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DEVELOPMENT AND VALIDATION OF A DISSOLUTION TEST FOR ACARBOSE IN PURE DRUG AND CONVENTIONAL DOSAGE FORM: A REVIEW

Heena I. Patel*, Kanchan B. Ghatge, Sheetal K. Kamble, Tejaswini S. Kapashe, Sachin S. Mali and Jayshree S. Patil

Y. D. Mane Institute of Pharmacy, Kagal 416 216, Maharashtra, India.

***Corresponding Author: Heena I. Patel**

Y. D. Mane Institute of Pharmacy, Kagal 416 216, Maharashtra, India.

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ABSTRACT

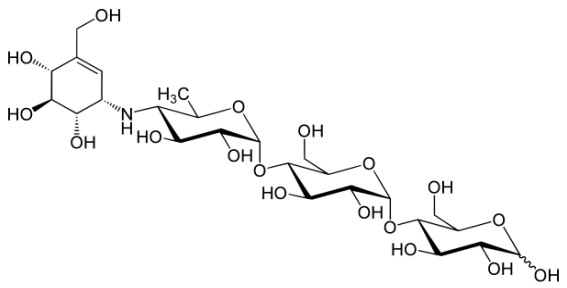
A basic, exact, and precise strategy was created and approved by an UV-spectrophotometric technique for deciding acarbose in unadulterated medication and 50 mg tablet plans. Disintegration testing has arisen in the drug field as a vital device to portray drug item execution. Acarbose, a much of the time endorsed antidiabetic, has no disintegration examine in true monographs. The current examination work meant to create and approve a disintegration test for the quality control of Acarbose by ICH rule tablets containing 50 mg of dynamic drug fixing (Programming interface). Comes about because of testing sink conditions and steadiness at 37 °C show that acarbose is steady in water. In vitro disintegration trial of Acarbose tablets were performed utilizing different test conditions however consistently under sink conditions. The impacts of filtration and deaeration were assessed. The most prejudicial test conditions were palatable: water (900 mL at 37 ± 0.5°C) as disintegration medium, paddle strategy (Contraption 2), 100 rpm, and 30 min. The UV spectrophotometric technique for assurance of delivered acarbose was created and approved. The strategy introduced linearity (r2 = 0.996) in the 27.5-82.5 µg/ml fixation range. The recuperations were great, going from 97.06% to 100.17%. The intraday and interlay accuracy results were 1.0587 % and 0.3952% RSD, separately. The created disintegration test is satisfactory for its motivation and can be applied for the quality control of 50-mg Acarbose tablets.

KEYWORDS: Acarbose unadulterated medication, Disintegration contraption, Sodium chloride, Hydrochloric corrosive (37%), water.

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disease characterized by hyperglycemia, glycosuria, hyperlipaemia, negative nitrogen balance and sometimes ketonaemia. A widespread pathological change is thickening of capillary basement membrane, increase in vessel wall matrix and cellular proliferation resulting in vascular complications like lumen narrowing. Acarbose It is a complex oligosaccharide which reversibly inhibits α-glucosidases, the final enzymes for the digestion of carbohydrates in the brush border of small intestine mucosa. It slows down and decreases digestion and absorption of polysaccharides and sucrose postprandic glycaemia is reduced without increasing insulin levels. Regular use tends to lower HbAlc, body weight and serum triglyceride. These beneficial effects, though modest, have been confirmed in several studies. Further, the stop-NIDD trial (2002) has shown that long-term Acarbose treatment in pre-diabetics reduces occurrence of type-2 DM as well as hypertension and cardiac disease. In diabetics, it reduces cardiovascular events.[2] Therefore, it was thought of interest to develop a simple, accurate, fast and cost effective method for analysing acarbose in its tablet formulation. This paper describes development and Validation of simple, specific, sensitive, accurate and precise Ultraviolet spectroscopic method for the estimation of acarbose in pure 50 mg tablet formulations

- **Acarbose**



MATERIAL AND METHODS

Dissolution mediums:

I. Buffer pH 1.2 (Artificial gastric Juice without pepsin)

Dissolve 20 gm of sodium chloride in 9 liters of deminralised water, add 70 ml of hydrochloric acid while stirring and check the buffer pH value 1.2 ± 0.5, make up the volume up to 10 liters demineralized water.

