Establishment and Analytical Validation of a Dissolution Method for Ciprofibrate Tablets: An Experimental Study

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ABSTRACT

Pharmaceutical industries use dissolution testing as a quality control measure in determining the in vitro release of active pharmaceutical ingredients (APIs) of solid oral dosage forms. One of the most frequently used lipid-lowering drugs (Ciprofibrate) does not have an official dissolution procedure covered in pharmacopeial monographs. The research was carried out to develop and analytically substantiate a dissolution procedure specifically for ciprofibrate tablets that would contain 100 mg of the API. Ciprofibrate was studied stabilities toward sink at 37°C in three media of dissolution, namely, phosphate buffer (pH 6.8), borate buffer (pH 8.0), and 0.1 N hydrochloric acid. Dissolution studies were carried out in vitro at different conditions by application of USP Apparatus 2 (paddle method), and special consideration was given to the effects of deaeration and filtration. The optimum and maximum discriminating form of dissolution was found to be 900 mL of phosphate buffer (pH 6.8) at 37.8 (C) with 75 rpm on stirring, 60 min. A validated UV spectrophotometric assay measured the release of ciprofibrate, and this solution was linear in the calibration range of 10–60 g/mL (r^2 = 0.999). The developed dissolution method is easy to use, repeatable, and has been validated as accurate, precise, and linear. It can, therefore, be used in routine quality control and a batch release test of ciprofibrate 100 mg tablets.

Keywords: 8 medium, BCS Class II formulation, ciprofibrate dissolution testing, phosphate buffer pH 6, USP Apparatus 2, UV spectrophotometric method validation

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Introduction

Dissolution testing has a key role in the development and quality assurance of goods manufactured in oral solid dose form.This test is considered an important resource that helps assess the release properties of drugs.[1] Dissolution testing, in the pharmaceutical industry and regulatory compliance, is not only needed to ensure continued quality assurance as a routine procedure but also to make in vitro in-vivo correlations (IVIVC), especially of poorly soluble drugs. According to the Biopharmaceutics Classification System (BCS), ciprofibrate is classified as a BCS Class II compound, that is, low water-soluble and high permeability, which means that ciprofibrate dissolution is the rate-limiting process in its absorption and bioavailability. It is, hence, imperative to develop a powerful and differentiating dissolution mechanism over ciprofibrate in order to maintain a uniform drug release pattern and activity.[2]

Ciprofibrate (2-(4-(2,2-disgusting cyclopropyl) phenoxy)-2-methylpropanoic acid) is a hypolipidemic agent employed in the treatment of dyslipidemic state through reduction of the levels of LDL and VLDL, with a concomitant elevation of the levels of HDL cholesterol. It is useful in heart conditions and helps in preventing cardiovascular complications; therefore, making it necessary to have batch-to-batch consistency and performance of its tablet formulation by using validated dissolution tests.[3,4]

Analytical validation of a dissolution procedure proves that the test system would always provide valid, precise, specific, and reproducible results under stated conditions and parameters.[5] In the absence of validation, dissolution data can be unreliable, as it might fail to capture product variabilities that are of paramount importance during formulation or manufacturing and can directly affect drug performance.[6] Due to the highly variable nature of dissolution testing, especially in poorly soluble drugs, it is essential to have a close control of the parameters in the test and a validation process as per regulation e.g. International Council on Harmonisation (ICH).[7]

Moreover, UV spectrophotometry is a less expensive and more dependable analysis tool used to measure ciprofibrate levels throughout the revelation processes.[8] Scientifically valid dissolution procedure may be developed by confirming the various parameters, including linearity, accuracy, precision, and robustness of a dissolution method.[9] The first aim of the proposed work is the development of the dissolution method of ciprofibrate tablets, as well as its analytical validation, which will satisfy the requirements of regular quality control and regulatory compliance.[17] The validation procedure refers to the testing of key performance attributes so that the applicability of the particular process with respect to its use.[10,11] Setting up such a validated procedure is likely to help ensure the quality and consistency of ciprofibrate release from tablets, and to reliably evaluate this release throughout its shelf life, and hence, the therapy.[12]

The originality of this work could be described by the fact that a biorelevant and cost-effective method of dissolution has been successfully developed and analytically validated, which is specific to one poorly water-soluble BCS Class II drug, ciprofibrate.[13] The developed work offers a system of a sustained-release tablet that was realized in a laboratory using adequate excipients and represents a foreseeable option to study the matter academically and industrially.[14] The test is efficient enough to evaluate the solubility of ciprofibrate in different conditions, since it performs the experiment using several pH buffer systems that simulate physiological conditions.[2,3] A credible UV-spectrophotometric technique was developed for the dissolution test, entailing an easy but authentic analysis strategy

that was inexpensive in contrast to other costly procedures (such as the HPLC). Moreover, the experimental procedure was also established in accordance with the Indian Pharmacopoeia and ICH; therefore, it could be relevant on a regulatory level too.[18,19] This study addresses an essential research deficiency on the elaboration of the dissolution methods of ciprofibrate and establishes the base of related future investigations of in vitro and in vivo correlation and ways to improve the bioavailability of the drug.[15,16]

