

FORMULATION AND EVALUATION OF PINDOLOL EXTENDED RELEASE PELLETS**Amit Patel^{*1}, Dr. Jeevan Patel², Dr. Sudha Vengurlekar³, Dr. Rajesh Nagar³**¹PG Scholar, University Institute of Pharmacy, Oriental University, Indore.²Associate Professor, University Institute of Pharmacy, Oriental University, Indore.³Professor, University Institute of Pharmacy, Oriental University, Indore.***Corresponding Author: Amit Patel**

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DOI: <https://doi.org/10.5281/zenodo.20744555>**How to cite this Article:** Amit Patel^{*1}, Dr. Jeevan Patel², Dr. Sudha Vengurlekar³, Dr. Rajesh Nagar³ (2026). Formulation And Evaluation Of Pindolol Extended Release Pellets. World Journal of Pharmaceutical and Medical Research, 12(6), 493–499.

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Article Received on 05/05/2026

Article Revised on 25/05/2026

Article Published on 01/06/2026

ABSTRACT

The present study aimed to develop and evaluate extended-release pellets of Pindolol using solution layering technology and polymer coating techniques. Pindolol, a non-selective beta-blocker with a short biological half-life, requires frequent dosing, which may reduce patient compliance. To overcome this limitation, extended-release pellets were prepared using sugar spheres as inert cores, followed by drug layering and functional coating with Ethyl Cellulose and Hydroxypropyl Methylcellulose (HPMC). The prepared pellets were evaluated for physicochemical properties, flow characteristics, hardness, dissolution behaviour, and release kinetics. The optimized formulation demonstrated sustained drug release up to 20 hours and exhibited satisfactory pharmaceutical properties. Drug release followed zero-order kinetics with diffusion-controlled release behaviour according to the Higuchi model. The study concludes that extended-release pellet formulation of Pindolol can improve therapeutic efficacy and patient compliance.

KEYWORDS: Pindolol, Extended Release Pellets, Ethyl Cellulose, HPMC, Multiparticulate System, Controlled Drug Delivery.**INTRODUCTION**

Extended-release drug delivery systems are designed to maintain therapeutic drug concentrations for prolonged periods while reducing dosing frequency and minimizing plasma concentration fluctuations. Multiparticulate pellet systems offer several advantages such as reduced dose dumping, uniform gastrointestinal distribution, improved bioavailability, and enhanced patient compliance.

Pindolol is a non-selective β -adrenergic blocker used in the treatment of hypertension and angina. Due to its short half-life of approximately 3–4 hours, frequent administration is required. Therefore, the development of an extended-release formulation is desirable to provide sustained therapeutic action and improve patient convenience.

MATERIALS AND METHODS**Materials**

Pindolol succinate, Mannitol, HPMC, Ethyl Cellulose, Sodium Lauryl Sulphate, Yellow Iron Oxide, Isopropyl

Alcohol, and Sugar Spheres were used in the formulation.

Preparation of Core Mixture Suspension

The core mixture suspension was prepared by accurately weighing the required quantities of Pindolol succinate and other excipients such as mannitol, sodium lauryl sulphate, HPMC, and yellow iron oxide. These ingredients were dispersed in purified water and stirred continuously using a mechanical stirrer until a homogeneous and uniform suspension was obtained. The prepared suspension was used immediately for drug layering onto the sugar spheres.

Preparation of Core Drug Pellets

Non-pareil sugar spheres (24/30 mesh size) were accurately weighed and loaded into a fluidized bed coater. The prepared drug suspension was sprayed onto the sugar spheres under optimized processing conditions using the solution layering technique. During spraying, the pellets were continuously fluidized to ensure uniform drug deposition on the surface of the sugar spheres. After

completion of drug loading, the pellets were dried at 40–45°C for 6–8 hours until the moisture content was reduced to less than 2%. The dried pellets were then sieved, and pellets passing through sieve #14 and retained on sieve #20 were collected for further coating.

Preparation of Sub-Coating Solution and Coating of Pellets

The sub-coating solution was prepared by dissolving the required quantity of Ethyl Cellulose in Isopropyl Alcohol under continuous stirring for approximately 15 minutes until a clear and uniform coating solution was obtained. The prepared solution was then sprayed onto the drug-loaded core pellets using a fluidized bed coating process. Appropriate coating conditions such as inlet temperature,

bed temperature, spray rate, and air pressure were maintained throughout the process to achieve uniform polymer coating. After coating, the pellets were dried, sieved, and the desired size fraction (#16 passed and #20 retained) was collected. Finally, the optimized extended-release pellets were filled into hard gelatin capsules equivalent to the required label claim.