II. Demineralized water

Dissolution medium volume:- 900 ml

Dissolution parameters

Apparatus type:- Apparatus 2 USP – Paddle

1. Method development:

Preparation of standard solution:

Weighed accurately approximately 11.1 mg of Acarbose pure drug into 200 ml amber colored volumetric flask, added 160 ml of dissolution medium. Adjust the temperature to 20 ºC, fill up to the mark with dissolution medium and mix thoroughly. (C- 55.56 mg/ ml)

Rotation speed: 100 rpm

A. Study design

I. Time points

Dissolution profiles of immediate release products typically show a gradual increase reaching 85%–100% at about 30–45 min. Thus, dissolution time points in the range of 15, 20, 30, 45, and 60 min are select for most immediate-release products.[22-26]

Time point: 30 min

II. Observations

Test substance: Undamaged one whole tablet into 900 ml dissolution medium.

Test solution: - filter the test specimens immediately upon sampling (membrane filter), and use filtrate as test solution.

A. Sample processing

After the samples are withdrawn from the dissolution medium, they may require additional processing to make them suitable for the analytical methodology used to determine the amount released. For example, filtration may be used to remove undissolved particulate matter, or samples may need to be protected from exposure to light or may need refrigerated storage. In addition, samples may have to be diluted to a level that is within the linear range of the method. [21]

B. Filters

Whatman 41 filter papers or 10 µ inline filters or 1 µ glass fiber filter.

Linearity

Linearity is typically established by preparing solutions of the drug substance, ranging in concentration from less than the lowest expected concentration to more than the highest concentration during release. A minimum of five concentrations is normally used.[22-24]

Aliquots of Acarbose stock solution (100 µg/mL) were diluted with buffer pH 1.2 Artificial gastric Juice without pepsin and Deminralised water to give concentrations of 27.5–82.5 µg/mL. Each solution was prepared in triplicate. The linearity was evaluated by linear regression analysis, which was calculated by the least square regression method. Typically, a square of the correlation coefficient ($r2 \geq 0.98$) demonstrates linearity. In addition, the y-intercept must not be importantly different from zero. The range of the procedure is the interval between the upper and lower concentrations of the drug substance (including these levels) that has been demonstrated to have a suitable level of precision, accuracy, and linearity using the procedure as written.[11-24]

Accuracy / Recovery

The recovery study was performed using a well-characterized lot of drug product with tight content uniformity Acarbose reference substance was added to the dissolution vessels in known amounts at the 80%, 100%, and 120% levels. Accordingly, 47, 50, and 53 mg of reference drug was added along with each 50-mg tablet. The dissolution test was performed on Glucobay tablets for 30 min using 900 mL of water as medium in a paddle apparatus at 100 rpm. Aliquots of 10 mL were filtered through Whatman No. 41 filter paper and analyzed by UV spectrophotometric method at the spiked concentration levels of 80%, 100%, and 120%, respectively. Each concentration was analyzed in triplicate.[21]

Precision

Repeatability is evaluated by obtaining replicate measurements of standard and/or sample solutions. It can be determined by calculating the RSD of the spectrophotometric readings for each standard solution, or by using the accuracy or linearity data. ICH guidance, Repeatability (intraassay) was determined by analyzing six samples of Glucobay tablets with the optimized dissolution test. Aliquots were collected and evaluated by the UV method at 220 nm. Thus, repeatability was evaluated with the relative standard deviation (RSD) of the data at the 100% level. [21-22]

Intermediate Precision/Ruggedness

The evaluation of intermediate precision was performed using a well-characterized lot of drug product of tight content uniformity. The intermediate precision (interday) was determined on different days by different analysts, and the RSD values were calculated. The dissolution test was performed on six Glucobay tablets for 30 min using 900 mL of water as dissolution medium in Apparatus 2 at 100 rpm. Aliquots of 10 ml were filtered with quantitative filter and analyzed by the UV spectrophotometric method. Each concentration was analyzed in triplicate.[21-26]

RESULT AND DISSCUSION

Filter compatibility evaluation:

The aftereffects of the channel assessment uncover that the outright contrasts between the groupings of standard example in Deminralised water and separated/

centrifuged tests were inside 98-102%. This exhibits the shortfall of Acarbose adsorption by the channel and the reasonableness of Whatman No. 41 channel paper in the disintegration test.

