The Pharma Innovation Journal 2016; 5(9): 110-119

www.ThePharmaJournal.com

The Pharma Innovation

ISSN: 2277- 7695
TPI 2016; 5(9): 110-119

www.thepharmajournal.com
Received: 17-07-2016
Accepted: 18-08-2016

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Preformulation and characterization studies of aceclofenac active ingredient

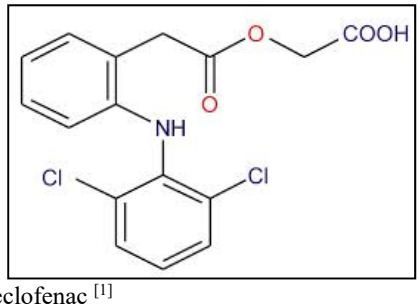
Shivani Kala and Divya Juyal

Abstract
Aceclofenac is a potent analgesic, anti-pyretic and anti-inflammatory agent used in the management of moderate-to-severe pain and in rheumatoid disorder, rheumatoid arthritis and ankylosing spondylitis. Almost all drugs are marketed as tablets, capsules or both. The current aim of the study was to systematically investigate some of the important physicochemical properties of Aceclofenac. Before the development of any dosage form, it is essential to find some fundamental physical and chemical properties of the drug molecule and other divided properties of the drug powder are determined. It helps to decide many of the approaches in formation and development. Thus before selection of excipients, the Preformulation study of any API should be completed for any successful formulation. Preformulation Studies like solubility, pKa, dissolution, melting point, stability in solid state; bulk density, flow properties, were investigated and reported.

Keywords: Aceclofenac, preformulation, anti-inflammatory

Introduction

Drug profile



Chemical Structure of Aceclofenac [1]

Mechanism of action [2]: Aceclofenac is a phenyl acetic acid derivative having potent analgesic and anti-inflammatory properties. Aceclofenac is a novel NSAIDs which exhibit multifactor mechanism of action. It is known for directly blocking PG_2 secretion of the site of inflammatory cells (intracellular action) it is Cox inhibitor.

Adverse drug reaction [2]: dyspepsia, abdominal pain, nausea and diarrhoea other rare side-effects include dizziness, constipation, vomiting, ulcer of mouth and tongue, rash, dermatitis, headache, fatigue.

Drug interaction [2]: The plasma concentrations of lithium, digoxin and methotrexate may increase with Aceclofenac therapy. It may increase the clotting time of anticoagulant drugs and decrease the diuretic drugs effect. Aceclofenac should not be co-administered with other NSAIDs and corticosteroids which may due to chance of incidence of side-effects. Aceclofenac also increase cyclosporine renal toxicity and precipitate convulsion when co-administered with ciprofloxacin, levofloxacin antibiotics.

Therapeutic uses [2]

- Osteoarthritis, Rheumatoid arthritis,
- Low back pain, Dental pain,
- Gynaecological pain,
- Inflammation and pain in conditions of ear, nose & throat infection.

Table 1: provides the list of various characteristics of Aceclofenac

S. No	Property	Explanation
1	Category	Non-Steroidal Anti-inflammatory drug
2	Dose	100 mg, twice daily
3	Chemical name (IUPAC)	[(2, 6, Dichlorophenyl) amino] phenylacetyl oxyacetic acid.
4	Chemical Formula	$C_{16}H_{13}Cl_2NO_4$
5	Molecular weight	354.2
6	Description	Almost white crystalline powder.
7	Solubility	Practically insoluble in water, freely soluble in acetone, soluble in alcohol.
8	pKa value	4.7
9	BCS class	II
10	Half life	4 hr
11	Melting point	149-150 ^{0}C
12	Λmax	275nm
13	Absorption	Rapidly absorbed after oral administration and the bioavailability is about 100% and Peak plasma concentrations (6.8-8.9 mg/L) are reached approximately 1.25 to 3h.
14	Distribution	Highly protein-bound (>99.7%). The volume of distribution is about 25 Liter.
15	Metabolism-	Metabolized by CYP2C9 pathway to the main metabolite 4-hydroxyaceclofenac.
16	Elimination	The mean plasma elimination half-life is 4 – 4.3h, approximately 70-80% of drug excreted by renal route (urine) as glucuronide of aceclofenac and diclofenac and 20% in faeces.

