International Research Journal on Advanced Engineering and Management
https://goldncloudpublications.com
https://doi.org/10.47392/IRJAEM.2025.053
e ISSN: 2584-2854
Volume: 02
Issue:02 February 2025
Page No: 334-338

U.V Spectroscopic Method for the determination of Dissolution and Assay of Aceclofenac SR60%W/W Pellets

Bandi. Sudhakar Rao[1], Srinivasarao.Tumati[2], Govindha chowdary[3], Venkanna.R[4], K. Manohar[5],
[1]Scholar, Department of chemistry B.E.S.T innovative University &Assistant professor Department of Chemistry, Government Degree College, Bhadrachalam. India.
[2]Research supervisor, B.E.S.T innovative university Associate Professor Department of chemistry, Vignan institute of technology and science, Hyderabad, India.
[3]Associate Professor Department of Chemistry Vignan Institute of Technology and Science, India.
[4]Associate Professor Department of chemistry, Spoorthy engineering college, Hyderabad, India.
[5]Assistant professor Department of chemistry Vignan institute of technology and science, Hyderabad, India.
Email ID: *sudhakar8513@gmail.com[1], prof.tumati@gmail.com[2], chowdary.ratp@gmail.com[3], venkanna.rapolu21@gmail.com[4], manimanohara@gmail.com[5]*

Abstract
Aceclofenac (C16H13Cl2NO4), chemically known as [(2-{2, 6-dichlorophenyl) amino} phenyl aceto oxyacetic acid], is a crystalline powder and its molecular weight is 354.19. It is practically insoluble in water with good permeability. In-house formulation was performed related dissolution test method was proposed for the determination of Aceclofenac SR60%w/w pellets. Apparatus USP-I (basket), Media: pH-6.8 phosphate Buffer, volume 900 ml per flask Temperature: 37°C±0.5°C velocity: 50RPM Time interval: 1st, 4th, 8th hours. The determination was accomplished by U.V Photo Spectrometer at 275nm. In house limit for dissolution of Aceclofenac in 1st hour 35-45, 4th hour 50-75, 8th hour not less than 80% in phosphate buffer pH 6.8. The proposed method was validated in terms of the accuracy, repeatability, linearity. Linearity was obeyed in the range of 2.5-5mg of Aceclofenac and repeatability (%RSD :< 0.2) was satisfactory. Dissolution and assay studies of Aceclofenac Pellets were calculated by the proposed method and obtained results were good.
Keywords: *Aceclofenac, U.V Photo Spectrometer, Dissolution tester, USP-I.*

1. Introduction
Aceclofenac chemically known as [(2-{2, 6-dichlorophenyl) amino} phenylacetooxyacetic acid], its molecular formula is C16H13Cl2NO4) and its molecular weight is 354.19.It is a crystalline powder, practically insoluble in water with good permeability. It is metabolized in human microsomes and human hepatocytes and form [2-(2', 6'-dichloro-4'-hydroxy- phenyl amino) phenyl] acetoxyacetic acid as the major metabolite and it is further conjugated. As per Biopharmaceutical Classification System (BCS) drug material are classified in to four classes upon their solubility and permeability. Aceclofenac is BCS Class II drug, having poorly solubility and highly permeable.[1] It is under the category of Non-steroidal Anti-inflammatory drugs (NSAID), similar to the diclofenac and mainly used for the controlling of pains and chronic conditions like osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis.The drug blocks the cyclooxygenase (COX) enzyme. This enzyme generates chemical prostaglandins at the injury site and causes pain, swelling and inflammation and fever. The incidence of gastric ulcerogenicity of aceclofenac was reported, it is significantly lower than that of the other frequently prescribed NSAIDs, for example 2-fold less than naproxen, 4-fold less than diclofenac, and 7-fold less than indomethacin.[1]

International Research Journal on Advanced Engineering and Management
https://goldncloudpublications.com
https://doi.org/10.47392/IRJAEM.2025.053
e ISSN: 2584-2854
Volume: 02
Issue:02 February 2025
Page No: 334-338

2. Experiments

Aceclofenac SR60%w/w pellets were formulated by the considering pre formulated study of Aceclofenac API and following excipients. Aceclofenac (API), Sugar 30#40 starch, HPMC-E5, cellos acetate (N-50), Isopropyl alcohol (IPA), Methylene dichloride (MDC), Diethyl acetate. Dissolution activity was the performed by considering the following dissolution parameters and dissolution procedure as follows.