Preparation of Pellets

Core pellets were prepared by solution layering of Pindolol suspension onto sugar spheres using a fluidized bed processor. The drug-loaded pellets were dried and subsequently coated with varying concentrations of Ethyl Cellulose dissolved in Isopropyl Alcohol to obtain extended-release properties.

Table 01: Composition of the core pellets in the formulation trials.

S. No	Ingredients (mg)	CF1	CF2	CF3	CF4	CF5	CF6	CF7	CF8
1	Pindolol	10	10	10	10	10	10	10	10
2	Manitol	12.5	12.5	12.5	12.5	12.5	125	125	12.5
3	Sodium laurylsulphate	10	9.5	9	8.5	8	7.5	7	6.5
4	Sugar spheres(24/30)	25	25	25	25	25	25	25	25
5	HPMC	1.5	2	2.5	3	3.5	4	4.5	5
6	Yellow oxide	1	1	1	1	1	1	1	1
	Total (mg)	60	60	60	60	60	60	60	60

Table 02: Composition of the coating material for the optimized core pellet.

S.No	Ingredients	PER F1	PER F2	PER F3	PER F4	PER F5	PER F6	PER F7	PER F8
7	Ethyl cellulose(mg)	2%	2.5%	3%	3.5%	4%	4.5%	5%	5.5%
8	Iso propyl alcohol(ml)	65ml	5ml	100ml	115ml	135ml	150ml	165ml	185ml

RESULTS AND DISCUSSION

Preformulation Studies

From the standard stock solution (1000 µg/mL), aliquots of 1, 2, 3, 4, 5 and 6 mL were transferred into separate

100 mL volumetric flasks and the volume was adjusted with pH 6.8 phosphate buffer to obtain concentrations of 10, 20, 30, 40, 50 and 60 µg/mL respectively.

Table 03: Calibration Data of Pindolol in pH 6.8 Phosphate Buffer at 261 nm.

S. No.	Concentration (µg/mL)	Absorbance
1	10	1.3658
2	20	2.7168
3	30	4.0678
4	40	5.4188
5	50	6.7698
6	60	8.1208

Calibration Curve

The absorbance values obtained for various concentrations of Pindolol were plotted against concentration. A straight-line relationship was observed over the concentration range of 10–60 µg/mL, indicating adherence to Beer-Lambert's law. The calibration curve exhibited excellent linearity with a correlation coefficient (R^2) value of 0.997.

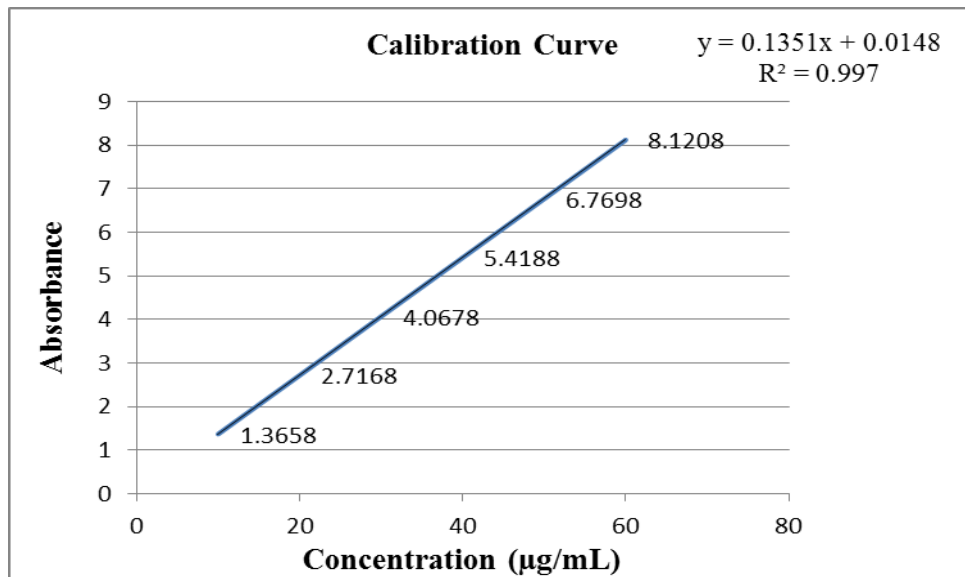


Figure 01: Standard curve of pindolol succinate.

Pindolol was obtained as a white crystalline powder with characteristic odor and bitter taste. The drug exhibited poor flow properties with a compressibility index of 34.55% and Hausner ratio of 1.528.