Various characteristics of Aceclofenac [3-4]

Material and Methodology

Procurement of Drug: Drug (Aceclofenac) was obtained as a gift sample from East African Pharmaceuticals ltd, Selaqui, Dehradun

Organoleptic properties

Organoleptic properties of the drug sample were studied by visual inspection.

Melting point determination [5]: Melting point of drug sample was determined by using melting point apparatus. A few quantity of drug sample was taken and placed in a thin walled capillary tube; the tube was approximately 10-12 cm in length with 1mm in diameter and closed at one end. The capillary which contain sample was placed in melting point apparatus and heated and when drug sample was melted the melting point of sample powder was noted.

pH Determination [6]: This was done by shaking a 1% w/v dispersion of the sample in water for 5min and the pH determination using a digital pH meter.

Loss on Drying: Weigh about 1.0g of sample, dry it at 105ºC for 3~4hrs.Cool for 30±5 minutes. It loses not more than 0.5% of its weight. Calculate as following formula:

Loss on Drying %= m1-m2/ m1-m×100%

Where:

m1── the weight of weighing bottle and sample

m2── the weight of sample and weighing bottle after drying

m ── the weight of weighing bottle dried to constant weight

Determination of solubility [7]

a. Qualitative Solubility

Qualitative solubility analysis of drugs were done by dissolving 5 mg of drug in 5 ml of distilled water and different solvents such as HCl (0.1N), Saline phosphate buffer (pH 7.4), Phosphate buffer(pH 6.8), ethanol, acetone and chloroform were used to determine the solubility of drug.

b. Quantitative Solubility

Quantitative solubility analysis of drugs were done by 5 ml each solvent and drug in gm(s) into the solvent till saturation of solvent. Different solvents were used for the solubility determination like distilled water, phosphate buffer (pH 7.4), Phosphate buffer (pH 6.8), HCl (0.1N) and NaOH (0.05N). This is done to determine the capacity of the solvent for dissolving the drug in it. The concentration of drug is measured by UV spectrophotometer

Determination of bulk density, bulkiness and compressibility index [7].

The bulk density of Aceclofenac was determined by the three tap method. 10g of Aceclofenac powder was carefully introduced into a 100 ml graduated cylinder. The cylinder was dropped onto a hard wood surface 50 times from a height of 1inch at an interval of 2 seconds. The bulk density was obtained by dividing the weight of the sample by volume of the sample contained in the cylinder.

Reciprocal of bulk density or the specific bulk volume gave the bulkiness. The percent compressibility index (I) of the aceclofenac was calculated using following formula and the results are given in Table.

$I = (1 - V/V_0) \times 100$

Angle of repose: The static angle of repose was measured a funnel was clamped with its tip 2cm above a graph paper placed on a flat horizontal surface. The powder was carefully poured through the funnel until the apex of the cone thus formed just reached the tip of the funnel. The mean diameters of the base of the powder cones were determined and the tangent of the angle of repose calculated using the equation:

$\tan \theta = h/r$

Partition Coefficient [7]: 10 mg drug was added in 50 ml of n-Octanol (pre saturated with water) and it was shaken and then 50 ml of distilled water (pre saturated with n- Octanol) was added and was shaken the mixture by mechanical shaker for 24 hours. After 24 hour both phases are separated. Absorbance was taken of both the phases and calculated the concentration in each phases

Po/w = Coil/Cwater

Particle Size: Transfer a small portion of the given sample on clean slide and disperse it uniformly and place the slide on the

stage of microscope. Focus the slide in low magnification (10x). Measure the size of each particle in terms of eyepiece divisions, a total of 100 particles should be considered, tabulate the particles in terms of division of eyepiece and no. of particles (frequency) obtained above, classify the diameter into size ranges and average frequency of particles in terms of no. distribution.