ACECLOFENAC SR60%W/W PELLETS [2-5]

2.1 Dissolution

- **Media:** Phosphate Buffer pH-6.8 900 ml per flask
- **Apparatus:** USP type 1 (Basket)
- **Temperature:** 37°C±0.5°C
- **Velocity:** 50RPM
- **Time:** 1st, 4th, 8th hours

- **Procedure:** Aceclofenac pellets equivalent to 100mg (166 mg of pellets) accurately weighted and transferred in to dissolution apparatus USP-I. Six dissolution vessels contains 6.8 phosphate buffer (900 ml each). Set the dissolution parameters and start the dissolution collect the samples in 1st, 4th, and 8th hour, approximately 15 ml from each flask and filter through what man No1 filter paper. Discord the first 5 ml and transfer 5ml in to 25 ml volumetric flask and make up to volume with phosphate buffer pH 6.8.and used for testing of dissolution profile.
- **Standard Preparation:** Weight accurately about 50.0 mg of Aceclofenac working standard into a 100 ml volumetric flask add 50 ml of methanol dissolve the working standard and make up to the volume with methanol and take the 10 ml of this solution dilute to 50 ml with buffer pH 6.8
- **Blank Buffer:** Determine the light absorption of standard and test samples utilizing the blank at 275nm using suitable U.V Spectro photometer.
- **Calculation:** Dissolution%
- AMT =Absorbance of sample, AST= Absorbance of standard, WTS = weight of standard,

Pmt=Weight of sample, Pot.Std. =Purity of working standard [6-10].

2.2 Determination of Assay

- **Standard Preparation:** 50 mg of Aceclofenac working standard is weighed accurately, put into a 100 ml volumetric flask. Added approximately 50 ml of methanol to dissolve and dilute to volume with methanol. From this solution take 10 ml in to 50 ml volumetric flask make up with methanol and from this take 5 ml dilute to 50 ml with methanol
- **Sample Preparation:** Equal to 50 mg working standard, Aceclofenac pellets transferred to 100 ml volumetric flask, and dissolve, make up with methanol. From this take 10 ml of the solution in to 50 ml volumetric flask make up with methanol. From this take 5ml in to 50 ml volumetric flak, make up with methanol.

Calculation:

- % of Aceclofenac =

$$\frac{AMT}{AST} \times \frac{WTS}{100} \times \frac{10}{50} \times \frac{5}{50} \times \frac{100}{PMT} \times \frac{50}{10} \times \frac{50}{5} \times \text{Pot.Std}$$

- AMT = Absorbance of sample, AST= Absorbance of standard, WTS = weight of standard,
- PMT = weight of sample, Pot.Std. =Purity of working standard.

2.3 Validation of Proposed Method

The proposed method is validated according to ICH Q2 guide lines by considering the parameters Accuracy, precision, linearity, Range, LOD, and LOQ. values are within the limits. Linearity Graph: Linearity of the product in proposed method was observed within the range of 2.5 mg to 5mg. Table 1 shows Linearity Graph.

Table 1 Linearity Graph

Concentration	Absorbance
2.5	0.541
3	0.649
3.5	0.757
4	0.865
4.5	0.973
5	1.082

International Research Journal on Advanced Engineering and Management
https://goldncloudpublications.com
https://doi.org/10.47392/IRJAEM.2025.053
e ISSN: 2584-2854
Volume: 02
Issue:02 February 2025
Page No: 334-338