Determining Solubility and Stability of Drug Substance in Various Media at 37°C

The solubility profile of acarbose demonstrates that the solubility is pH dependent. PH exhibited substantial solubility at pH 1.2. The maximum solubility was observed in water. The solubility of acarbose increases as the pH decreases (Table 1) since acarbose is a weak base and exists in ionized form at a p*K*a of 12.06.[18] The solubility of acarbose in water was tested because water is a ideal dissolution medium for acarbose. In addition, water quality is variable depending on the source and water pH is variable depending on the API and the excipients. Water is not considered a physiologically relevant medium as it is not representative of the gastric environment.[21]

Drug solubility and solution stability are important properties to be considered when selecting the dissolution medium. If standard solutions are not stable in a dissolution medium for at least 24 h at ambient temperature, it should not be chosen. Stability study results (Table 2) reveal that the change in concentration of drug samples stored in different dissolution media (artificial gastric juice without enzyme buffer pH 1.2 and water; and in light at 25 °C over 2 days was less than 3% o f that of reference solutions.[23]

Table 1: Solubility of acarbose.

Buffer	pH	Average Absorbance mean ± SD (*n* = 3)	Concentration (mg/mL)	*Cs*/*Cd*
Artificial gastric juice	1.2	0.1478 ± 0.080	0.5556	3.854
Water	-	0.1555 ± 0.072	0.5561	4.591

Table 2: Stability data of acarbose.

Buffer	pH	0-h conc. (mg/mL)	24 hrs conc. (mg/mL)	24 hrs % difference with 0-h (*n* = 3)	48 hrs conc. (mg/mL)	48 hrs % difference with 0-h (*n* = 3)
Artificial gastric juice	1.2	0.5456	0.5325	1.2 %	0.5239	2.52 %
Water	-	0.5561	0.5435	.94 %	0.5346	2.01 %

Deaeration

The effect of dissolved gases in the medium on Acarbose dissolution revealed that the amount of dissolved drug was less in nondeaerated medium and the results were more variable. Thus, deaerated dissolution media was needed during dissolution study.[1,21]

Optimization of dissolution test

Correlation of the solubility and stability data and the influence of sink conditions indicate that water; is suitable dissolution media. The results of the dissolution study are depicted in Figures 2–5. The results indicate that dissolution of Acarbose from Glucobay tablets was not pH dependent. In the case of sodium chloride buffer pH 1.2, the amount dissolved was less as compared with water, probably due to a decrease in the surface ionization at pH 1.2.

Dissolution of drug from a dosage form involves at least two consecutive steps, disintegration (liberation of the drug from the formulation matrix) followed by dissolution of the drug (solubilization of the drug particles) in the dissolution medium. For most of the immediate-release formulations of poorly soluble drugs, the rate of dissolution is intrinsically controlled. Although the solubility of acarbose was greater in water than in sodium chloride buffer pH 1.2, the amount of acarbose dissolved in the water was less than in the pH 1.2 buffer. The dissolution profiles demonstrate incomplete dissolution of Acarbose tablets in sodium chloride buffer pH 1.2, in paddle apparatus, at the stirring speeds of 100 rpm. The percent release was less than 85% within 30 min; therefore, the minimum requirements established by USFDA were not satisfied (*26*). On the other hand, the use of water as a dissolution medium with a paddle apparatus at 100 rpm yielded a satisfactory dissolution of the drug in the first 30 min of the test, with drug release greater than 85%.[21]

Biopharmaceutics Classification System referred to in several FDA Guidance's, highly soluble, highly permeable drugs formulated into rapidly dissolving products need not be subjected to a profile comparison if they can be shown to release 85% or more of the active drug substance within 15 min. For these types of products, a one-point test or disintegration will suffice. However, most products do not fall into this category. Dissolution profiles of immediate release products typically show a gradual increase reaching 85%–100% at about 30–45 min. The dissolution test conditions suggested by FDA for Acarbose tablets, namely a collection time of 30 min, are inadequate, and more

samples are essential. Drug release was greater with the paddle apparatus.[11]

The selection of the stirring speed was based on the recommended range for Apparatus 2 for tablets. The effect of rotation speed of the paddles on the dissolution profile of acarbose was examined at 100 rpm. In general, mild agitation conditions and less volume of dissolution medium should be maintained during dissolution testing to allow maximum discriminatory power since the dissolution apparatus tends to become less discriminating when operated at faster speeds, resulting in a flatter drug release profile.[26]

When water was used as the dissolution medium, acarbose showed a faster dissolution rate, which was not desirable because this condition may not reflect in vivo performance and an adequate capacity to differentiate between different formulations. The dissolution profile obtained in sodium chloride buffer pH 1.2 for paddle apparatus at 100 rpm was slower and may have better capacity to differentiate the formulations. One of the desirable features of the dissolution method is its discriminatory capacity. In sodium chloride buffer pH 1.2, drug release was slower than in water. (Table 3 - 4).[27]