Drug-Excipient Compatibility

FTIR studies confirmed the absence of significant chemical interaction between Pindolol and formulation excipients, indicating compatibility.

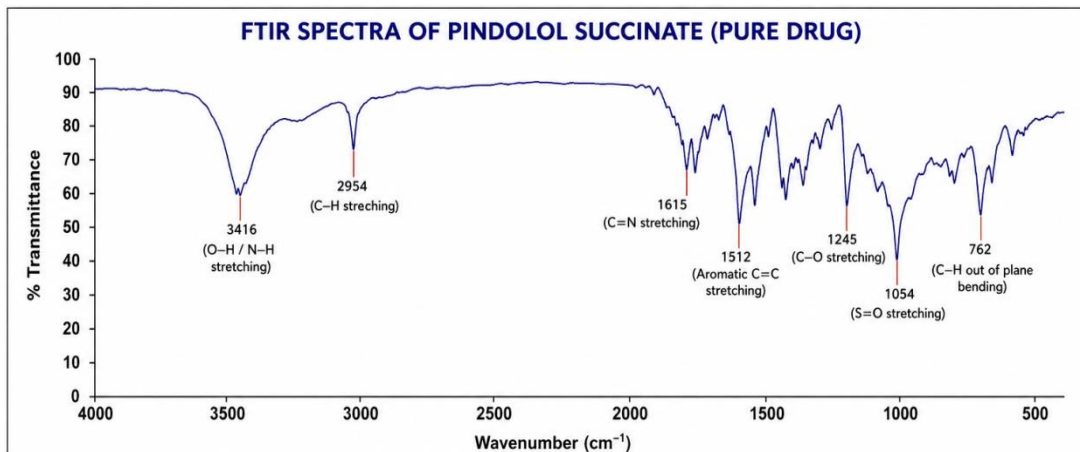


Figure 02: FTIR spectra of Pure Drug.

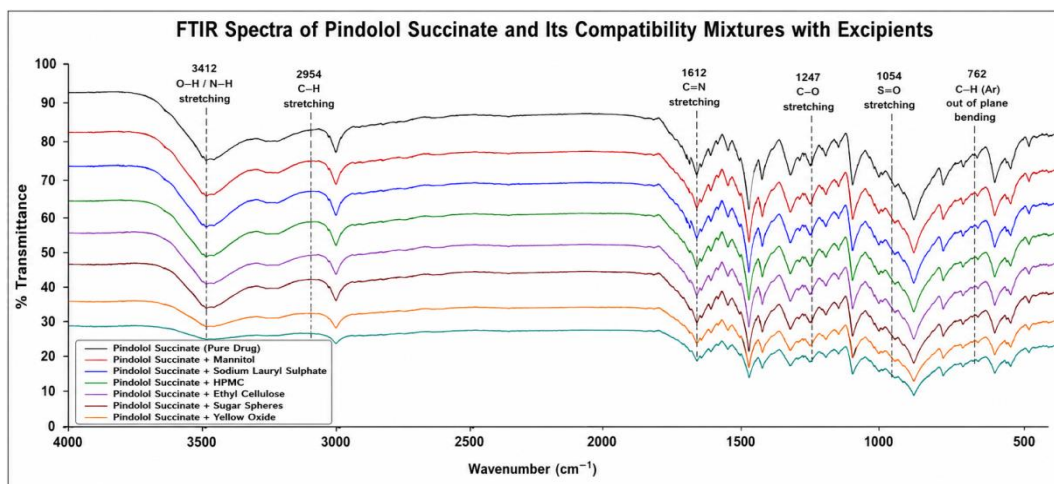


Figure 03: FTIR spectra of Pure Drug- excipients.

Evaluation Parameters

The prepared pellets were evaluated for various parameters including organoleptic characteristics, bulk density, tapped density, compressibility index, Hausner

ratio, angle of repose, sieve analysis, drug-polymer compatibility by FTIR, in-vitro dissolution studies, drug release kinetics, and stability studies to assess the quality and performance of the formulation.

Table 04: Physical characters of optimized Pindolol polymer coated pellets.

S.No.	Characteristics	Results
1.	Physical appearance	Yellowish crystalline powder.
2.	Dimension	1.6mm-2mm
3.	Hardness	9N
3.	Bulk density	0.37gm/ml
4.	Tapped density	0.425gm/ml
5.	Compressibility index	11.793%
6.	Hausner's ratio	1.1317%
7	Angle of repose	28.53

Sieve analysis

The sieve analysis has been performed to check the size of the coated pellets, and the results revealed that the pellets are of uniform in size and they are in the size of

16 μ - 20 μ . The size of the pellets is determined by identifying the sieve which has allowed the pellets to pass and the sieve on which the sample is collected.

