World Journal of Pharmaceutical and Life Sciences

www.wjpls.org

Impact Factor: 8.21 Coden USA: WJPLA7

FORMULATION AND CHARACTERIZATION OF CONTROLLED SELF PORE FORMING TABLET OF ROSIGLITAZONE

Mukesh Kumar Yadav*, V.P. Gupta, Bhupendra Tiwari

Globus College of Pharmacy, Bhopal, M. P.

***Corresponding Author: Mukesh Kumar Yadav**

Globus College of Pharmacy, Bhopal, M. P.

DOI: https://doi.org/10.5281/zenodo.22159805

How to cite this Article: Mukesh Kumar Yadav*, V.P. Gupta, Bhupendra Tiwari. (2026). Formulation and Characterization of Controlled Self Pore Forming Tablet of Rosiglitazone. World Journal of Pharmaceutical and Life Sciences, 12(9), 70–74.

Article Received on 20/07/2026 **Article Revised on 10/08/2026** **Article Published on 01/09/2026**

ABSTRACT

Controlled self-pore forming osmotic tablet systems are advanced oral drug delivery systems designed to provide predictable and sustained drug release, independent of gastrointestinal pH and motility. The present study aimed to formulate and characterize a controlled self-pore forming tablet of rosiglitazone to enhance its therapeutic efficacy, improve patient compliance, and maintain prolonged plasma drug concentrations. Rosiglitazone tablets were prepared by direct compression using suitable osmotic agents, hydrophilic polymers, pore-forming agents, and excipients. The prepared formulations were evaluated for pre-compression parameters, including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, while post-compression studies included hardness, thickness, friability, weight variation, drug content, and content uniformity. The formulations were further characterized for in vitro dissolution, swelling behavior, membrane integrity, and stability under accelerated storage conditions. The effect of pore-forming agent concentration on drug release was also investigated to optimize the formulation. Among the developed formulations, the optimized formulation exhibited satisfactory physicochemical properties, excellent tablet integrity, uniform drug content, and a controlled release profile over the desired duration, following near zero-order release kinetics. Stability studies confirmed that the optimized formulation remained physically and chemically stable throughout the study period. The findings demonstrate that controlled self-pore forming osmotic tablets of rosiglitazone represent a promising oral controlled-release delivery system capable of providing reproducible drug release, minimizing fluctuations in plasma drug concentration, and improving therapeutic outcomes in the long-term management of type 2 diabetes mellitus.

KEYWORDS: Rosiglitazone; Controlled self-pore forming tablet; Osmotic drug delivery system; Controlled drug release; Oral controlled-release formulation; Osmotic pump tablet; Pore-forming agent; Hydrophilic polymer.

INTRODUCTION

Diabetes mellitus is one of the most prevalent chronic metabolic disorders worldwide and is characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The increasing incidence of type 2 diabetes mellitus (T2DM), driven by sedentary lifestyles, obesity, and aging populations, has become a major public health concern. Long-term uncontrolled hyperglycemia leads to severe microvascular and macrovascular complications, including nephropathy, neuropathy, retinopathy, cardiovascular diseases, and stroke. Effective glycemic control is therefore essential to prevent disease progression and improve the quality of life of patients. Oral antidiabetic therapy remains the preferred treatment approach for most patients with T2DM because of its convenience, patient acceptance, and cost-effectiveness. However, conventional oral dosage forms often require repeated administration due to rapid drug release and elimination, resulting in fluctuations in plasma drug concentration that may reduce therapeutic efficacy and increase the risk of adverse effects.[1]