Materials and Methods

The active pharmaceutical ingredient (API) used in making the sustained-release tablet was ciprofibrate, which was obtained commercially and used in the laboratory. They were produced to have 100 mg of ciprofibrate per tablet, which was translates into 155 mg of sustained-release mixture. The manufacturing process consisted of the CIP API powder 100 mg combined with excipients according to the required exact amount to create ten tablets with a strength of 100 mg, based on the requirements provided in the Indian Pharmacopoeia (IP). The studyers prepared various media of dissolution; phosphate buffers (pH 6.4, 6.8 and 7.2), borrow ate buffer (pH 8.0), 0.1 zon hydrochloric acid and distilled water. As a solvent, methanol (A.R. grade), in which ciprofibrate was highly soluble, has been used. Other reagents used were HPLC-grade methanol, HPLC-grade acetonitrile, LR-grade methanol, and HPLC-grade water, which were prepared as recommended in the IP and pharmaceutical regulations.

Instruments used in the present work were a tablet compression machine (Rimek Mini Press) to produce tablets, a digital ultrasonic cleaner (sonicator bath), and a mechanical stirrer to select and homogenize the preparation of dissolution media. The absorbance and solubility were measured with a Shimadzu UV-1800 spectrophotometer, and the area under the pharmacokinetic concentration profile was determined with a Shimadzu LC-20AT high-performance liquid chromatography (HPLC) system. Other additional equipment was a Tempo Instruments hot air oven to dry the samples, a Shimadzu weighing balance, AUX-220 (Japan), which was used to make the correct measurements, and a pH meter to prepare the buffer. The quality control tests of tablets included mechanical strength and friability determination with the Monsanto hardness tester and USP Roche friabilator, respectively.

Solubility Determination and Sink Conditions

Ciprofibrate has a practically insoluble nature in water, as is experimentally confirmed, at the outset of this work, and elsewhere. The drug has high solubility in organic solvents; thus, a standard solution (100 µg/mL) and (1060 µg/mL) were prepared in methanol as the first step of calibration. The solubility of the six dissolution media was assessed, including phosphate buffer pH 6.2, phosphate buffer pH 6.4, phosphate buffer pH 7.2, neutralized phthalate buffer pH 4.4, borate buffer pH 8.0, and 0.1 N HCl. Each medium was placed in 10 mL, and excess drug was added to the medium, which was stirred mechanically at room temperature for 24 h, filtered using Whatman paper, and analyzed spectrophotometrically at a wavelength of 275 nm. A standard dissolution volume of 900 mL of labeled dose of ciprofibrate (100 mg) will give a dose concentration (Cd) of 0.111 mg/mL (111.11 µg/mL). Solubility (Cs) in each medium required to meet sink conditions must therefore be more than three times this (>333.3 µg/mL), yielding a Cs/Cd ratio of more than 3. Cs values were determined and Cs/Cd calculated, and only media that passed this test were deemed to be suitable-for dissolution testing. Phosphate buffer pH 6.8 and borate buffer pH 8.0 gave Cs/Cd higher than 3 in our study, which is sufficient sink, but solubility in acidic, neutral, or near-neutral buffer failed to provide sufficient sink. Even though the borate buffer exhibited a great solubilizing ability, it is not biorelevant due to the absence of borate ions in gastrointestinal fluids. Its application can be rationalized to investigate alkaline solubility, though in vivo performance has to be predicted by experiment in physiologically relevant media, including FaSSIF and FeSSIF, which include bile salts and phospholipids. Therefore, although borate and phosphate buffer pH 6.8 may be convenient to use in the daily quality control purposes, it is required that IVIVC research in the future may use biorelevant dissolution media to reflect drug solubilization in vivo.

Selection of a Suitable Dissolution Medium

The results from determining the sink condition and the data gathered from assessing the drug's solubility rate were utilized as a guide for choosing the best dissolution media for the remaining experimental work.

Tablet Making

A sustained-release tablet was prepared in the university laboratory using the drug's API. The preparation was done by mixing the CIP drug with the listed excipients.