Table 05: Particle size distribution polymer coated pellets.

S.No	Sieve number	PER CF1 (mg)	PER CF2 (mg)	PER CF3 (mg)	PER CF4 (mg)	PER CF5 (mg)	PER CF6 (mg)	PER CF7 (mg)	PER CF8 (mg)
1	12	0	0	0	0	0	0	0	0
2	16	8.4	7.9	2.5	1.9	1.4	4.5	2.06	2.07
3	18	3.4	2.8	1.4	1	0.97	1.6	2.48	1.45
4	20	88.2	89.3	96.1	98.03	97.8	93.39	95.46	96.48

In-vitro Dissolution Studies

The optimized formulation exhibited sustained release of Pindolol over a period of 20 hours. The polymer-coated

pellets effectively controlled the drug release rate and minimized burst release.

Table 06.

S. No.	Cumulative % drug release			
	1st Hr.	4th Hr.	8th Hr.	20th Hr.
PER F1	48.51	72.35	92.49	99.85
PER F2	41.25	69.83	86.48	98.67
PER F3	36.55	57.67	83.36	98.22
PER F4	29.43	52.60	79.47	97.97
PER F5	26.83	47.58	76.58	97.83
PER F6	21.22	37.67	69.16	98.16
PER F7	13.83	33.67	56.67	97.33
PER F8	18.67	27.25	47.38	94.54

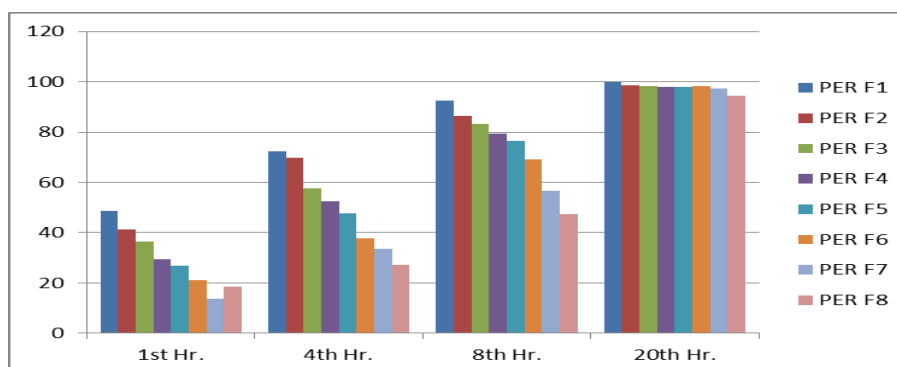


Figure 03: Cumulative % drug release of Pindolol Extend Release Pellets.

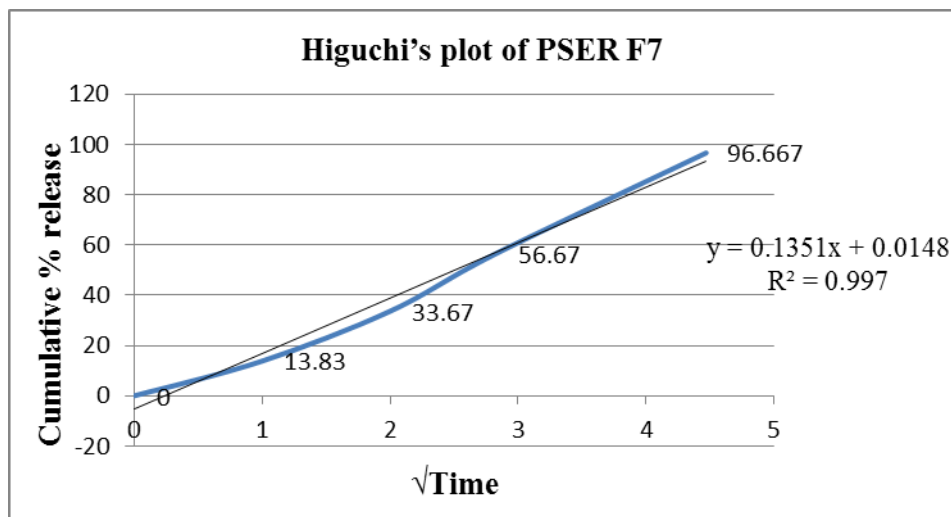
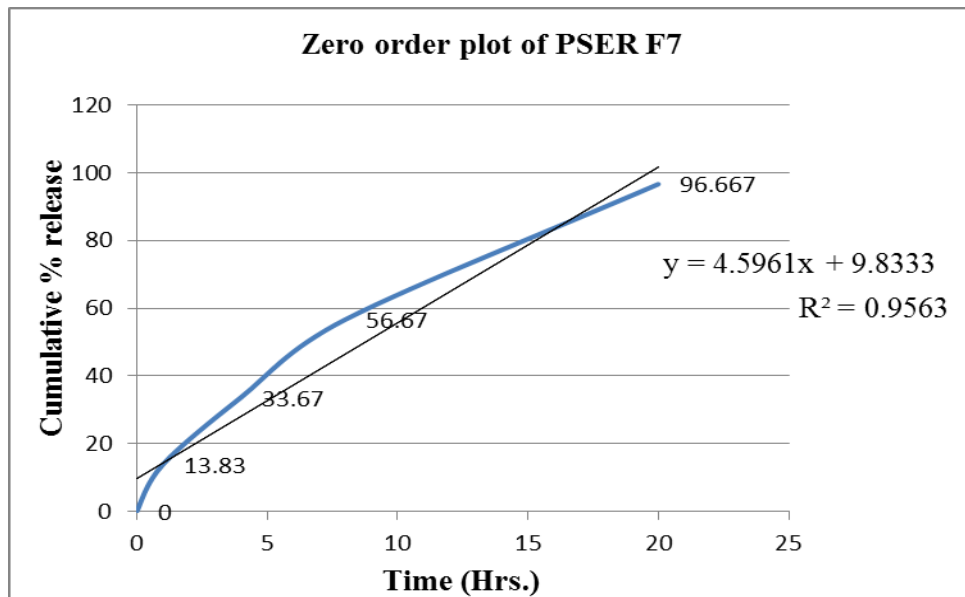
In-vitro Release kinetics