Rosiglitazone is an oral antidiabetic drug belonging to the thiazolidinedione class, which acts as a potent agonist of

the peroxisome proliferator-activated receptor-gamma (PPAR-γ). Activation of this receptor enhances insulin sensitivity in adipose tissue, skeletal muscle, and the liver, thereby improving glucose uptake and reducing hepatic glucose production. Rosiglitazone effectively lowers blood glucose levels without directly stimulating insulin secretion, making it particularly useful in patients with insulin resistance. Despite its therapeutic effectiveness, conventional rosiglitazone tablets exhibit limitations such as the need for regular dosing and variable plasma drug concentrations, which may influence patient compliance and treatment outcomes. Therefore, the development of a controlled-release dosage form capable of maintaining therapeutic drug levels over an extended period is highly desirable.[2]

Controlled drug delivery systems have been developed to overcome the shortcomings of immediate-release formulations by delivering drugs at predetermined rates for prolonged periods. These systems maintain relatively constant plasma drug concentrations within the therapeutic window, reduce dosing frequency, minimize peak-to-trough fluctuations, decrease dose-related adverse effects, and improve patient compliance. Various controlled-release technologies, including matrix tablets, reservoir systems, gastroretentive formulations, multiparticulate systems, and osmotic drug delivery systems, have been extensively investigated. Among these, osmotic drug delivery systems have attracted significant attention because they provide predictable and reproducible drug release that is largely independent of physiological variables such as gastrointestinal pH, motility, food intake, and enzymatic activity.[3]

The osmotic drug delivery system is based on the principle of osmosis, in which water from the gastrointestinal tract enters the tablet through a semipermeable membrane due to the osmotic pressure difference between the external environment and the tablet core. As water penetrates the core, the drug dissolves or forms a suspension, generating osmotic pressure that forces the drug solution out through one or more delivery pores at a controlled rate. Since osmotic pressure is the primary driving force for drug release, the system provides highly reproducible release profiles with minimal influence from external physiological conditions. This unique mechanism makes osmotic tablets one of the most reliable controlled-release technologies for drugs requiring prolonged and consistent plasma concentrations.[4]

Self-pore forming osmotic tablets represent an advanced modification of conventional osmotic pump systems. Instead of requiring mechanically drilled delivery orifices, these formulations contain pore-forming agents incorporated into the semipermeable membrane. Upon contact with gastrointestinal fluids, the pore-forming agents dissolve and leach out from the membrane, creating numerous microscopic pores through which the drug is released. This self-forming pore mechanism simplifies the manufacturing process, eliminates the need for specialized laser drilling equipment, reduces production costs, and improves manufacturing efficiency while maintaining controlled and reproducible drug release. The size, number, and distribution of the pores can be carefully regulated by adjusting the concentration and type of pore-forming agents used in the formulation. The performance of a controlled self-pore forming osmotic tablet depends on several formulation variables, including the composition of the core tablet, the concentration of osmotic agents, the type and quantity of hydrophilic polymers, the characteristics of the semipermeable membrane, the amount of pore-forming agents, and the coating thickness. Osmotic agents generate the pressure necessary for drug release, while hydrophilic polymers regulate water uptake and maintain tablet integrity. The semipermeable membrane controls the influx of water into the tablet without allowing significant drug diffusion through the membrane itself. Appropriate optimization of these formulation components is essential to achieve a near zero-order drug release profile, in which the drug is released at an approximately constant rate over the desired duration. An ideal controlled self-pore forming tablet should possess excellent mechanical strength, uniform drug distribution, adequate hardness, low friability, consistent membrane characteristics, and reproducible drug release. Comprehensive evaluation of such formulations includes pre-compression studies such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio to assess powder flow properties. Post-compression evaluations include weight variation, hardness, thickness, friability, drug content, content uniformity, and disintegration characteristics. Further characterization involves swelling studies, membrane integrity analysis, in vitro dissolution testing, release kinetic modeling, and accelerated stability studies to ensure the formulation maintains its quality, safety, and efficacy during storage.[5]