Drug Identification Studies

Chemical Identification: Dissolved 10 mg of Aceclofenac in 10 mL of ethanol (95), and to 1 mL of this solution, added 0.2 mL of a mixture of equal volume of a solution of potassium ferricyanide (6 in 1000) and a solution of iron (III) chloride (9 in 1000). Allowed to stand in the dark for 5 minutes, added 3 mL of a solution of hydrochloric acid (10 in 1000), and allowed to stand in the dark for 15 minutes again: A blue color was developed and a precipitate was formed.

FTIR Study

FTIR study of drug sample and identification studies was performed by potassium bromide (KBr) dispersion method (Shimadzu). Samples were prepared with KBr pellets (2 mg sample in 200 mg KBr) with a hydrostatic force of 5.2 N cm^{-2} for 3 minutes. The scanning range was 400 to 4000 cm-1 and the resolution was 4 cm-1.

DSC Analysis- DSC thermograms of Aceclofenac was recorded in a Differential Scanning Calorimeter (Shimadzu, Model no: DSC-60).

UV-visible spectrophotometrically study: Weighed 10 mg of Aceclofenac and dissolved in 10 ml of pH 6.8 phosphate buffer solution (1000µg/ml). From this solution 1ml was taken and diluted to 10ml with PBS to get a solution containing 100µg/ml. From this 1ml was diluted to 10ml to get working standard solutions of 10µg/ml. This solution was scanned between 200-400 nm and an absorption maximum was determined and compared with literature value.

Preparation of calibration curve in phosphate buffer (pH 6.8): Weighed 10 mg of Aceclofenac and dissolved in 10 ml of pH 6.8 phosphate buffer solution (1000µg/ml). From this solution 0.5 ml, 1ml, 2ml, 3ml, 4 ml was taken and diluted up to 100ml using pH 6.8 phosphate buffer solution to obtain a working standard solution of 5- 40 µg/ml. The prepared concentrations were analyzed in UV-Visible spectroscopy at 273 nm.

Linearity and Calibration: The linearity of the calibration curve was estimated by plotting the graph in between absorbance (nm) (y) versus concentration (µg/ml) (x) of Aceclofenac in the concentration range 5-40 µg/ml. A calibration curve was prepared by measure the absorbance at 273 nm. The Statistical evaluation parameter like as the slope, intercept, regression coefficient, standard deviation ($R^{2)}$, and relative standard deviation were determined.

UV Spectrophotometric studies: The absorbance maximum was found to be 273nm in phosphate buffer pH 6.8.

Calibration curve of Aceclofenac in Phosphate Buffer pH 7.4: Spectrophotometric method of USP was used for estimation of Aceclofenac. The method is based on the measurement of absorbance at 276nm in phosphate buffer of pH 7.4.

Stock solution

100 mg Aceclofenac was dissolved in methanol in a 100 ml volumetric flask and the solution was made up to volume with methanol.

Dilutions

Stock solutions of Aceclofenac was subsequently diluted with phosphate buffer of pH 7.4 to obtain a series dilutions containing, 5-40 µg /ml of Aceclofenac solution. The absorption of these solutions was measured in UV-VIS spectrophotometer at 276 nm using phosphate buffer of pH 7.4 as blank.

Preparation of calibration curve in methanol: Weighed amount of Aceclofenac was dissolved in Methanol to obtain a 0.1mg/mL solution. This solution was subjected to scanning between 200-400mm and absorption maximum was determined. No effect of dilution on absorption maxima was detected.

