



# ENHANCED SUSTAINED RELEASE CHARACTERISTICS OF PROPRANOLOL HYDROCHLORIDE IN FORMULATION SR008 WITH HPMC K100M

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*Propranolol hydrochloride, microcrystalline cellulose (PH-101), Microcrystalline Cellulose (PH-102), HPMC (K15 M), HPMC (K100 M), HPMC (K4 M), HPC LF, Isopropyl alcohol, Povidone (K-30), Magnesium Stearate were used in the different formulations. Among different formulations, SR008 having HPMC K100M was showing better sustained release characteristics, 69.1%, 76.6%, 82.3% for 8, 10, 12 hr. respectively compared to other formulations with 71% moisture content and 71N hardness.*

**Keywords:** -Drug, Propranolol, Cardiovascular, Polymers, Patient.

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## I. INTRODUCTION

When it comes to the pharmaceutical industry, drug delivery is an essential component that is continuously undergoing development in order to improve therapeutic effectiveness and patient compliance. Sustained release formulations have become more popular among the many different types of drug delivery systems due to their capacity to progressively release therapeutic ingredients over a prolonged period of time. There is a formulation known as SR008 that comprises Propranolol Hydrochloride (PH) and Hydroxypropyl Methylcellulose (HPMC) K100M. This formulation shows promise in terms of providing a regulated and extended release of the active pharmaceutical

component. Propranolol Hydrochloride is a non-selective beta-adrenergic antagonist that is commonly used for the management of cardiovascular disorders such as hypertension and angina. Because of its short half-life, however, it is necessary to administer it often, which might result in changes in plasma levels as well as possible adverse effects. These issues are intended to be addressed by sustained release formulations, which attempt to provide a regulated release profile, minimize peak-to-trough variations, and improve patient adherence. In the process of developing formulations for sustained release, the selection of polymers is of the utmost importance. Hydroxypropyl Methylcellulose (HPMC) K100M emerges as a good option owing to its exceptional gelling

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qualities and biocompatibility. Polyhydroxymethyl cellulose (HPMC) is a derivative of cellulose that, when hydrated, creates a matrix that resembles gel. This matrix controls drug release by processes of diffusion and erosion. In the current investigation, the features of sustained release of propranolol hydrochloride in formulation SR008 are investigated. This formulation makes use of HPMC K100M as the release-controlling polymer. The need of a dependable and patient-friendly dosage form that is capable of maintaining therapeutic drug levels over a prolonged period of time was the driving force behind the creation of SR008 as a pharmacological vehicle. To accomplish this objective, it is necessary to have a full knowledge of the interaction that exists between the components of the formulation, the manufacturing processes, and the kinetics of drug release that are produced as a consequence. The purpose of this research is to shed light on the sustained release behavior of SR008 via the use of systematic inquiry. This will provide significant insights for professionals working in the pharmaceutical industry, including formulators, and doctors.

The process of sustained release in SR008 is dependent on the one-of-a-kind characteristics of HPMC K100M, which, when it comes into contact with water conditions, transforms into a gel matrix. This matrix performs the function of a barrier, therefore regulating the diffusion of propranolol hydrochloride from the dosage form into the media that is around it. Additionally, the erosion features of HPMC contribute to the sustained release profile, which ensures that the medicine is released in a regulated and steady manner over the course of sufficient time. Its capacity to offer a balance between mechanical strength, hydration rate, and drug release kinetics served as the justification for the selection of HPMC K100M as the material of choice. To achieve the intended release profile, the formulation development process requires careful selection of excipients and optimization of their concentrations. This is done in order to obtain the desired release profile. In SR008, the composition of the