The present study focuses on the formulation and characterization of controlled self-pore forming tablets of rosiglitazone using suitable osmotic agents, pore-forming agents, hydrophilic polymers, and semipermeable membrane-forming materials. Different formulations were prepared and systematically evaluated to identify the optimized formulation capable of providing prolonged and reproducible drug release. The influence of formulation variables on tablet performance and drug release behavior was investigated through comprehensive physicochemical characterization and dissolution studies. The optimized formulation was expected to exhibit desirable mechanical properties, excellent stability, and a controlled drug release profile approaching zero-order kinetics over an extended period.[6,7]

METHODOLOGY

Formulation of rosiglitazone core tablets using wet granulation method

All the formulations are prepared by wet granulation method. A core tablet of rosiglitazone were prepared by wet granulation method. Ingredients were weighed

accurately and shifted through # 40 mesh. Accurately weighed lactose, HPMC EV5 and sodium chloride osmogen mix with drug mixed in cage blender for 10 min at 20 rpm again passed through # 40 mesh sieve. To make the binder solution, IPA was used to dissolve precisely weighed PVP K-30. Using a ready-made binder solution, the aforementioned blend was granulated. The granules were dried in a tray dryer at 65 °C until their LOD ranged from 2% to 3% by weight. Dried granules were fed through an oscillating granulator with a mesh size of 20. Magnesium stearate and talc were accurately weighed and passing through # 60 mesh. Magnesium stearate and talc were used to lubricate the a for mentioned blend in a cage blender for 3 minutes at 20 rpm. The granules were compressed after being tested for pre compression settings. Compression was carried out.[8]

Table 1: Composition of self pore forming osmotic tablet.

Ingredients	**Formulation code**								
Quantity (mg)	RC1	RC2	RC3	RC4	RC5	RC6	RC7	RC8	RC9
Rosiglitazone	50	50	50	50	50	50	50	50	50
Sodium Chloride	10	10	10	20	20	20	30	30	30
HPMC EV5	50	75	100	50	75	100	50	75	100
PVP K- 30	15	15	15	15	15	15	15	15	15
Pharmatose 200	150	125	100	140	115	90	130	105	80
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	3	3	3	3	3	3	3	3	3
Total Weight (mg)	280	280	280	280	280	280	280	280	280

Coating of core tablets

Spray coating was used to apply coating solution to the core tablet. Eudragit RLPO was dissolved in acetone to create the coating solution, which was then well agitated to dissolve the polymer. 1% weight-to-volume PEG 400 and sorbitol were added to this solution. According to the composition, four test coating solutions were made. The coating solutions were stirred properly and stored in closed container.[9,10]

Table 2: Composition of Coating Solutions.

Ingredients	**C1**	**C2**	**C3**	**C4**
Eudragit RLPO (mg)	25	30	25	30
PEG 400 (mg)	10	10	10	10
Sorbitol (% w/v)	0.5	0.5	1	1
Acetone (ml)	100	100	100	100
Amaranth 3%	Q.S	Q.S	Q.S	Q.S

Characterization of osmotic tablet

Weight Uniformity

Twenty tablets were weighed individually and average weight was determined. The individual tablet weight was compared with average tablet weight.[11,12]

Thickness and Diameter

Tablet was selected at random from individual formulations and thickness was measured by using vernier caliper scale, which permits accurate measurement. Tablet thickness should be controlled within a ± 0.5% variation of standard value.[12,13]

Hardness and Friability

Tablet was selected at random from individual formulations and hardness was measured using Monsanto hardness tester. Friability of core tablets was carried out on a Roche Friabilator for 20 accurately weighed tablets. Friability of the tablets should be less than 1%.[14,15]

Content Uniformity

The weight and powder of five pills were done. Rosiglitazone (50 mg) was dissolved in 0.1N HCl, and 100 ml of the mixture was created. Different dilutions of the mentioned solution were made to get concentrations of 5, 10, 15, 20, and 30 mcg/ml. Using a double beam UV visible spectrophotometer, the absorbance of the various solutions was calculated using 0.1N HCl as a blank as the reference. The data were subjected to a linear regression analysis after the graph of absorbance v/s concentration was generated.[16]