3. Results

3.1 Dissolution Profile Results

Table 2 Dissolution Profile Results

Bowel	Dissolution Profile in 1st hour 35-45% Average value		Dissolution Profile in 4th hour 50-75% Average value		Dissolution Profile in 8th hour NTL 80% Average		Remarks
	Qualitech Pharma	Innovator Product	Qualitech Pharma	Innovtor product	Qualitch pharma	Innovator product	Limit
1st Bowel	37%	40%	55%	67%	83%	92%	
2nd Bowel	35%	42%	53%	66%	82%	91%	
3rd Bowel	36%	41%	55%	65%	85%	90%	
4th Bowel	35%	43%	54%	64%	84%	93%	
5th Bowel	38%	46%	56%	66%	83%	92%	
6th Bowel	37%	45%	55%	64%	84%	91%	
Average	36.33%	42.8%	54.66%	65.33%	83.5%	91.5%	
RSD value	0.333	0.058	0.0188	0.0185	0.0144	0.0114	<0.2

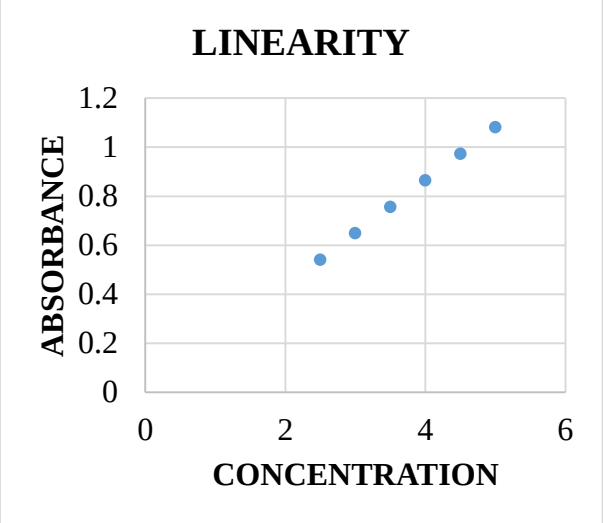

Figure 1 Linearity for RSD for Qualitech Product

Figure 1 Comparison of Innovator product and Qualitech product Dissolution profile in 1st, 4th, 8th Hours.

Table 2 Qualitech Product Dissolution

Qualitech	Innovator
0.033	0.058
0.0188	0.0185
0.0144	0.0114

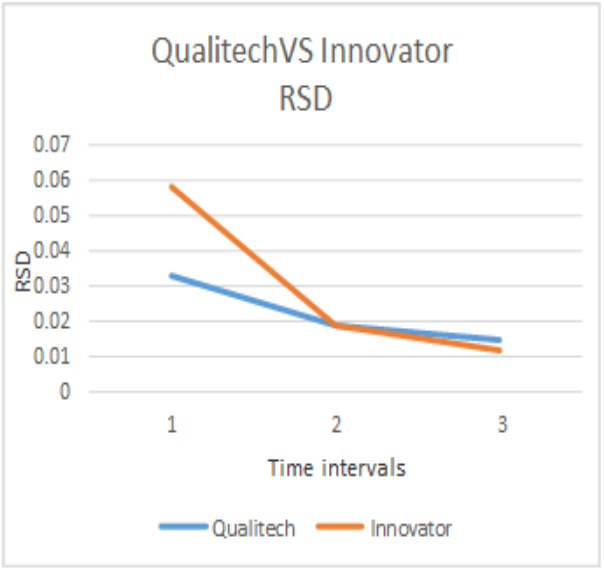

Figure 2 Qualitech VS Innovator

4. Discussion

Aceclofenac SR Pellets 60% w/w were formulated by considering Aceclofenac as active pharmaceutical ingredient and excipients sugar 30# 40, starch, HPMC-E5, cellulose acetate (N-50), Iso propyl alcohol, methylene dichloride, (MDC), Diethyl acetate, Dissolution profile was verified by considering, Aceclofenac SR pellets 60% w/w manufactured by Qualitech pharma and Innovator product, Figure 2.

International Research Journal on Advanced Engineering and Management
https://goldncloudpublications.com
https://doi.org/10.47392/IRJAEM.2025.053
e ISSN: 2584-2854
Volume: 02
Issue:02 February 2025
Page No: 334-338

Table 3 Dissolution Profile & RSD Value

S.no	Dissolution profile		RSD value	
	Innovator Product	Qualitech Products	Innovator Product	Qualitech Products
1st hour	42.8%	36.33%	0.058	0.033
4th hour	65.33%	54.66%	0.0185	0.0188
8th hour	91.5%	83.5%	0.0114	0.0144

Better results were observed for Innovator product compared with Qualitech pharma product. For this analysis proposed analytical method was validated according to ICHQ2 guidelines and obtained analytical results were good and found to be within the limits. Linearity of the product according proposed method is between (2.5 to 5 mg). The proposed formulation and analytical method are useful for the regular manufacturing and analysis of Aceclofenace SR pellets 60%, shown in Table 1 to Table 3.