excipient is fine-tuned to guarantee that Propranolol Hydrochloride is compatible with HPMC K100M. This allows for the therapeutic advantages to be maximized while the possible side effects are minimized. It is equally important to consider the manufacturing process since it has an effect on the formulation's physical and chemical characteristics, which ultimately has an effect on how the medicine is released into the body. An extensive number of in vitro and in vivo tests have been carried out in order to carry out a full evaluation of the sustained release features of SR008 medication. The purpose of in vitro dissolution experiments is to model the release profile of propranolol hydrochloride under physiological settings. These studies provide significant data on release kinetics, dissolving rates, and the influence of a variety of environmental variables. In addition to these investigations, in vivo pharmacokinetic studies are conducted to evaluate the performance of the formulation in live creatures. These studies provide information about the patterns of absorption, distribution, metabolism, and excretion. The data that were obtained from these experiments not only support the sustained release profile of SR008, but they also give a foundation for understanding the components that influence its performance that are impacting its performance. Methodical research is conducted to explore several aspects of the formulation, including polymer concentration, particle size, and production factors, with the goal of optimizing the formulation for improved therapeutic effects. Furthermore, the impact of physiological factors, such as pH and gastrointestinal motility, on drug release is thoroughly investigated in order to guarantee that the formulation is effective across a wide range of clinical settings. Propranolol Hydrochloride and HPMC K100M are both components of the sustained release formulation SR008, which is a potential improvement in the field of medication delivery for cardiovascular diseases. This exhaustive study goes into the complex aspects of the formulation, shedding light on the processes that regulate continuous

release and giving priceless insights that may be used for future research and development. SR008 stands out as a testament to the ongoing efforts to optimize drug delivery systems, offering a potential solution for improving therapeutic outcomes and patient compliance in the management of cardiovascular diseases. This is a testament to the fact that the pharmaceutical industry continues to prioritize patient-centric approaches.

## II. REVIEW OF LITERATURE

**Khamkat, Piyaliet al., (2023)** The purpose of this project is to design and create sustained-release tablet formulations of propranolol hydrochloride utilizing various grades of HPMC and MCC, as well as to evaluate these formulations in laboratories. Several grades of polymers were investigated and compared with regard to their effects on the release of drugs from tablets as well as some other features. The Components and Procedures: In the various formulations, propranolol hydrochloride, microcrystalline cellulose (PH-101), microcrystalline cellulose (PH-102), high-performance micro cellulose (HPMC) (K15 M), high-performance micro cellulose (K100 M), high-performance micro cellulose (K4 M), high-performance cellulose (HPC LF), isopropyl alcohol, povidone (K-30), and magnesium stearate were used. For the manufacture of tablets, the procedures of direct compression, dry granulation, and wet granulation were used. Among the various formulations, SR008 with HPMC K100M had superior sustained release characteristics, with 69.1%, 76.6%, and 82.3% for 8, 10, and 12 hours respectively. This was in comparison to other formulations that had a moisture content of 71% and a hardness of 71N. The extension of the release of propranolol hydrochloride has been effectively accomplished by the use of the matrix embedding approach that makes use of HPMC K100M. It is especially useful for creating directly compressed sustained-release matrix tablets that meet the necessary criteria and have drug release characteristics that are easily repeatable. Once daily doses of the developed formulations may be prescribed, which results in a decrease in both the

frequency of dosage and the amount of medicine that is taken on a daily basis. This is in contrast to the standard formulation, which requires prescriptions three times a day. It has been determined that HPMC K100M, when used in the proper amounts, is acceptable for the formulation of sustained-release tablets that display diffusion-controlled Higuchi kinetics for propranolol hydrochloride.

**Mulani, Hareshet al., (2011)** in preparation for its use in extended release matrix tablets, the properties of Kollidon® SR, a novel excipient based on polyvinyl acetate and povidone, were investigated. The following formulation and process factors were examined to determine their impact on tablet characteristics and drug release: the concentration of Kollidon® SR in the tablet, the inclusion of an external binder for wet granulation, the presence of an enteric polymer in the matrix, the mode of manufacture, and the compression force. The use of the model independent f2 similarity factor was utilized in order to assess the similarities that were present in the release profiles. Through research, it was discovered that Kollidon® SR is appropriate for extended release matrix tablets that are pH-independent. In order to establish a coherent matrix that was capable of extending the release of the medications that were integrated, it was required to have a minimum concentration of thirty percent polymer. It was shown that increasing the concentration of Kollidon® SR in the tablet resulted in a delayed release of the medicine. The release of the drug was determined by the square root of time-dependent kinetics, which suggests that the release mechanism was regulated by diffusion. The drug's solubility in water had an effect on the rate at which it was released into the body. Wet granulation resulted in a quicker rate of drug release compared to direct compression; hence, direct compression was selected as the technique of choice for the production of Kollidon® SR extended release systems. In the presence of an external binder or enteric polymer in the matrix, it was discovered that Kollidon® SR was the primary agent responsible for limiting the release of