Standard Stock Solution

A stock solution containing 1000mcg/mL of pure drug was prepared by dissolving 50mg of Aceclofenac in sufficient methanol to produce 50mL solution in a volumetric flask. From this solution 5 - 40 µg/ml of dilutions were made. The prepared concentrations were analyzed in UV-Visible spectroscopy at 276 nm

Working standard solution

10mL of the stock solution was further diluted to 100mL with methanol to obtain a working
Standard solution containing 100mcg/mL

Linearity and Calibration

The aliquots working standard solution was diluted serially with sufficient methanol to obtain the concentration range of 5-40 mcg/mL. A calibration curve for Aceclofenac was obtained by measuring the absorbance at the max of 276 nm. Statistical parameters like the slope, Intercept, coefficient of correlation, standard deviation, Relative standard deviation, and error was determined.

Drug Stability Studies [10]

Solid State Stability: the primary objective is to identify the stable storage conditions for API in solid state and identify the possible deterioration of drug on storage conditions the solid state study may be affected by changes in purity and Crystallinity during storage.
Weighed samples (250 mg) were paced in vials and exposed at various condition of temperature, humidity in stability chamber at room temperature, 40±2 ℃ and 75±5% humidity conditions and at refrigerator for upto 12 weeks and were after studied for physical tests in 4^{th}, 8^{th} and 12^{th} week for various Organoleptic and FTIR study.

Photo stability Studies: For photo stability studies drug samples both in solid state form were paced in different containers i.e. pain glass and amber colored glass and kept in sunlight for 12 weeks and were further analysed for Organoleptic studies, FTIR and UV absorbance

Liquid State Stability: the primary objective is to identify the stable storage conditions for API in solution form and identify the possible deterioration of solution form of drug on storage

conditions that may be due to hydrolysis, oxidation etc. Weighed samples (50 mg) were dissolved in phosphate buffer (Ph 6.8) and paced in vials and closed properly and were exposed at room temperature upto 12 weeks and were after studied for physical tests in 4th, 8th and 12th week by UV Spectroscopic study.

Result and Discussions

Organoleptic properties: Organoleptic properties of the drug sample were found to be as given in table below.

Table 2: Organoleptic properties of Aceclofenac

Organoleptic properties	Result
Colour	White powder
Crystallinity	Crystalline in nature
Taste	Slightly bitter in taste
Odour	Odourless

Melting point determination: Melting point of drug was found to be 149 °C, which is well within the range of literature specification, 149-150 °C indicating the identity and purity of drug sample as Aceclofenac.

Table 3: Melting point determination of Aceclofenac

S. No	Melting point (°C)	MEAN ± SD (n=3)
1	149	150±1.15
2	151	
3	149	

pH Determination: The data presented here is for triplicate determinations.

Table 4: pH determination of Aceclofenac

S. No	pH	MEAN ± SD (n=3)
1	7.3	7.13±0.208
2	7.2	
3	6.9	

Loss on Drying: loss on drying of API was found to be 0.03% of its original weight

Determination of solubility

a. **Qualitative Solubility:** Results of qualitative solubility of the drug in different solvents are given below in table

Table 5: Qualitative Solubility of Aceclofenac in various solvents

Solvents (5 ml)	Solubility of the drug (5 mg)
Distilled water	+
0.1 N HCl	+++
6.8 PH Buffer	++
7.4 PH Buffer	+++
Ethanol	+++
Methanol	++
Chloroform	++
Acetone	+

+ Insoluble
++ Poorly soluble
+++ Slightly soluble
++++ Freely soluble

b. Quantitative Solubility

Results of qualitative solubility of the drug in different solvents are given below in table 6

Table 6: Quantitative Solubility of drug in different solvents

Name of Solvent	Concentration of drug in Solvent
Distilled water	55.86 µg/mL, at 37 °C
Phosphate buffer (pH 6.8)	10.34 mg/mL, at 37 °C
Phosphate buffer (pH 7.4)	5.314 mg/mL, at 37 °C
HCl (0.1N)	15.79 µg/mL, at 37 °C
NaOH (0.05N)	1.304 mg/mL, at 37 °C

Determination of bulk density, bulkiness and compressibility index: The data presented here in table 7 is for triplicate determinations.