Acknowledgement

Here with I am submitting research paper entitled U.V. Spectroscopic Method For The Determination Of Dissolution And Assay Of Aceclofenac Sr60%W/W Pellets for publishing in your journal, this work is original, this work is not incorporated and not published any journal, book, magazine
Corresponding Author; Dr. Srinivasarao.Tumati (On behalf of all authors).

Competing Interest: I/We declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

List of Abbreviations

1. USP-II (Paddle): United States pharmacopeia –dissolution type instrument paddle
2. RPM: Rotation per minute
3. U.V Photo Spectrometer: Ultra violet photo spectrometer
4. ICH: International council on harmonization
5. LOD: Limit of detection
6. LOQ: Limit of quantification
7. Mg: milligram
8. RSD: Relative standard deviation
9. A.R grade: Analytical reagent grade
10. API: Active Pharmaceutical ingredient.
11. nm: Nanometers
12. mL: milli liters
13. w/w: weight//weight
14. PPMS: Parts per million
15. SD: Standard deviation.

Funding: I/We declared and conformed that no funding was received for the research work.

References

[1]. James Regun Karmoker, Shuvro Sarkar, Prince Joydhar, Sayeeda Fahmee Chowdhury Comparative in Vitro equivalence evaluation of some Aceclofenac generic tablets marketed in Bangladesh". Pharm. Innov. J. 2016, Vol (5), Page: 3-7.

[2]. "Aceclofenac international" drug.com 2 November 2020 retrieved4 December 2020

[3]. G. Kurmaiah, Srinivasarao.Tumati, P.Govindhachowdary, Ramana reddy. Assay and Dissolution Test Method for the Analysis of Rosuvastatin Drug Dosage Forms-Pellets-15%. Int. J. Inno. Res. Technol. 2024, Vol. (11), Page: 2135-2140.

[4]. Srinivasarao.Tumati, G.Kumaraiah, G.Kalpana, P. Govindha Chowdary. Dissolution test method for the analysis of dissolution profile of the pantoprazole and domperidone blended pellets. J. Basic Sci, 2023, Vol. (23) Page: 545-555.

[5]. G. Kalpana.; G. Kurmaiah, Srinivasarao Tumati; P. Chandrapraprakashrao, Review on U.V. Spectroscopic method development and validation, 2023, Int. J. Res. and Anal. Rev. 2023. Vol. (10). Page: 730-738.

[6]. Venkanna. R; Srinivasarao. Tumati; B.C. K Reddy; Srinivas Rao. Raya Pati. HPLC Method for Determination of Impurity profile in Ibuprofen 200mg and Methocarbamol 500mg caplets. 2018. J. Sci. Res. Rev. Vol. (7). Page: 72-76.

[7]. Venkanna. R; Srinivasarao. Tumati; Revathi. A. Assay determination of Rabeprazole pellets dosage forms by HPLC. 2018, Int. J. Sci. Res. Vol. (7). Page: 792-794.

International Research Journal on Advanced Engineering and Management
https://goldncloudpublications.com
https://doi.org/10.47392/IRJAEM.2025.053
e ISSN: 2584-2854
Volume: 02
Issue:02 February 2025
Page No: 334-338

[8]. "Aceclofenac international". Drugs.com. 2November2020.Retrieved 4 December 2020.
[9]. "List of nationally authorised medicinal products. Active substance: aceclofenac". European Medicines Agency. 26 November 2020. Archived (PDF) from the original on 4 November 2021. Retrieved 31 October 2022.
[10]. Fischer J; Ganellin CR. Analogue-based Drug Discovery. John Wiley & Sons. 2006. Vol (1). p. 517. ISBN: 978-3-527-31257-3.