In-vitro Drug Release Studies

The release rate of rosiglitazone from tablets was determined using the Dissolution Apparatus II (paddle method). The experiment was carried out in 750 mL of 0.1 N HCl for two hours, and then the solution was dissolved at a pH of 6.8 (adjusted by adding 250 mL of 0.2 M trisodium phosphate). A 5 mL aliquot was taken and 5 mL of fresh medium was reintroduced to maintain the original volume at regular intervals. Rosiglitazone was detected using UV spectrophotometric method in aliquots after 2 hours of dissolution in 0.1M HCl and 2 hours of dissolution in phosphate buffer pH 6.8. %.[17]

RESULT

Evaluation Parameters of Formulation, Optimization of self pore forming tablet

Table 3: Evaluation of flow property of powder blend of batches.

Formulation code	Angle of repose(0°)	Bulk density	Tapped density	Compressibility index (%)	Hausner's ratio
RC1	28.94±0.64	0.41±0.012	0.46±0.01	10.86957±0.112	1.1211±0.32
RC2	28.77± 0.75	0.39±0.019	0.44±0.011	11.36364±0.321	1.1285±0.31
RC3	29.21±0.85	0.38±0.017	0.44±0.012	11.62791±0.432	1.1319±0.32
RC4	27.91±1.07	0.40±0.019	0.45±0.013	11.11111±0.231	1.125±0.123
RC5	29.44±0.51	0.39±0.011	0.44±0.014	11.36364±0.943	1.12825±0.86
RC6	28.39±0.69	0.38±0.015	0.43±0.012	11.62791±0.123	1.1319±0.56
RC7	28.24±068	0.41±0.02	0.46±0.014	10.86957±0.654	1.1219±0.64
RC8	29.52±0.39	0.40±0.015	0.45±0.016	11.11111±0.765	1.125±0.332
RC9	28.88±0.63	0.39±0.013	0.44±0.011	11.36364±0.113	1.128205±042

The granules prepared for nine batches of tablet formulations were evaluated for flow and compression properties. All batches of granules showed excellent flow properties with angle of repose value between 27.91 ± 1.07 to 29.52± 0.39 so, it indicated good flow property. By analysing the bulk and tapped densities, the packaging capacity of granules was determined to be between 0.38 and 0.41 gm/cm3 and 0.43 and 0.46 gm/cm3, respectively. Bulk and tapped density were used to determine the compressibility of granules. The Carr's index was determined to be in the 10–11% range, indicating strong granule compression ability. The Hausner's ratio values were in the range of 1.11 to 1.13, which indicates that granules have excellent flow and compression capabilities.

Table 4: Evaluation of flow property of powder blend of batches.

Batch Code	Average Weight(mg)	Weight variation %	Hardness ($kg/cm^{2)}$	Diameter (mm)	Thickness (mm)	Friability (%)	Drug content(%)
RC1	280.11±1.2	0.26	6.66±0.17	6.481 ± 0.03	3.61±0.02	0.21±0.022	99.23±0.04
RC2	280.21±1.6	0.22	6.43±0.19	6.465 ±0.02	3.60±0.02	0.14±0.022	99.42±0.05
RC3	279.54±1.7	0.30	6.89±0.13	6.473 ± 0.03	3.61±0.02	0.12±0.04	99.41±0.05
RC4	280.47±1.8	0.35	5.89±0.17	6.511 ± 0.01	3.61±0.04	0.29±0.046	99.40±0.04
RC5	280.53±1.3	0.41	6.17±0.16	6.482 ± 0.04	3.61±0.03	0.16±0.023	98.61±0.03
RC6	280.0±1.42	0.48	6.75±0.18	6.479 ± 0.02	3.63±0.02	0.17±0.04	98.86±0.05
RC7	279.24±1.2	0.34	5.84±0.18	6.491 ± 0.05	3.61±0.01	0.19±0.04	99.11±0.03
RC8	280.35±1.1	0.36	6.91±0.1	6.50 ± 0.01	3.61±0.01	0.18±0.047	99.12±0.04
RC9	279.62±1.3	0.37	6.84±0.11	6.51 ± 0.12	3.60±0.03	0.17±0.063	98.81±0.06

Table 5: Evaluation of Coated tablet.