Table 7: Physicochemical properties of Aceclofenac

S.NO	Name of Test Performed	Result (n=3)
1	True Density (gm/cc)	1.72 ± 0.42
2	Bulk Density (gm/cc)	0.674 ± 0.57
3	Bulkiness	1.484 ± 0.57
4	Compressibility Index (%)	13.85 ± 0.35
5	Angle of Repose (o)	30.16 ± 1.15
6	Partition Coefficient	1.30± 0.35

Partition Coefficient: The partition coefficient shows that the drug is lipophilic in nature.

Particle Size: The results of the Microscopic evaluation for the measurement of particle size of the drug particles are given below

Table 8: Particle size determination of Aceclofenac

SNO	Size Range	Mid-Point (MP)	No of Particles (N)	MP X N	MP X N X LC (d)
1	0 – 1	0.5	5	25	4.75
2	1 – 2	1.5	8	4	22.8
3	2 - 3	2.5	13	32.5	61.75
4	3 – 4	3.5	25	87.5	166.25
5	4 - 5	4.5	23	103.5	196.65
6	5 - 6	5.5	26	143	271.7
		Total	100		723.9

Particle size was found to be 7.24 µm. Particle size distribution pattern depicted in fig. shows that drug particles are distributed in a range of 1-6 µm and maximum number of particles are present in size range of 4-6 µm.

