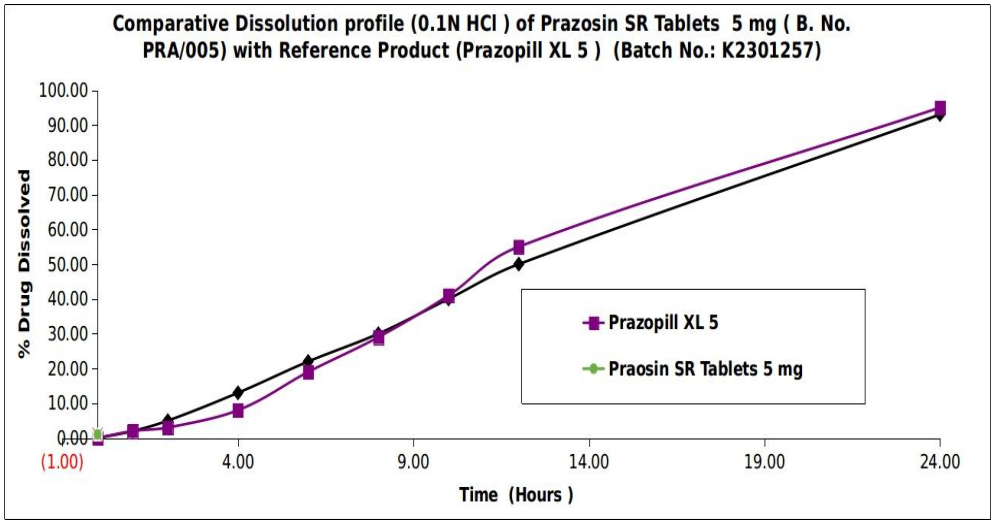

Fig No 1: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) ((Hydrochloric acid (0.1N), pH 1.2).

Table 2: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) (pH 4.5 Acetate Buffer).

Dissolution Medium	pH 4.5, Acetate buffer															
Sample	Dissolution Profile (%)															
	B. No: PRA/005								B. No : K2301257							
	Prazosin SR Tablets 5 mg								Prazopill XL 5							
	1Hr	2 Hrs	4 Hrs	6 Hrs	8 Hrs	10 Hrs	12 Hrs	24 Hrs	1 Hr	2 Hrs	4 Hrs	6 Hrs	8 Hrs	10Hrs	12Hrs	24 hrs
Unit-1	2	6	15	23	33	39	43	63	4	9	17	23	29	38	42	52
Unit-2	3	7	12	19	27	34	38	63	4	9	16	25	35	39	45	59
Unit-3	3	6	13	19	27	35	39	62	5	10	16	22	29	35	39	60
Unit-4	3	9	17	27	36	37	36	58	4	7	16	24	32	35	38	59
Unit-5	3	6	11	20	30	36	43	66	5	7	17	26	35	39	46	58

Unit-6	3	8	16	26	36	41	46	64	4	5	13	21	29	36	46	61
Min (%)	2	6	11	19	27	34	36	58	4	5	13	21	29	35	38	52
Max (%)	3	9	17	27	36	41	46	66	5	10	17	26	35	39	46	61
Average (%)	3	7	14	23	31	37	41	63	4	8	16	23	32	37	43	58
Similarity Factor(f_2)	**81**															
Difference Factor(f_1)	**5**															

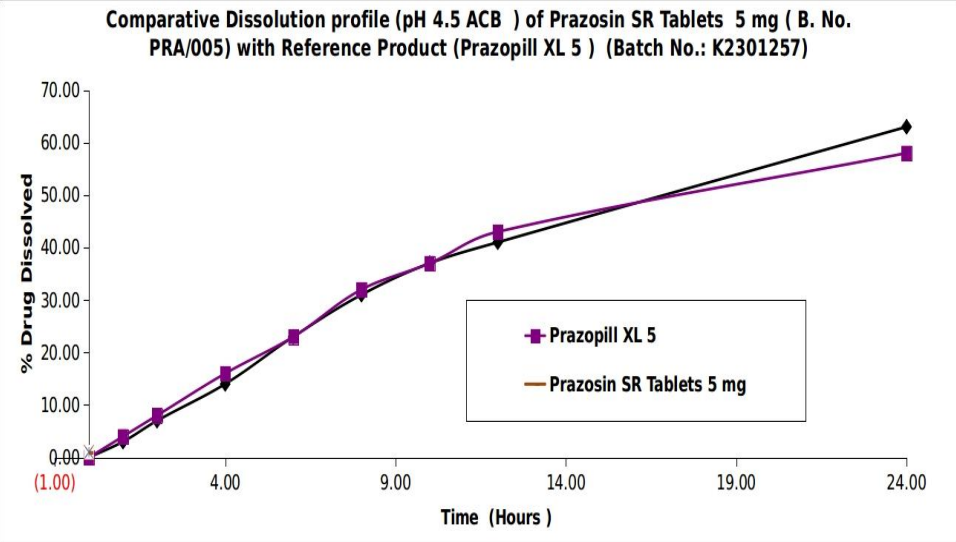

Fig. No. 2: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) (pH 4.5 Acetate Buffer).