- The CIP drug + Excipient was passed out in sieve number #60.
- Addition of prepared PVP K3O solution in dropwise.
- A dump was made from the mixture, which was passed through sieve number #25.
- Granulation was prepared and dried in the hot air oven at a temperature of 50°C.
- The dried granules were repassed through sieve number #22 and collected in a zip bag.
- Afterward magnesium stearate and talc were added to the final mixing and punching of tablets.

Quality Control Test for 100-mg Ciprofibrate Tablets

The prepared sustained-release tablet for 100 mg ciprofibrate drug was subjected to quality control tests for tablet with respect to ICH guidelines.

Stability Testing

A stability test was carried out on the CIP drug in selected sample solutions; each sample solution without the drug was initially used to set the baseline. The sam-

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ple was further analyzed spectrophotometrically in the UV machine for obtaining absorbance at a wavelength of 275. Analysis of each sample solution containing the ciprofibrate drug was carried out at different time intervals after over 48 h, where the drug concentration was observed.

UV Validation

For the UV analysis of the CIP medication, a straightforward and dependable procedure was employed. The standard solution was created by combining 100 mg of the drug with 100 mL of AR-grade methanol to create a 1000 ugmL solution. From this solution, a 100 ugmL stock solution was created. The concentration of each aliquot of the medication solution was changed using the given values of 10–60 ug/mL for the corresponding pH buffer solutions. Analyzing and interpreting the test findings served to validate the method. The baseline was established using spectrometric measurements in the UV for each separate buffer solution based on its accuracy, precision, and linearity. The test was conducted using 0.1 N HCL, 6.8 phosphate, and 8.0 borate buffer solutions, with the use of a dissolution device. At first, the device was allowed to stabilize at a temperature of 37°C. Each ciprofibrate pill was submerged in a 900 mL vessel of the dissolution device before the dissolution test was conducted. The instrument's stirring speed was regulated to 50, 75, and 100 rpm using the paddle device; 5 mL samples were taken at various time intervals, including 5, 15, 30, 45, 1–4 h, and 24 h. The samples were examined spectrophotometrically at 275 nm in the UV apparatus.

Results

The solubility study revealed that Ciprofibrate exhibited pH-dependent solubility. In phosphate buffer (pH 6.8), the concentration was 0.3211 mg/mL with a Cs/Cd ratio of 1.938. In borate buffer (pH 8.0), the solubility increased to 1.0160 mg/mL with a Cs/Cd ratio of 5.871. The highest solubility was observed in 0.1 N HCl (pH 1.2), with a concentration of 1.0248 mg/mL and a Cs/Cd ratio of 15.736. These findings indicate that the drug is more soluble in acidic conditions compared to neutral or alkaline media (Table 1).

The stability study of ciprofibrate in various buffer systems over 48 h showed minimal degradation under most conditions. In phosphate buffers, a gradual decrease in concentration was observed, with pH 6.4 showing a 5.289% reduction at 24 h and 7.4932% at 48 h; pH 6.8 exhibited a larger difference of 7.86% at 24 h and 16.72% at 48 h; and pH 7.2 showed 9.982% and 10.802% differences at the respective time points. In phthalate buffer (pH 4.4), the changes were comparatively small, with 4.36% at 24 h and 7.976% at 48 h. Borate buffer (pH 8.0) demonstrated good stability, with differences of 1.897% and 2.572% at 24 and 48 h, respectively. The highest stability was observed in 0.1 N HCl, with only 2.032% and 2.632% differences over 24 and 48 h. Overall, ciprofibrate was most stable under acidic and alkaline conditions, with greater degradation occurring near neutral pH (Table 2 and Figure 1).

The linearity study for ciprofibrate demonstrated an excellent correlation between concentration and absorbance within the calibration range of 2–12 µg/mL. The regression equation was found to be $y = 0.3224x - 0.0042$, with a slope of 0.3224 ± 0.0069 and an intercept of 0.0042 ± 0.0034. The correlation coefficient (r) was 0.9997, indicating a highly linear relationship and confirming the method's suitability for accurate quantification of ciprofibrate across the tested concentration range (Table 3).

The forced degradation study of ciprofibrate under different stress conditions revealed significant degradation in acidic, basic, oxidative, and photolytic environments, while no degradation was observed under normal conditions (methanol: water, ambient temperature). Acid hydrolysis with 1 N HCl resulted in 60.27% degradation after 3 h. Basic oxidation with 1 M NaOH showed the highest degradation, reaching 69.92% after 5 h. Oxidative stress using H_2O_2 led to 60.17% degradation in 3 h. Photolytic exposure for 2 h caused 54.37% degradation. Under normal storage conditions, the drug remained stable with no detectable degradation even after 24 h. These results indicate that ciprofibrate is highly susceptible to degradation under acidic, alkaline, oxidative, and light conditions but stable in neutral, ambient environments (Table 4).