Formulation	Average Weight (mg)	Weight Variation %	Thickness of coated tablet	Thickness of film(mm)
RC1	286.95±1.35	0.41	4.19±0.01	0.58
RC2	286.60±1.09	0.36	4.20±0.01	0.60
RC3	285.95±1.21	0.35	4.20±0.02	0.59
RC4	286.60±1.15	0.35	4.21±0.01	0.60
RC5	285.05±1.17	0.36	4.20±0.01	0.59
RC6	286.10±1.47	0.40	4.20±0.02	0.59
RC7	286.80±1.08	0.34	4.21±0.01	0.60
RC8	287.63±1.03	0.39	4.20±0.02	0.59
RC9	286.31±1.12	0.380	4.14±0.012	0.61

In-vitro drug release of self pore forming tablets

Table 6: In-vitro dissolution data (cumulative percent release).

Time hrs.	RC1	RC2	RC3	RC4	RC5	RC6	RC7	RC8	RC9
1	2.1±0.2	2.1±0.14	1.9±0.5	2.4±0.4	2.4±0.33	2.3±0.09	2.6±0.12	2.5±0.09	2.4 ±0.11
2	7.7±0.21	7.8±0.58	7.2±0.3	8.8±0.41	8.5±0.21	7.8±0.17	9.1±0.54	9.6±0.61	9.3±0.42
3	17.05±1	17.02±0.6	17.25±1.2	21.1±1.2	20.18±0.8	19.11±0.7	22.52±0.9	21.58±0.8	20.58±1.4
4	26.25±2.12	26.4±0.8	24.55±1.5	30.96±1.3	28.85±1.9	26.93±1.6	32.79±2.2	30.88±3.2	29.88±3.1

6	34.5±128	33.2±1.2	32.98±1.5	39.27±2.2	36.57±1.3	34.09±2.3	42.81±1.8	39.12±1.5	37.12±1.3
8	45.06±1.8	44.6±1. 6	43.79±1.4	53.8±2.1	50.95±2.7	48.52±1.9	56.96±1.7	53.66±1.7	50.52±1.
12	58.8±1.51	66.38±1.4	54.35±0.7	67.66±3.1	64.12±1.5	61.15±1.8	70.83±1.0	66.03±2.4	63.15±1.9
18	70.1±148	68.18±1.5	65.5±1.9	81.29±2.7	77.52±2.8	74.90±1.9	84.15±1.9	80.02±2.6	78.90±1.3
24	80.8±1	77.8 ± 0.8	75.27±2.1	94.24±1.5	89.9±1.1	87.11±2.4	99.02±1.4	91.79±1.6	90.12±1.7

CONCLUSION

Among all the developed formulations, RC7 was identified as the optimized formulation because it exhibited the most desirable balance between tablet integrity, mechanical strength, drug content, and controlled drug release. RC7 showed excellent flow characteristics before compression, adequate hardness, low friability, uniform weight variation, and high drug content, demonstrating the robustness of the formulation. The optimized concentration of osmotic agents, hydrophilic polymers, and pore-forming agents in RC7 produced an ideal semipermeable membrane with uniformly distributed micropores, allowing controlled penetration of gastrointestinal fluid.

The optimized formulation successfully achieved prolonged and predictable drug release, satisfactory physicochemical properties, and excellent stability, making it a promising controlled-release oral dosage form for the long-term management of type 2 diabetes mellitus. The developed osmotic tablet system has the potential to improve patient compliance by reducing dosing frequency, minimizing plasma drug concentration fluctuations, and enhancing therapeutic efficacy. This study also provides a valuable platform for the future development of controlled self-pore forming osmotic drug delivery systems for other drugs requiring sustained and reproducible oral delivery.