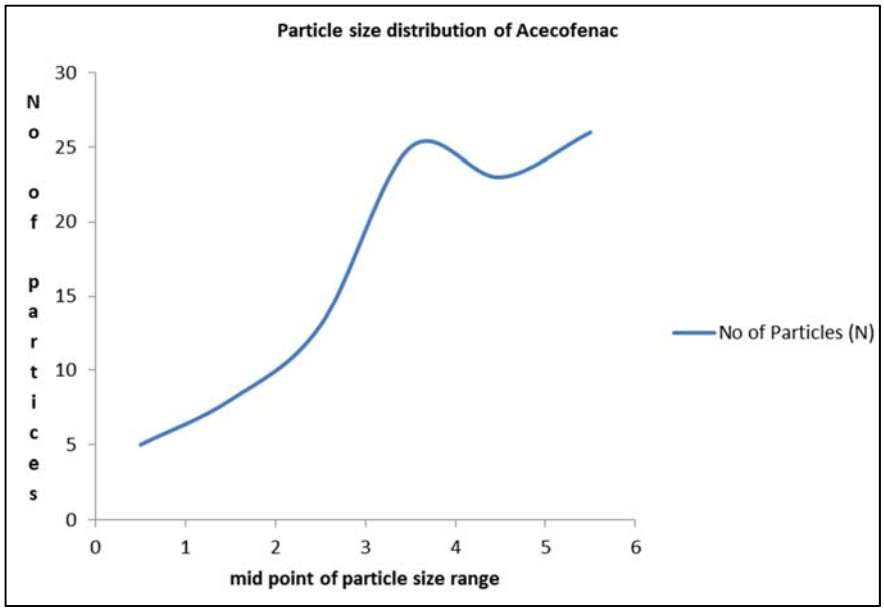


Fig 2: Particle size distribution of Aceclofenac

Drug Identification Studies

FTIR Study

FTIR study of drug sample is shown below with interpretation

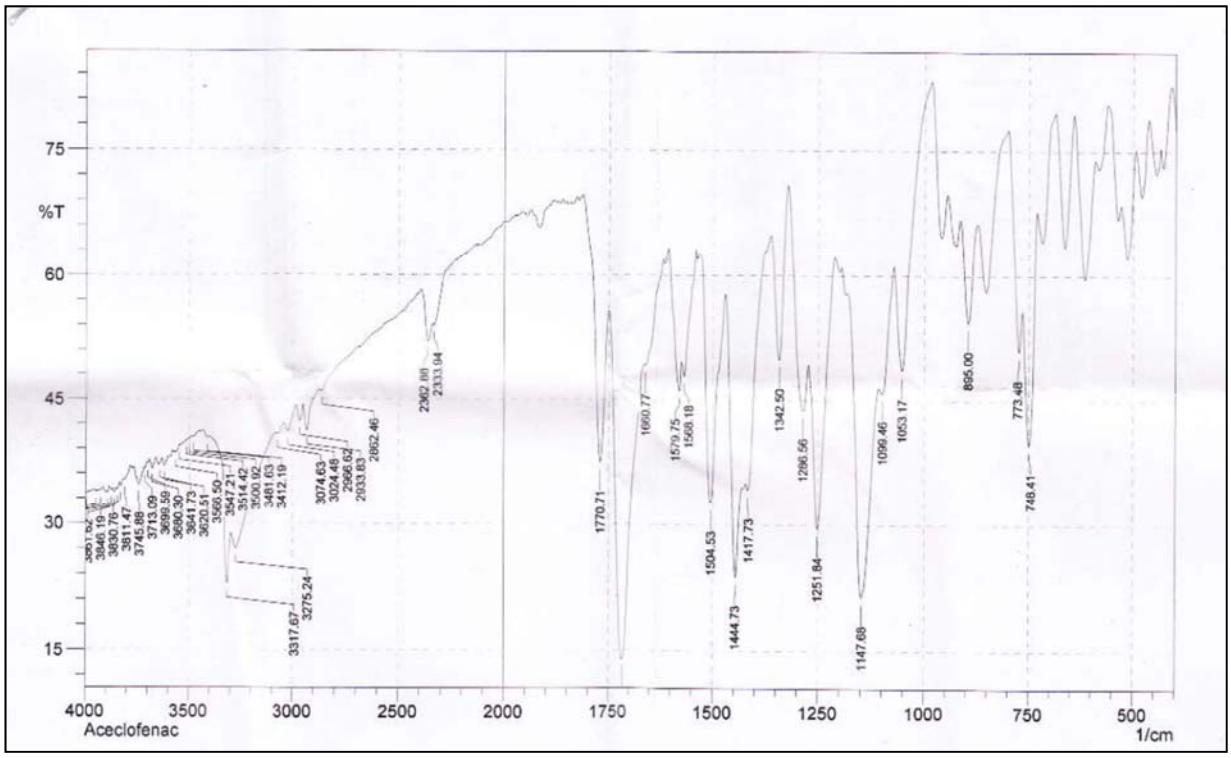


Fig 3: FTIR of Aceclofenac API

Table 9: FTIR characteristic bands of aceclofenac sample

S.NO.	Literature value(cm^{-1})	Observed value(cm^{-1})	Assignments of bands
1.	3400-3250	3317	N-H str.
2.	2963-2669	2862.19	C-H str.
3.	1850-1650	1770.71	C=O str.
4.	1500-1400	1444.73	C-C str.
5.	852-550	773.48	C-Cl str.

DSC Analysis- The thermograms obtained were observed. The thermograms showed endothermic peak at 161.94 ºC.