chemical substances. In the course of the stability test that was conducted under accelerated settings, it was noticed that there was a notable decrease in the dissolving rates that were related with an increase in tablet hardness. The formulation of propranolol matrix tablets that was produced was evaluated in comparison to the product that was specified as the reference (Inderal® LA capsules). After careful consideration, it was determined that Kollidon® SR has the potential to be an effective excipient for the manufacturing of pH-independent prolonged release matrix tablets.

**Salger, S.V et al., (2010)** specifically, the current investigation focuses on the formulation of sustained-release matrix tablets containing the anti-hypertensive medication propranolol hydrochloride. The rate retarding polymer that is employed is Hydroxypropyl methyl cellulose K100M, and the diluents that are used are lactose and dibasic calcium phosphate. The pace at which the medication is released was explored, and the impacts of the amount of the polymer as well as the influence of co-excipients such as lactose and dibasic calcium phosphate were taken into consideration. The findings of the current research indicate that the ratio of drug to HPMC is the primary factor that determines the pace at which propranolol hydrochloride is released from HPMC K100M matrices with respect to the drug. When the effect of excipients on the release of the medication was investigated, it was found that lactose, which is an excipient, increased the rate at which propranolol hydrochloride was released. On the other hand, dibasic calcium phosphate (DCP) displayed a slower release rate that was seen. A number of characteristics, including hardness, friability, uniformity of weight, uniformity of drug content, invitro drug release, and short-term stability tests, were tested for the sustained release matrix tablets that were manufactured. In the sequence of lactose to dibasic calcium phosphate, the values of dissolving time at 50% and 90% for the co-excipients were as follows: lactose > 2.

**Gendle, R et al., (2010)** Through the use of polymers (HPMC K100M, HPMC K15M, and

HPMC K 4M) as a cost-effective, non-toxic, readily accessible, and appropriate hydrophilic matrix system, the purpose of this study was to manufacture sustained release tablets containing highly water-soluble Tramadol HCl. Using the wet granulation process, sustained release tablets of Tramadol HCl with a dosage of fifty milligrams were manufactured. Subsequently to the examination of the tablets' different physical features. Two hours were spent in 0.1 N hydrochloric acid for the dissolving test, and ten hours were spent in phosphate buffer with a pH of 6.8. The release profile does not alter after the pills have been stored for a period of three months. After using the zero order plot, the Higuchi, Korsmyer, and Peppas equation was used in order to reach the release kinetics that provided the best possible match. Due to the fact that the proportion of Tramadol HCl that is released after 12 hours is very close to 100 percent, the data that was acquired demonstrated that the formulations are helpful for a sustained release of the drug.

**Malviya, Rishabhaet al., (2010)** Within the scope of this inquiry, an effort was made to use gum acacia and tamarind gum as release modifiers in order to create sustained release matrix tablets of diclofenac sodium. For both gum acacia and tamarind gum, six batches of sustained release matrix tablets containing diclofenac sodium were made by using various drug: polymer ratios, including 1:1, 1:1.5, 1:2, 1:2.5, 1:3, and 1:3.5. These ratios were used to manufacture the tablets. The tablets were examined for their hardness, friability, and weight fluctuation, and an invitro release was carried out in phosphate buffer saline (PBS) with a pH of 7.4 for a period of twenty-four hours. A further investigation was conducted to investigate the dispensability of gums at varying concentrations. This study included swelling. When it came to its physical characteristics, the tablet that was manufactured was within acceptable limitations. Acacia gum had a greater degree of edema than tamarind gum. Using the matrix tablet (Batch F) of the tamarind gum, we were able to achieve a more effective sustained drug release of

98.7%. The findings demonstrated that the drug release from matrix tablets made with natural polymers may be maintained for a period of time more than twelve hours, and that the drug release varies depending on the concentration of polymer present in the matrix tablets.