Table 3: Dissolution release rate of glucobay tablets in Water, Paddle apparatus, 100 rpm,

Sr. No.	Time	Bowl no. 1	Bowl no. 2	Bowl no. 3	Bowl no. 4	Bowl no. 5	Bowl no. 6	Average % release
1	5	31.25	32.09	32.52	33.16	30.89	31.08	32.83
2	10	50.29	49.98	48.75	47.25	48.25	46.15	48.45
3	15	78.85	79.89	77.08	76.98	79.15	78.48	78.40
4	20	86.01	89.60	88.57	87.25	85.48	84.64	86.93
5	30	101.02	100.45	99.81	98.04	99.15	99.58	99.68

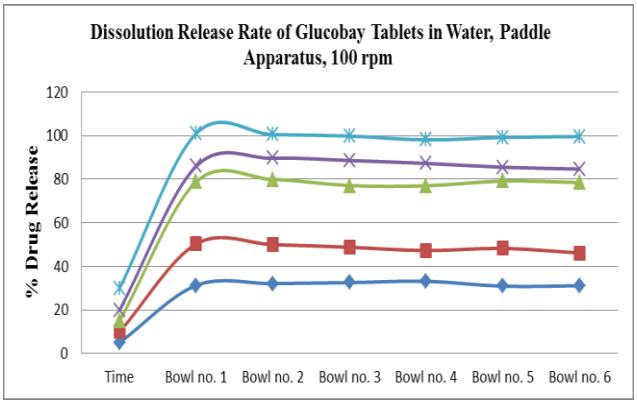
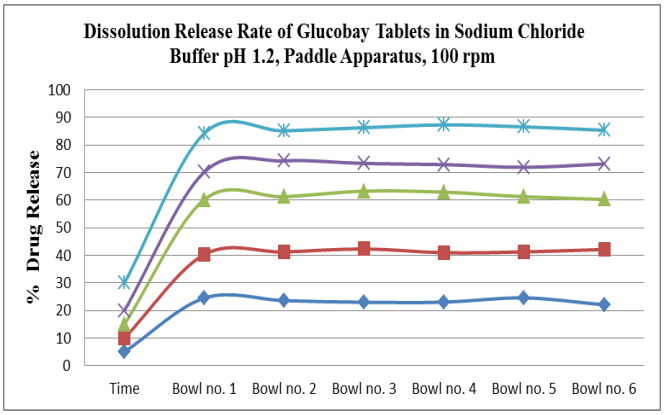


Table 4: Dissolution Release Rate of Glucobay Tablets in Sodium Chloride Buffer pH 1.2, Paddle Apparatus, 100 rpm.

Sr. No.	Time	Bowl no. 1	Bowl no. 2	Bowl no. 3	Bowl no. 4	Bowl no. 5	Bowl no. 6	Average % release
1	5	24.52	23.59	22.98	23.05	24.58	22.08	23.46
2	10	40.29	41.22	42.31	40.96	41.25	42.11	41.35
3	15	60.22	61.23	63.27	62.89	61.24	60.25	61.52
4	20	70.22	74.23	73.28	72.87	71.89	73.12	72.61
5	30	84.25	85.12	86.24	87.26	86.54	85.32	85.79



Validation of dissolution test

After the best experimental conditions were selected, the dissolution test was validated.[21-25]

Specificity

When the placebo tablets were subjected to the dissolution test and analyzed, the corresponding absorbance was equivalent to 1.24% Acarbose concentration. According to ICH guidelines, the dissolution method is specific if the interference is not more than 2%. The dissolution method was specific.[21,22]

Linearity

To assess linearity, a standard curve for acarbose was constructed by plotting average absorbance versus concentration (Table 5). The curves depict good linearity in the range of 27.50 - 82.50 µg/ml. The line equation was $y = 13.53x - 12.70$ with a slope of 13.53 and $r2$ of 0.996. The RSD for each point was less than 2%. These data indicate that the method is linear for acarbose within the specification limits.[11,21]

Table 5: Dissolution test linearity results for acarbose.

Sr. No.	Level of addition (%)	Concentration (µg/ml)	Absorbance ± Standard Deviation (n = 3)
1	50	27.5	0.0777 ± 0.00118
2	80	44	0.1244 ± 0.00189
3	100	55.56	0.1554 ± 0.00236
4	120	66	0.1866 ± 0.00284
5	150	82.5	0.2332 ± 0.00355

Accuracy

The accuracy expresses the agreement between the accepted value and the observed value. According to ICH guidelines, the recovery for a dissolution test must be in the range of 95–105%. The percent recovery was from 97.06 % to 100.17 %. The accuracy of the method is acceptable (Table 6). [21]

Table 6: Dissolution test accuracy results for acarbose.