Table 3: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) (pH 6.8 Phosphate Buffer).

Dissolution Medium	**Phosphate Buffer pH 6.8**															
Sample	**Dissolution Profile (%)**															
	B. No: PRA/005								**B. No : K2301257**							
	Prazosin SR Tablets 5 mg								**Prazopill XL 5**							
	1Hr	**2 Hrs**	**4 Hrs**	**6 Hrs**	**8 Hrs**	**10 Hrs**	**12 Hrs**	**24 Hrs**	**1Hr**	**2 Hrs**	**4 Hrs**	**6 Hrs**	**8 Hrs**	**10 Hrs**	**12 Hrs**	**24 hrs**
Unit-1	2	4	8	15	23	30	34	64	2	6	7	12	18	24	30	75
Unit-2	1	3	6	11	15	20	26	49	1	3	7	14	20	24	32	49
Unit-3	2	4	9	18	26	31	36	61	2	4	12	12	30	24	31	59
Unit-4	2	4	9	15	23	30	37	54	1	3	12	20	18	24	32	49
Unit-5	2	5	10	18	26	31	35	53	2	4	9	14	20	25	46	60
Unit-6	2	3	7	12	18	25	32	56	2	5	9	20	30	39	47	76
Min (%)	1	3	6	11	15	20	26	49	1	3	7	12	18	24	30	49
Max (%)	2	5	10	18	26	31	37	64	2	6	12	20	30	39	47	76
Average (%)	2	4	8	15	22	28	33	56	2	4	9	16	23	27	37	61
Similarity Factor(f_2)	**79**															
Difference Factor(f_1)	**7**															

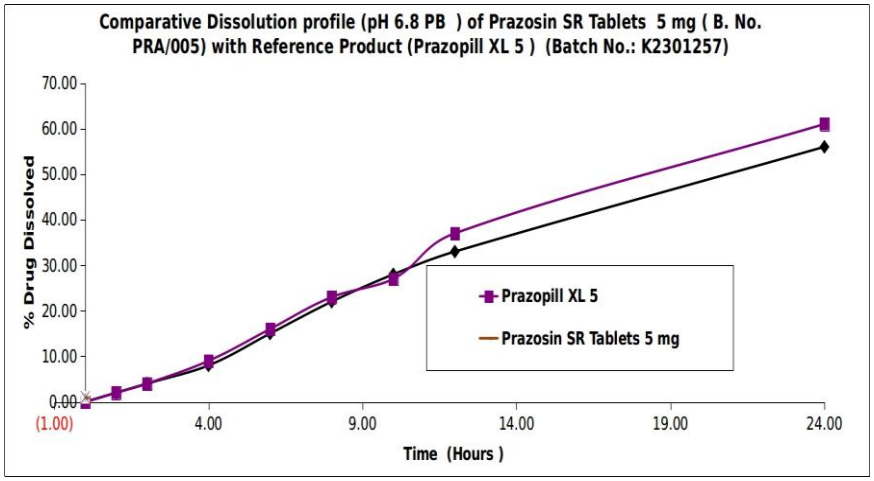

Fig. No. 3: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) (pH 6.8 Phosphate Buffer).

Table 4: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) (Hydrochloric Acid 0.1 N with 2% SLS).

Dissolution Medium	Hydrochloric Acid 0.1 N with 2% SLS															
Sample	Dissolution Profile (%)															
	B. No: PRA/005								B.No : K2301257							
	Prazosin SR Tablets 5 mg								Prazopill XL 5							
	1 Hr	2 Hrs	4 Hrs	6 Hrs	8 Hrs	10 Hrs	12 Hrs	24 Hrs	1 Hr	2 Hrs	4 Hrs	6 Hrs	8Hrs	10Hrs	12Hrs	24 hrs
Unit-1	2	8	25	37	56	72	85	106	6	12	22	41	63	82	96	105
Unit-2	3	13	30	45	61	77	91	103	8	12	22	42	62	82	83	105
Unit-3	4	13	32	52	64	86	95	103	6	12	22	42	63	83	98	108
Unit-4	5	15	32	44	58	71	83	107	6	12	20	48	60	72	84	105
Unit-5	5	15	30	46	61	75	87	103	8	12	20	48	59	72	98	108
Unit-6	4	13	29	44	57	69	79	100	6	12	20	47	60	72	84	105
Min (%)	2	8	25	37	56	69	79	100	6	12	20	41	59	72	83	105
Max (%)	5	15	32	52	64	86	95	107	8	12	22	48	63	83	98	108
Average (%)	4	13	30	45	60	75	87	104	7	12	21	45	61	77	91	106
Similarity Factor(f_2)	70															
Difference Factor(f_1)	5															