Table 1 | Solubility rate of ciprofibrate

Buffer	pH	Absorbance (mg/mL) Mean ± SD (n = 3)	Conc. (mg/mL)	Cs/Cd
Phosphate	6.8	0.0919 ± 0.872	0.3211	1.938
Borate	8.0	0.2821 ± 0.347	1.0160	5.871
0.1 N HCl	1.2	1.176 ± 0.372	1.0248	15.736

Table 2 | Stability data for ciprofibrate

			24 h		48 h	
Buffer	pH	Conc. 0-h (mg/mL)	Conc. (mg/mL)	% Difference With 0-h (n = 3)	Conc. (mg/mL)	% Difference With 0-h (n = 3)
Phosphate	6.4	0.9035	0.8529	5.289	0.8349	7.4932
	6.8	0.2998	0.2869	7.86	0.4683	16.72
	7.2	0.1175	0.1026	9.982	0.1266	10.802
Phthalate	4.4	0.0429	0.0465	4.36	0.0457	7.976
Borate	8.0	1.021	0.9781	1.897	0.8992	2.572
0.1 N HCl	-	2.369	2.45	2.032	2.42	2.632

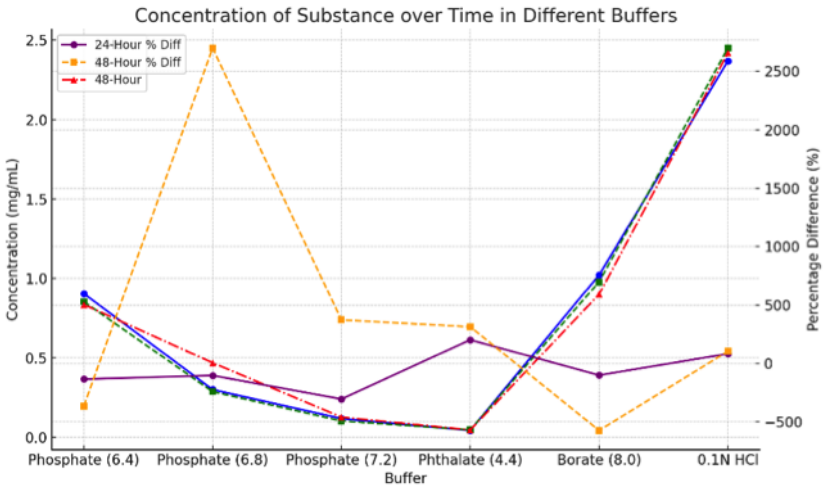

Fig 1 | Stability data for ciprofibrate: Y-axis indicates concentration changes and percentage differences over time (0, 24, and 48 h) for different buffers in the X-axis. The blue, green, and red lines represent the concentrations at 0, 24, and 48 h, respectively, while the purple and orange lines show the percentage differences at 24 and 48 h compared to the 0-h concentration

Table 3 | Linearity results for ciprofibrate

Parameters	Results
Calibration range	2–12 µg/mL
Regression formula	y = 0.3224*x* – 0.0042
Slope ± standard deviation	0.3224 ± 0.0069
Intercept ± standard deviation	0.0042 ± 0.0034
Correlation coefficient (*r*)	0.9997

Table 4 | Results from the forced degradation study of CIP

Condition	Time (h)	Degradation (%)
1 N HCl acid hydrolysis	3	60.27
Basic oxidation (1 M NaOH)	5	69.92
(H_2O_2) oxidation	3	60.17
Photolysis	2	54.37
Norms (methanol: water, ambient temperature)	2	No degradation
	6	
	8	
	24	

The accuracy test resulted in high reproducibility of the ciprofibrate assay technique. Precision within a day was determined at 24, 48 and 72 h by six replicate determinations (n = 6 Determination of intraday precision: n = 6 tablets per time point). The average assay values were 101.67% – 0.77 RSD, 100.46% – 0.49 RSD, and 100.32% – 0.78 RSD, respectively, with all the values falling well within the acceptance criteria of 0.20 RSD, which is the acceptable assay methods. Interday accuracy that was measured over 3 days with n = 6/day gave an average of 101.20% + 0.98 RSD. All time points showed close overlap of the 95% confidence intervals with the label claim, which is also a positive indication of the reproducibility. One-way ANOVA (GraphPad Prism 10.0 software, GraphPad Software Inc., San Diego, CA, USA) was used to test intra- and interday variability, and no differences were found to be significant ($p > 0.05$). These findings show that the method is accurate, reproducible, and reliable in routine ciprofibrate analysis (Table 5).