**Radhika, P et al., (2009)** the objective of this research was to create a novel monolithic matrix tablet that would be capable of delivering glipizide in a zero-order fashion and continue to do so for an extended length of time. Using a medicine in a formulation that contains polymer such as Hydroxypropyl methyl-cellulose K 100 (HPMCK) and Eudragit L 100, two different techniques were investigated. Due to the fact that the granules were manufactured using the wet granulation process, they were formulated as F-1 and F-2. In order to build up polymers with other components, F-3 and F-4 need the use of the aforementioned. An analysis was performed on the granules of various formulations to determine their angle of repose, loose bulk density and tapped density, compressibility index, total porosity, and drug content. A range of  $25.0 \pm 0.8$  to  $28.0 \pm 1.1$  was observed for the angle of repose, while the compressibility index (%) varied from  $12.92 \pm 0.02$  to  $13.08 \pm 0.03$  for the compressibility index. When the angle of repose is less than thirty degrees, it indicates that the granules have very excellent flow qualities. The lower values of the compressibility index provided more evidence in favor of this. All aspects of the granules, including their compressibility, flow characteristics, and drug content, were good. With altering formulation composition, it was noted that all of the formulations exhibited uniform thickness (C.V < 0.5%), uniform weight, and there were very few significant differences detected amongst the formulations. The pharmacopoeial limit for the percentage of deviation in the weight variation test is 7.5% difference for tablets larger than 130 mg to 324 mg. This restriction applies to tablets that have a weight variation. It was determined that the formed matrix tablet had the following technological characteristics: thickness, diameter, weight

variation test, drug content, hardness, and friability. Additionally, the in vitro drug release was assessed using a dissolving equipment. Out of the many different formulations that were identified, the formulation (F3) that was preferred comprised of thirty milligrams of HPMCK and thirty-five milligrams of Eudragit L100. This formulation was put through stability testing for a period of three months at a temperature of four degrees Celsius. The temperature at room temperature was maintained between 25 degrees Celsius and 45 degrees Celsius, with a relative humidity of  $75 \pm 5\%$ . Additionally, the stability of the release pattern was conserved. According to the results of the kinetic release treatment, the drug is released in a manner that is consistent with zero order kinetics ( $r^2 = 0.9959$ ). The Kores Meyer equation yielded a value of  $r^2 = 0.9853$ , which was quite near to one, suggesting that the drug was indeed released using zero order kinetics. In accordance with the Kores Meyer equation, the regression values for the formulations F-1, F-2, and F-4 were found to be 0.9823, 0.9785, and 0.9742, respectively. With regression values of 0.9619 and 0.9959, respectively, the similar plot for (log cumulative % drug release vs time) for Korsmeyer-Peppas equation demonstrated a strong linearity for the commercially available sustained release tablet and formulation F-3. This was the case for both formulations. Through the use of a scanning electron microscope, it was determined that the optimized batch of matrix tablet F-3 exhibited both diffusion and erosion mechanisms. Based on the findings, it seems that the tablet F-3 formulation of glipizide has the potential to function therapeutically better than the one that is currently available on the market, which would result in improved efficacy.

**Rao, Raghavendra et al., (2009)** A variety of polymers, including Hydroxypropyl methyl cellulose (HPMC) and natural gums such as Karaya gum (KG) and carrageenan (CG), were used in order to accomplish the primary goal of this study, which was to construct sustained release matrix tablets containing water-soluble Tramadol hydrochloride. During the course of the research, several