The dissolution data best fitted the Zero-order kinetic model, indicating a constant release rate. Higuchi model

analysis suggested diffusion-controlled drug release through the polymeric coating.

Table 07: In-Vitro Drug Release kinetics for PER 7.

S. No	Zero order data		Higuchi's data	
	Time(Hrs.)	Cumulative % release	Squareroot oftime	Cumulative % release
1	0	0	0	0
2	1	13.83	1	13.83
3	4	33.67	2	33.67
4	8	56.67	2.83	56.67
5	20	96.667	4.47	96.667

**Stability Studies**

The stability studies were carried out according to ICH guidelines for optimized formulation i.e. PER F7. The stability studies were carried out under 3 conditions i.e. Long term stability ($25\pm 2^{\circ}\text{C}/60\% \pm 5\% \text{RH}$),

Intermediate ($30\pm 2^{\circ}\text{C}/65\% \pm 5\%$) and Accelerated stability studies ($40\pm 2^{\circ}\text{C}/75\% \pm 5\% \text{RH}$). Then the pellets were stored under 3 conditions and the samples were withdrawn at every one month and evaluate the pellet parameters like description, assay and dissolution.

Table 08: Physical evaluation of stability studies for optimized PER F7 at different conditions carried out for 3 months duration.

Test	Month	Description	Assay
25 ⁰ C/60%RH (long term)	1	White to off white color	99.8
	2	White to off white color	99.67
	3	White to off white color	99.61
30 ⁰ C/ 65%RH (Intermediate)	1	White to off white color	98.45
	2	White to off white color	98.37
	3	White to off white color	97.91
40 ⁰ C/ 75%RH (Accelerated)	1	White to off white color	98.23
	2	White to off white color	98.05
	3	White to off white color	97.86

Test	Month	Cumulative % drug release (time in Hrs)			
		1	4	8	20
25 ⁰ C/60%RH (long term)	1	13.33	33.167	53.833	93.667
	2	13.83	33.67	56.67	97.33
	3	12.98	32.65	54.67	95.833
30 ⁰ C/ 65%RH (Intermediate)	1	13.75	33.59	56.59	97.13
	2	13.71	33.55	56.55	96.89
	3	13.65	33.48	56.51	96.73
40 ⁰ C/ 75%RH (Accelerated)	1	13.67	33.51	56.53	97.01
	2	13.61	33.44	56.49	96.75
	3	13.55	33.29	56.41	96.45

CONCLUSION

The study successfully developed Pindolol extended-release pellets using solution layering and polymer coating techniques. The optimized formulation showed satisfactory pharmaceutical characteristics and sustained drug release for up to 20 hours. The multiparticulate pellet system may serve as an effective alternative to conventional immediate-release formulations by improving patient compliance and therapeutic performance.

ACKNOWLEDGEMENT

The authors express sincere gratitude to the University Institute of Pharmacy for providing laboratory facilities and technical support for carrying out this research work.

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