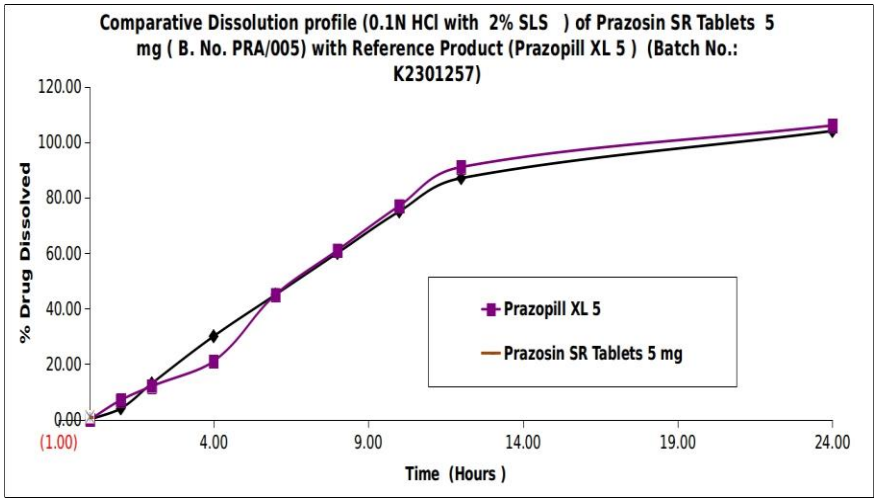

Fig. No 4: Comparison of Dissolution Profile Data from Prazosin SR Tablets 5 mg and Reference product (Prazopill XL 5) (Hydrochloric Acid 0.1 N with 2% SLS).

Summary of Report

S. No	Dissolution Media	Results	Acceptance Criteria
1	**Hydrochloric acid buffer (0.1 N), pH 1.2**	Similarity Factor (f2) is **75** Difference Factor (f1) is **8**	Similarity Factor (f2) should be between **50 -100** Difference Factor (f1) should be between **0 - 15**
2	**Acetate buffer pH 4.5**	Similarity Factor (f2) is **81** Difference Factor (f1) is **5**	Similarity Factor (f2) should be between **50 -100** Difference Factor (f1) should be between **0 - 15**
3	**Phosphate buffer pH 6.8**	Similarity Factor (f2) is **79** Difference Factor (f1) is **7**	Similarity Factor (f2) should be between **50 -100** Difference Factor (f1) should be between **0 – 15**
4	**Hydrochloric acid buffer, 0.1 N Hydrochloric Acid with 2% Sodium Lauryl sulphate.**	Similarity Factor (f2) is **70** Difference Factor (f1) is **5**	Similarity Factor (f2) should be between **50 -100** Difference Factor (f1) should be between **0 – 15**

CONCLUSION

Based on the obtained test results. **The results meet the acceptance criteria** Among different dissolution mediums The drug substance is less soluble in pH 4.5 acetate Buffer medium and pH 6.8 Phosphate Buffer medium Then 0.1 N hydrochloric Acid medium and 0.1 N hydrochloric Acid with 2% SLS medium and **The dissolution profile for the test product of Bal Pharma (FR&D) (Prazosin SR Tablets 5 mg) compared against the Reference sample (Prazopill XL 5) is found satisfactory Which is Compared in terms of difference factor (f1) and similarity factor (f2). In conclusion, the study focused on the sustained-release formulation of Prazosin 5 mg tablets has successfully demonstrated the appropriateness of drug release characteristics compared to the reference product**. Through testing and analysis, we have established that the sustained-release mechanism in the generic formulation aligns closely with the reference product, ensuring the intended release profile of the active ingredient. The comprehensive assessment, encompassing dissolution studies and potential influencing factors, provides confidence in the equivalence of drug release from the sustained-release Prazosin 5 mg tablets. **This finding holds significance not only in meeting regulatory standards but also in assuring healthcare practitioners, patients, and regulatory bodies of the therapeutic consistency and efficacy of the generic formulation compared to the reference product.** These results support the viability and reliability of **the generic sustained-release Prazosin 5 mg tablets as an alternative to the reference product.** The study's outcomes contribute valuable insights to pharmaceutical science, providing a basis for informed decision-making by healthcare professionals and regulatory authorities, ultimately enhancing accessibility to cost-effective yet efficacious medication options for patients.

BIBLIOGRAPHY

1. Verma P, Thakur AS, Deshmukh K, Jha AK, Verma S. Routes of drug administration. International Journal of Pharmaceutical Studies and Research, Jul., 2010; 1(1): 54-9.
2. http:/en.wikepiedia.org/wiki/Tablets
3. Aulton, ME., 2007. pharmaceutics- "The Sciences of dosage form design" third edition. international student edition, Churchill living stone, 2007; 419-421.
4. Goyal S, Agarwal G, Agarwal S, Karar PK. Oral sustained release tablets: an overview with a special emphasis on matrix tablet. American journal of advanced drug delivery, 2017; 5(4).
5. http//en.wikipedia.org/wiki/Chromatography
6. https://www.news-medical.net/high-blood pressure hypertension.
7. https://medicineplus.gov/drug info/ meds.
8. https://go.drugbank.com/drugs/Db00457.
9. https://www.mayoclinic.ory/alpha-blockers.
10. https://en.wikipedia.org/prazosin.