proportions of medication to polymer, such as 1:1 and 1:2, were used. The release rates were adjusted by combining two distinct rate controlling materials and a triple mixture of three separate rate controlling materials. This was done after the ratio of drug to polymer had been fixed in order to regulate the release of the medication up to the required time. Following the assessment of the tablet's physical qualities, the in vitro release research was carried out in 0.1 N HCl with a pH of 1.2 for a period of two hours, and then in phosphate buffer with a pH of 6.8 for a period of twelve hours. Research was conducted to investigate the impact of polymer concentration as well as polymer mix concentration. There were a variety of ratios that were adopted, including 80:20, 60:40, 50:50, 40:60, and 20:80. The data on dissolution was evaluated using the power law expression developed by Korsmeyer and Peppas, as well as a modified power law expression. Through the use of matrix tablets that comprised a polymer mix of HPMC and CG, it was discovered that the release of the medicine was effectively maintained for a period of twelve hours. Formulation F16, which comprises 20% HPMC K15M and 80% CG, is the one that releases the medication in a manner that follows Zero order kinetics. This is accomplished by swelling, diffusion, and erosion. The release profile of formulation F16 was equivalent to that of the product that is already on the market. Tramadol hydrochloride was shown to be

stable in the matrix tablets (40±2°C/75±5%RH) after being subjected to stability experiments for a period of three months. According to the findings of the DSC and FTIR investigation, there was no evidence of any chemical interaction between the medicine and the excipients.

### III. RESEARCH METHODOLOGY

#### Materials

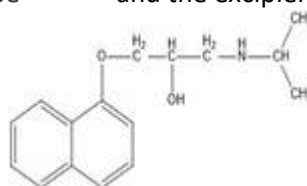
Propranolol hydrochloride, microcrystalline cellulose (PH-101), microcrystalline cellulose (PH-102), high-performance micro fluid cellulose (HPMC) (K15 M), high-performance micro fluid cellulose (K100 M), high-performance micro fluid cellulose (K4 M), high-performance cellulose (HPC LF), isopropyl alcohol, povidone (K-30), and magnesium stearate were all acquired from Alkem Labs.

Analytical reagents such as hydrochloric acid (AR grade), sodium chloride (AR grade), disodium hydrogen phosphate anhydrous (AR grade), citric acid monohydrate (AR grade), sodium hydroxide (AR grade), potassium dihydrogen phosphate (AR grade), methanol (HPLC grade), acetonitrile (HPLC grade), and water high-performance liquid chromatography (Mili Q) were also acquired from Alkem Labs.

### IV. DATA ANALYSIS AND INTERPRETATION

#### Formulation

It has been determined that several formulations, ranging from SR-001 to SR-008, have been generated by using the medication and the excipients that are listed in Table 1.



**Table 1: Comparative composition profile of different formulation.**

Sl. No.	Ingredients	Batch No.							
		SR-001 (mg/ta b)	SR-002 (mg/ta b)	SR-003 (mg/ta b)	SR-004 (mg/ta b)	SR-005 (mg/ta b)	SR-006 (mg/ta b)	SR-007 (mg/ta b)	SR-008 (mg/ta b)
1	Propranolol Hydrochloride	39	39	39	39	36	39	39	39
2	HPMC K 4M	12.2	-	-	12.2	24	-	-	-
3	HPMC K	-	24	24	-	-	24	24	24

	15M								
4	HPMC K 100M	-	12.2	12.2	-	12.2	12.2	13	18
5	HPC LF	-	-	-	25	-	-	-	-
6	Avicel PH 101	-	-	76.93	76.94	76.96	76.97	74.43	69.43
7	Avicel PH 102	220	220	-	-	-	-	-	-
8	Povidone	-	-	4.7	4.7	4.7	4.7	4.7	4.7
9	Magnesium stearate	1.49	1.49	0.73	0.73	-	-	-	-
10	Isopropyl alcohol	qs	qs	qs	qs	qs	qs	qs	qs
	Total weight	100	100	80	80	80	80	80	80

The following table provides an overview of the components that make up a pharmaceutical formulation, including the different components and the amounts of each component that are expressed in milligrams per tablet (mg/tab). In the formulation, the active component is propranolol hydrochloride, which is present in levels that are constant throughout all of the tablets. A number of excipients, including but not limited to HPMC K 4M, HPMC K 15M, HPMC K 100M, HPC LF, Avicel PH 101, Avicel PH 102, Povidone, and Magnesium Stearate, are also used into the tablet formulation in particular amounts in order to achieve the targeted features. Because it is a solvent, isopropyl alcohol is used in each and every composition. Every tablet has a total weight of 80 mg, with the exception of the initial formulation, which has a total weight of 100 mg. The whole weight of each tablet is standardized. This formulation offers a complete overview of the components and the amounts of those ingredients that are distributed over the several batches.