The robustness study for ciprofibrate showed that deliberate small variations in analytical conditions did not significantly affect assay results, demonstrating the method's reliability. The mean ± RSD% values were 100.32 ± 0.97% and 99.87 ± 1.69% for the addition of 8 mL and 15 mL methanol, respectively. Sonication for 15 min and 25 min yielded results of 102.14 ± 0.32% and 102.41 ± 0.39%, respectively. Storage for 24 h at room temperature (25°C) resulted in 101.72 ± 0.46%, while analysis under regular conditions gave 100.01 ± 0.70%. These results confirm that the method is robust and unaffected by minor procedural changes (Table 6).

Optimization of Dissolution Test

- The results obtained from solubility and stability, with consideration to the influence of sink condition, were used to determine the dissolution media; 0.1 N HCl, 6.8 phosphate and 8.0 borate buffer solutions were selected as the dissolution media.
- The dissolution of ciprofibrate drug required a neutral pH solution and higher concentration per µg/ml. The drug was readily dissolved in organic solvents like methanol, as stated in literature review; this was tested and found to be true. More literature surveys show that the drug belongs to the BCS class-ll drug, which is associated with a poor dissolution rate. The drug was also readily dissolved in acetonitrile during buffer selection and the trial phase.
- All the buffer showed fast dissolution rate, buffer however due to its alkaline nature which has further effects on the drugs stability, 6.8 phosphate buffer which is more on a neutral pH proves to be the most stable.

Table 5 | Precision result for ciprofibrate over time

Sr. No.	Time (h)	Mean ± RSD%
1	24 (n = 6)	101.67 ± 0.77
	48 (n = 6)	100.46 ± 0.49
	72 (n = 6)	100.32 ± 0.78
	Inter-day[a]	101.20 ± 0.98

Table 6 | Results from robustness test for ciprofibrate

Sr. No.	Analytical Condition	Mean* ± RSD%
1	Addition of 8 mL of methanol	100.32 ± 0.97
2	Addition of 15 mLof methanol	99.87 ± 1.69
3	Sonication for 15 min	102.14 ± 0.32
4	Sonication for 25 min	102.41 ± 0.39
5	24 h at room temperature (25°C)	101.72 ± 0.46
6	Regular conditions	100.01 ± 0.70

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Table 7 | Dissolution test linearity results for ciprofibrate

Sr. No.	Concentration (µg/mL)	Absorbance ± Standard Deviation
1	10	0.2378 ± 0.002951
2	20	0.4635 ± 0.006404
3	30	0.7032 ± 0.002193
4	40	0.9051 ± 0.002562
5	50	1.1124 ± 0.000938
6	60	1.3601 ± 0.001001

The calibration data for ciprofibrate demonstrated a strong linear relationship between concentration and absorbance over the range of 10–60 µg/mL. The absorbance values (mean ± SD, n = 3) increased proportionally with concentration, from 0.2378 ± 0.002951 at 10 µg/mL to 1.3601 ± 0.001001 at 60 µg/mL. The low standard deviation values across all concentrations indicate high repeatability and precision of the measurements. These results confirm the suitability of the method for accurate and reliable quantification of ciprofibrate within the tested range (Table 7).

Table 8 | Cumulative drug release for dissolution profile

Time	Cumulative Drug Release			
0	0	0	0	0
1	7.53 ± 0.27	8.01 ± 0.31	9.41 ± 0.26	8.02 ± 0.68
2	20.46 ± 0.26	17.64 ± 03	21.63 ± 0.71	29.72 ± 0.38
3	29.17 ± 0.82	29.25 ± 0.16	27.44 ± 0.35	43.62 ± 0.23
4	29.17 ± 0.83	34.61 ± 0.31	32.38 ± 0.11	49.78 ± 0.85
5	29.17 ± 0.84	53.38 ± 0.19	43.14 ± 0.57	54.46 ± 0.81
6	29.17 ± 0.85	66.44 ± 0.53	52.37 ± 0.63	60.36 ± 0.98
7	29.17 ± 0.86	72.69 ± 0.93	58.39 ± 0.13	66.45 ± 0.51
8	29.17 ± 0.87	71.63 ± 0.82	63.45 ± 0.94	71.82 ± 0.53
9	29.17 ± 0.88	75.45 ± 0.58	72.09 ± 0.32	8.45 ± 0.39
10	29.17 ± 0.89	81.55 ± 0.87	81.33 ± 0.65	2.52 ± 0.76
11	29.17 ± 0.90	86.51 ± 0.69	87.75 ± 0.68	86.47 ± 0.32
12	29.17 ± 0.91	91.62 ± 0.45	95.19 ± 0.99	91.32 ± 0.64