Sr. No.	Parameters	Levels		
1	Total Amount (mg)	50	50	50
2	Level of addition (%)	80	100	120
3	Amount added (mg)	47	50	53
4	Average amount recovered (mg)	46.05	50.06	52.81
5	Average % recovery^	97.06 ± 2.1577	100.17 ± 2.5023	98.40 ± 2.1941

^ *Each reading is mean ± SD (n = 3)*

Precision

The percent RSD did not exceed 5% for the repeatability and intermediate precision, demonstrating suitable precision (Tables 7 and 8).

Table 7: Dissolution test precision (Intraday) results for acarbose.

Sr. No.	Time (min)	Average % Release ± SD (n = 3)		
		8 am	1 pm	6 pm
1	5	31.021 ± 0.5972	32.921 ± 0.8772	33.243 ± 0.4723
2	10	50.891 ± 1.1653	52.675 ± 1.6832	53.775 ± 0.9189
3	5	74.943 ± 0.8007	77.464 ± 1.5658	78.628 ± 0.8243
4	20	85.594 ± 0.873	87.682 ± 0.9191	88.938 ± 0.9322
5	30	98.865 ± 1.0362	99.791 ± 1.0459	99.952 ± 1.0473
6	Average at 30 min	99.536 ± 1.0432		
7	% RSD at 30 min	1.0587		

Table 8: Dissolution test precision (Interday) results for acarbose.

Sr. No.	Time (min)	Average % Release ± SD (n = 3)		
		Day 1	Day 2	Day 3
1	5	34.831 ± 0.9137	33.434 ± 0.5410	35.345 ± 0.7012
2	10	49.592 ± .9493	47.951 ± 0.9178	50.592 ± 0.4867
3	15	79.044 ± 0.2792	76.43 2 ± 0.2717	79.349 ± 0.2802
4	20	87.982 ± 0.3106	85.892 ± 0.3033	89.982 ± 0.3176
5	30	101.204 ± 0.3573	98.421 ± 0.3473	100.214 ± 0.3537

6	Average at 30 min	99.958 ± 0.3527
7	% RSD at 30 min	0.3952

Robustness

The robustness of the method was demonstrated by changing the analyst, and the instrument. The percent RSD values were within the specified limit of 5% indicating the robustness of dissolution method (Tables 9 – 10). [21-24]

Table 9: Robustness of dissolution test with change in analyst.

Sr. No.	Time (min)	Average % Release ± SD (*n* = 3) Analyst 1	Analyst 2
1	5	34.823 ± 0.4684	33.483± 0.8001
2	10	50.261 ± 1.2482	49.201± 1.1401
3	15	77.593 ± 0.8047	78.359 ± 0.8127
4	20	86.952 ± 0.8804	88.612 ± 0.8972
5	30	99.258 ± 1.049	100.029 ± 1.0127
6	Average at 30 min	99.643 ± 1.0088	
7	RSD at 30 min	1.0548	

Table 10: Robustness of dissolution test with change in equipments.

Sr. No.	Time (min)	Average % Release ± SD (n = 3) Equipment 1	Equipment 2
1	5	31.214 ± 0.9549	32.412 ± 0.9915
2	10	49.596 ± 0.8748	50.824 ± 0.8964
3	15	77.468 ± 1.2034	79.688 ± 1.237
4	20	84.235 ± 1.3084	87.352 ± 0.7784
5	30	98.214 ± 1.0063	99.258 ± 1.0163
6	Average at 30 min	98.738 ± 1.0109	
7	RSD at 30 min	1.0438	

CONCLUSION

The disintegration test created and approved for Acarbose tablets is thought of as acceptable. The most separating conditions for disintegration testing of Acarbose tablets (i.e., Water medium, paddle mechanical assembly, mixing rate of 100 rpm, and assortment season of 30 min) seem, by all accounts, to be the best condition. The Approval shows that the disintegration test is proper for evaluation of acarbose in tablet drug structure for in vitro examinations, introducing selectivity, linearity, accuracy, exactness, and power. The technique is sufficient for use in quality control testing of Acarbose tablets since a disintegration test isn't demonstrated in an authority monograph, yet is remembered for Pharmacopeias Discussion.

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