#### Preformulation studies of Propranolol hydrochloride sustained release tablet

The results of this research provide evidence that the transition from SR-004 to SR-008 was

effective. According to the data shown in Table 2, both SR-005 and SR-008 have favorable flow characteristics.

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**Table 2: Evaluation parameters for Preformulation studies.**

Sl. No.	Batch no.	Process of formulation	Moisture content (%)	Bulk density (g/ml)	Tapped density (g/ml)	Compressibility index (%)	Hausner ratio	Flow character
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1	SR-001	Direct compression	5.18	0.3980	0.5340	29.80	1.40	Poor
2	SR-002	Dry granulation	5.43	0.6170	0.7540	16.29	1.39	Poor
3	SR-003	Aqueous granulation	NA	NA	NA	NA	NA	Poor
4	SR-004	Non-Aqueous granulation	4.8	0.3347	0.4170	19.90	1.20	Fair
5	SR-005	Non-Aqueous granulation	4.64	0.3662	0.4250	13.7	1.10	Good
6	SR-006	Non-Aqueous granulation	5.61	0.345	0.451	19.45	1.22	Fair
7	SR-007	Non-Aqueous granulation	4.44	0.3449	0.4010	13.99	1.160	Fair
8	SR-008	Non-Aqueous granulation	4.30	0.3229	0.3675	12.23	1.140	Good

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An overview of the several batches (SR-001 to SR-008) of a pharmaceutical formulation is shown in the table. This overview includes information on the manufacturing process, the amount of moisture present, the bulk density, the tapped density, the compressibility index, the Hausner ratio, and the flow character.

The formulation of batch SR-001 is accomplished by the use of direct compression. It has a moisture content of 5.18 percent, a bulk density of 0.3980 grams per milliliter, and a tapped density of 0.5340 grams per milliliter. The compressibility index is 29.80 percent, the Hausner ratio is 1.40 percent, and the flow characteristics are not very pleasant.

Dry granulation is used in batch SR-002, which has a moisture content of 5.43 percent, a bulk density of 0.6170 grams per milliliter, and a tapped density of 0.7540 grams per milliliter. In addition to having poor flow properties, it has a compressibility index of 16.29% and a Hausner ratio of 1.39.

There is a dearth of information on the moisture content, bulk density, tapped density, compressibility index, Hausner ratio, and flow character characteristics for Batch SR-003, which was formed using aqueous granulation.

Non-aqueous granulation is used to make batches SR-004 through SR-008, each of which has a different flow character, bulk density, tapped density, compressibility index, Hausner ratio, and moisture content. The compressibility index of SR-005 is 13.7%, indicating that it has strong flow characteristics. Similarly, the compressibility index of SR-008 is 12.23%, indicating that it also has good flow characteristics. The other batches have flow characteristics that are satisfactory. In general, the table offers a condensed summary of the formulation procedures and the most important quality characteristics for each batch under consideration.

#### V. CONCLUSION

Propranolol Hydrochloride and HPMC K100M are the two components that make up the sustained release formulation SR008, which has shown good promise for improving the treatment of cardiovascular diseases. The findings of this research highlight the relevance of HPMC K100M in delivering regulated and sustained drug release, hence addressing the constraints of standard dosing regimens. This prolonged release profile of SR008 has been validated by the painstaking formulation development and extensive characterization that was carried out, which



was backed by in vitro and in vivo experiments. The results not only contribute to a better knowledge of the performance of the formulation, but they also provide useful insights that may be used in future research to optimize drug delivery systems. In the ongoing search for patient-friendly dosage forms, SR008 has emerged as a significant option. This highlights the ongoing development of pharmaceutical research, which aims to increase therapeutic effectiveness and patient adherence in the treatment of cardiovascular disease.

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