REFERENCES

1. Indurkhya, A., Patel, M., Sharma, P., Abed, S. N., Shnoudeh, A., Maheshwari, R., & Tekade, R. K. Influence of drug properties and routes of drug administration on the design of controlled release system. In Dosage Form Design Considerations, 2018; 179-223. Academic Press.
2. Rahman, H., Krishnamoorthy, B., Tamilselvan, N., Siram, K., Karthik, S., & Hariprasad, R. Nanomaterials in drug delivery: existing scenario and potential scope. In Nano biomaterials in Drug Delivery, 2016; 197-228. William Andrew Publishing.
3. Junyaprasert, V. B., & Morakul, B. Nanocrystals for enhancement of oral bioavailability of poorly water-soluble drugs. Asian journal of pharmaceutical sciences, 2015; 10(1): 13-23.
4. Khalane, L., Alkunte, a., & Birajdar, a. Sustained release drug delivery system: a concise review. Terminology, 2016; 4: 5.
5. Mene HR. Formulation aspects in development of controlled porosity osmotic pump tablet pharmaceutical and biological evaluations, 2016; 3(1): 1-18.
6. Ghosh T, Ghosh A. Drug delivery through osmotic systems–an overview. Journal of Applied Pharmaceutical Science, Apr. 2011; 30: 38-49.
7. Sahoo, C. K., Sahoo, N. K., Rao, S. R. M., Sudhakar, M., & Satyanarayana, K. A review on controlled porosity osmotic pump tablets and its evaluation. Bulletin of Faculty of Pharmacy, Cairo University, 2015; 53(2): 195-205.
8. Suroshe RS, Wakade RB, Panchale WA, Sakhare AD, Rathod RR, Pophalkar PB. Development and characterization of osmotic drug delivery system of model drug. World Journal of Pharmaceutical Research, Sep 10, 2018; 7(18): 1158-71.
9. Bhateja P, Asija R, Singh Y, Piplani M. An Insight into Osmotic Drug Delivery Systems. Letters in Drug Design & Discovery, Jan. 1, 2023; 20(1): 16-30.
10. Verma RK, Arora S, Garg S. Osmotic pumps in drug delivery. Critical Reviews™ in Therapeutic Drug Carrier Systems, 2004; 21(6).
11. Dash, S., Murthy, P. N., Nath, L., & Chowdhury, P. Kinetic modelling on drug release from controlled drug delivery systems. Acta Pol Pharm, 2010; 67(3): 217- 223.
12. Allen L, Ansel HC. Ansel's pharmaceutical dosage forms and drug delivery systems. Lippincott Williams & Wilkins, 2013 Dec 23.
13. Zentner, G. M., Rork, G. S., & Himmelstein, K. J. Osmotic flow through controlled porosity films: an approach to delivery of water-soluble compounds. Journal of Controlled Release, 1985; 2: 217-229.
14. Patel A, Mehta T, Patel M, Patel K, Patel N. Recent patent in controlled porosity osmotic pump. Recent Patents on Drug Delivery & Formulation, Apr. 1, 2013; 7(1): 66-72.
15. Guo, J. H. Effects of plasticizers on water permeation and mechanical properties of cellulose acetate: ant plasticization in slightly plasticized polymer film. Drug Developmentand Industrial Pharmacy, 1993; 19(13): 1541-1555.
16. Reddy KR, Rajendar M, Kiran G. Effect of various osmogens on drug release profiles of self pore forming osmotic tablets of azathioprine.
17. Guo, J. H. An investigation into the formation of plasticizer channels in plasticized polymer films. Drug development and industrial pharmacy, 1994; 20(11): 1883-1893.