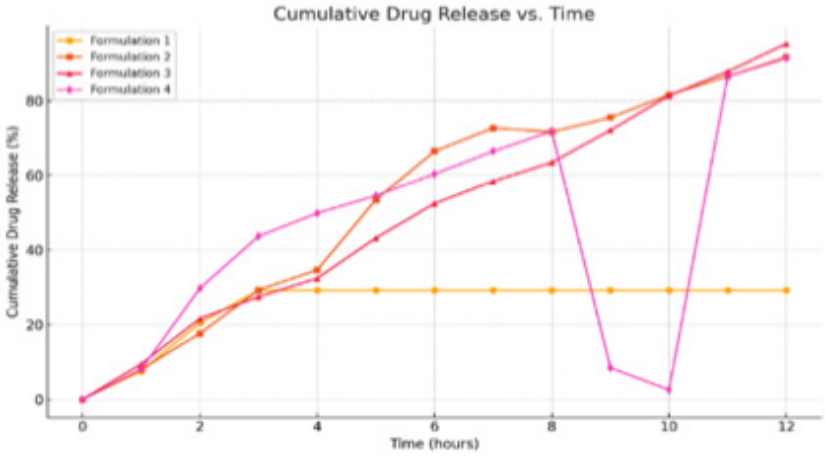

Fig 2 | Cumulative drug release for dissolution profile

The in vitro drug release study showed distinct release profiles for the four formulations over a 12-h period. Formulation 1 exhibited a burst release of 7.53% ± 0.27% at 1 h, followed by a rapid increase to 20.46% ± 0.26% at 2 h and 29.17% ± 0.82% at 3 h, after which the release plateaued, maintaining ~29.17% up to 12 h, indicating incomplete release. Formulation 2 displayed a steady and sustained release, starting with 8.01% ± 0.31% at 1 h, reaching 53.38% ± 0.19% at 5 h, and achieving 91.62% ± 0.45% by 12 h. Formulation 3 also showed controlled release, with 9.41% ± 0.26% at 1 h, increasing to 63.45 ± 0.94% at 8 h, and completing 95.19% ± 0.99% release by 12 h. Formulation 4 had a faster release profile, reaching 29.72% ± 0.38% at 2 h, 66.45% ± 0.51% at 7 h, and 91.32% ± 0.64% at 12 h. Overall, Formulations 2, 3, and 4 achieved nearly complete drug release within 12 h, while Formulation 1 showed limited release, suggesting a stronger drug retention or formulation-controlled barrier (Table 8 and Figure 2).

The accuracy study for ciprofibrate dissolution testing was evaluated at three levels of addition (80%, 100%, and 120% of the target amount). At the 80% level, the average amount recovered was 25.5 mg, corresponding to a mean recovery of 92.368% ± 2.1278%. For the 100% level, the recovery was 30.053 mg, with an average percentage recovery of 100.17% ± 2.4989%. At the 120% level, the recovery was 32.164 mg, giving an average recovery of 97.14% ± 2.126%. These results fall within the acceptable limits for analytical method accuracy, confirming that the method is accurate and reliable for quantifying ciprofibrate in dissolution studies (Table 9).

The dissolution test linearity study for ciprofibrate demonstrated a strong proportional relationship between concentration and absorbance over the range of 10–60 µg/mL. The absorbance values (mean ± SD, n = 3) increased consistently from 0.2378 ± 0.002951 at 10 µg/mL to 1.3601 ± 0.001001 at 60 µg/mL. The low standard deviation across all concentrations indicates excellent precision. These results confirm that the method exhibits high linearity, making it suitable for accurate quantification of ciprofibrate in dissolution studies within the tested range (Table 10).

The dissolution profile of ciprofibrate at three different time points of the day (8:00 am, 12:00 pm, and 5:00 pm) showed consistent drug release patterns. At 5 min, the average % release ranged from 30.863% ± 0.5325% to 33.321 ± 0.4513%. By 10 min, release increased to 50.463% ± 1.1682%–54.872 ± 1.7543%, except for the 5:00 pm run, which showed a slightly lower release of 42.457% ± 0.7689%. At 15 and 20 min, the release exceeded 64%, reaching above 69% at 30 min. At 40 min, drug release values were closely aligned across runs, ranging from 72.589% ± 0.8758% to 73.578% ± 1.4847%, with an overall average of 73.262% ± 1.0121% and a %RSD of 1.701. These

Table 9 | Dissolution test accuracy results for ciprofibrate

Sr. No.	Parameter	Levels		
1	Tablet amount (mg)	15	15	15
2	Level of addition (%)	80	100	120
3	Amount added (mg)	12	80	18
4	Average amount recovered (mg)	25.5	30.053	32.164
5	Average % recovery	92.368 ± 2.1278	100.17 ± 2.4989	97.14 ± 2.126

Table 10 | Dissolution test linearity results for ciprofibrate

Sr. No.	Concentration (µg/mL)	Absorbance ± Standard Deviation
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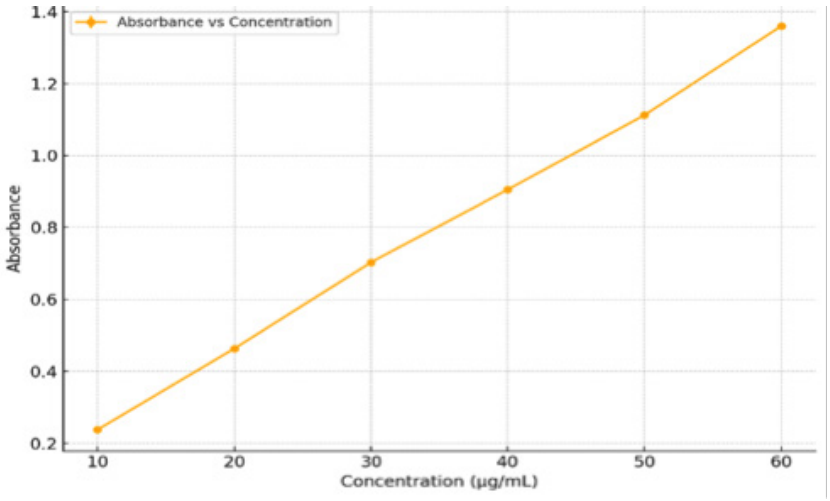

Fig 3 | Calibration curve concentration and absorbance

Table 11 | Dissolution test intra-day precision results for ciprofibrate

		Average % release ± SD (n = 3)		
Sr. No.	Time (min)	8:00 am	12:00 am	5:00 pm
1	0	0.019 ± 0.8738	0.028 ± 1.1584	0.026 ± 1.5468
2	5	30.863 ± 0.5325	33.241 ± 0.8866	33.321 ± 0.4513
3	10	50.463 ± 1.1682	54.872 ± 1.7543	42.457 ± 0.7689
4	15	64.848 ± 1.1274	66.567 ± 1.2349	66.739 ± 1.4911
5	20	66.598 ± 0.4765	67.891 ± 1.0272	69.289 ± 1.2317
6	30	69.667 ± 0.7979	70.467 ± 0.3883	72.025 ± 0.8624
7	40	72.589 ± 0.8758	73.578 ± 1.4847	73.569 ± 0.6924
8	Average at 40 min	73.262 ± 1.0121		
9	%RSD at 40 min	1.701		

results indicate good reproducibility and minimal variation in dissolution performance regardless of the time of testing (Table 11).

The dissolution profiles across all three time points demonstrate a consistent and monotonic increase in drug release, confirming the absence of previously observed anomalies. Minor variability at early time points (e.g., at 10 min) is within acceptable experimental limits and does not affect the overall release pattern. The average drug release at 40 min was found to be 73.262% ± 1.0121%, with an RSD (%) of 1.701, which is well within acceptable limits (≤2%). These results confirm the method's consistency and reliability for dissolution testing of ciprofibrate (Table 12).

The dissolution study comparing two different mobile phases for ciprofibrate showed comparable drug release profiles. With mobile phase I, release increased from 32.467 ± 0.7819% at 5 min to 69.541 ± 0.9413% at 30 min, reaching 71.395 ± 1.066% at 40 min. For mobile phase II, release values ranged from 34.091 ± 0.4385% at 5 min to 70.289 ± 1.477% at 30 min, achieving 74.215 ± 0.9963% at 40 min. The overall average % release at 40 min as 72.866 ± 1.098%, with an RSD of 1.432, indicating minimal variability. These findings suggest that both mobile phases provide consistent and reliable dissolution results for ciprofibrate (Table 13).

Ciprofibrate tablets were formulated using suitable excipients, including diluents, binder, disintegrant, lubricant, and glidant to ensure proper tablet characteristics. The prepared tablets were evaluated for quality control parameters, such as weight variation, hardness, friability, and drug content, as per pharmacopeial standards. All parameters were found within acceptable limits, indicating uniformity and mechanical strength of the tablets. The drug content confirmed uniform distribution of the active ingredient. The dissolution study showed consistent drug release (~73% at 40 min), with low variability (%RSD < 2%), demonstrating good reproducibility of the method. Overall, the formulation was found to be suitable and reliable for dissolution method validation.[17–19]

Conclusion

The current study has shown and proved a new method of dissolution testing of ciprofibrate sustained-release tablets, which is relevant and reliable in the quality of pharmaceuticals. The manufacturing process was conducted under clean and controlled conditions, whereby it yielded reproducible, stable, and pharmacopoeia-compliant tablets, besides having satisfactory physical properties. An optimized excipient composition has been used to successfully produce sustained-release tablets containing 100 mg of ciprofibrate, with a final product of good mechanical strength and homogeneity. Dissolution experiments conducted in well-controlled experimental conditions and selected buffer media gave valid, repeatable, and discriminatory findings. This is especially

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Table 12 | Dissolution test inter-day precision results for ciprofibrate

Time (min)	Day I	Day II
0	0.033 ± 0.9652	0.048 ± 1.156
5	33.362 ± 0.867	35.918 ± 0.5672
10	52.657 ± 1.0238	51.169 ± 0.9562
15	65.891 ± 0.9911	62.903 ± 0.6954
20	71.128 ± 1.185	68.532 ± 0.6971
30	71.167 ± 1.1109	69.533 ± 1.5932
40	72.572 ± 1.0063	71.662 ± 0.3597
Average at 40 min	73.682 ± 1.0041	
RSD (%) at 40 min	1.3785	

Table 13 | Robustness of dissolution test with change in mobile phase

Sr. No	Time (min)	Mobile Phase I	Mobile Phase II
1	0	0.026 ± 1.1462	0.063 ± 0.9628
2	5	32.467 ± 0.7819	34.091 ± 0.4385
3	10	50.365 ± 1.125	47.586 ± 1.1469
4	15	62.497 ± 0.8317	63.194 ± 1.5372
5	20	67.287 ± 1.491	67.136 ± 0.8378
6	30	69.541 ± 0.9413	70-.289 ± 1.477
7	40	71.395 ± 1.066	74.215 ± 0.9963
	Average at 40 min	72.866 ± 1.098	
	RSD (%) at 40 min	1.432	

relevant to ciprofibrate, which is the BCS Class II drug, and the rate-limiting process in its absorption is its dissolution. The required analytical approach, which was UV spectrophotometry, was found to be precise, accurate, and repeatable when analyzing ciprofibrate in various media. Its validation method proved it to be suitable in routine analysis, especially when used alongside suitable dissolution media, reflecting physiological pH conditions. Ciprofibrate appeared to be typically well-soluble at low and high pH values, but not in the neutral pH range, which highlights the necessity of biorelevant testing, including gastric conditions simulations.

This paper identifies the possibility of determining the best dissolution parameters and media of poorly soluble drugs to enhance the predictability of in vivo behavior. Future studies ought to be aimed at developing in vitro–in vivo correlations (IVIVC) and the use of biorelevant dissolution media, as well as alternative drug delivery approaches, including nanoparticle preparations or solid suspensions, to increase the bioavailability of ciprofibrate. Moreover, the combination of pharmacokinetic modeling and machine learning can further optimize dissolution testing procedures and can be used to facilitate the design of controlled drug delivery systems. The next procedures will involve the IVIVC calculations to determine the bioavailability of ciprofibrate more accurately and use the validated methodology in bioequivalence trials. In addition to ciprofibrate, this method can also be regarded as useful with the other BCS Class II medications, thus ushering in larger breakthroughs in the field of pharmaceutical formulation and analysis. The study would be able to be a strong dissolution method to ciprofibrate with major revisions to enhance the methodological rigor, address any inconsistencies, and improve clarity that could inform future IVIVC and formulation development initiatives.

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Table 14 | Composition and quality controlpParameters of ciprofibrate tablets

Sr. No.	Category	Parameter/Ingredient	Function/Specification	Result/Quantity (Mean ± SD)
1	Formulation	Ciprofibrate	Active pharmaceutical ingredient (API)	100 mg
2		Microcrystalline cellulose (MCC)	Diluent	80 mg
3		Lactose monohydrate	Diluent	60 mg
4		Croscarmellose Sodium	Disintegrant	10 mg
5		Polyvinylpyrrolidone (PVP K-30)	Binder	8 mg
6		Magnesium stearate	Lubricant	2 mg
7		Talc	Glidant	5 mg
8		Total weight	—	265 mg
9	Quality control	Weight variation	±5% deviation	264.8 ± 2.15 mg
10		Hardness	4–8 kg/cm²	5.6 ± 0.42 kg/cm²
11		Friability	NMT 1.0%	0.42% ± 0.08%
12		Drug content (assay)	98%–102%	99.12% ± 1.05%
13	Dissolution	Drug release at 40 min	—	73.262% ± 1.0121%
14		Relative standard deviation (%)	NMT 2%	1.701%

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