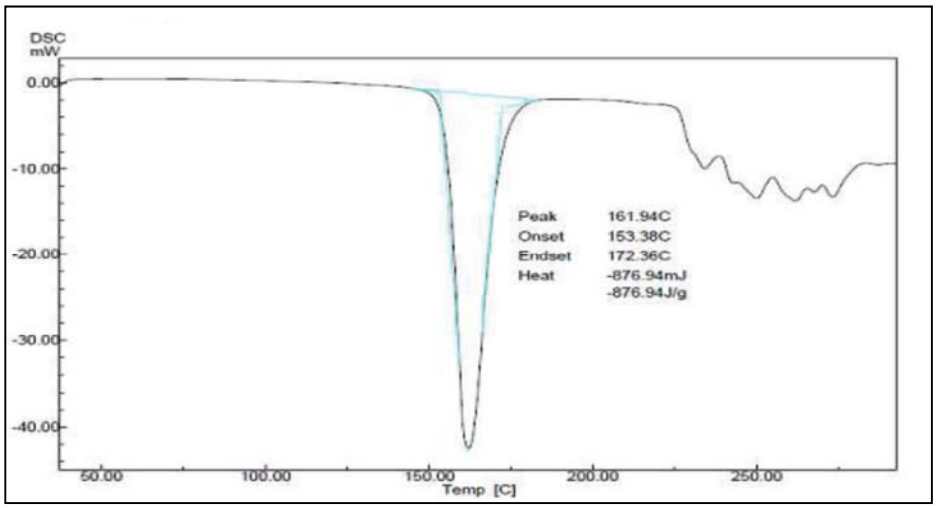


Fig 4: DSC Thermogram of aceclofenac drug sample

UV-visible spectrophotometrically study

Table 10: List of absorption maxima (λmax) value of aceclofenac

Drug Name	Method	λmax(nm)	Linear Range(µg/ml)	Reference
Aceclofenac	UV-Visible Spectrophotometric	275	5-40	I.P[1]
		273	5-40	Segun A. Aderibigbe *et al.*,[8]
		273.2	5-40	Sharma Shivkant *et al.*,[9]

Preparation of calibration curve in phosphate buffer (pH 6.8)-

Linearity and Calibration- The linearity of the calibration curve was estimated by plotting the graph in between absorbance (nm) (y) versus concentration (µg/ml) (x) of Aceclofenac in the concentration range 5-40 µg/ml. A calibration curve was prepared by measure the absorbance at 273 nm. The Statistical evaluation parameter like as the slope, intercept, regression coefficient, standard deviation (R^2), and relative standard deviation were determined.

UV Spectrophotometric studies-The absorbance maximum was found to be 273nm in phosphate buffer pH 6.8.

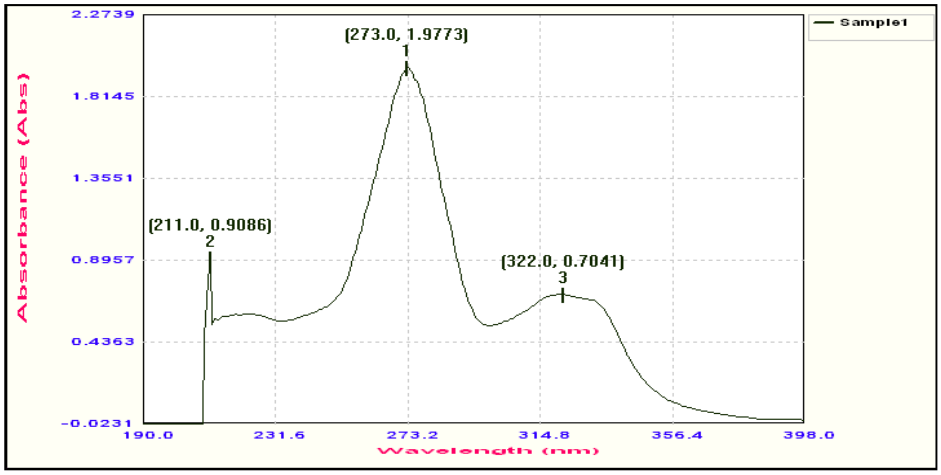


Fig 5: Absorption maxima (λmax) of aceclofenac in phosphate buffer pH 6.8

Table 11: Calibration curve data of aceclofenac in phosphate buffer solution pH 6.8

S. No.	Concentration (µg/ml)	Absorbance (nm)			MEAN ± SD (n=3)
1.	0	0	0	0	0
2.	5	0.125	0.135	0.129	0.130 ±0.005033
3.	10	0.2328	0.2340	0.2332	0.2332 ± 0.0006
4.	20	0.4259	0.4270	0.4264	0.4264 ± 0.0006
5	30	0.6162	0.6178	0.6170	0.6170 ± 0.0008
6.	40	0.8249	0.8263	0.8256	0.8256 ± 0.0007

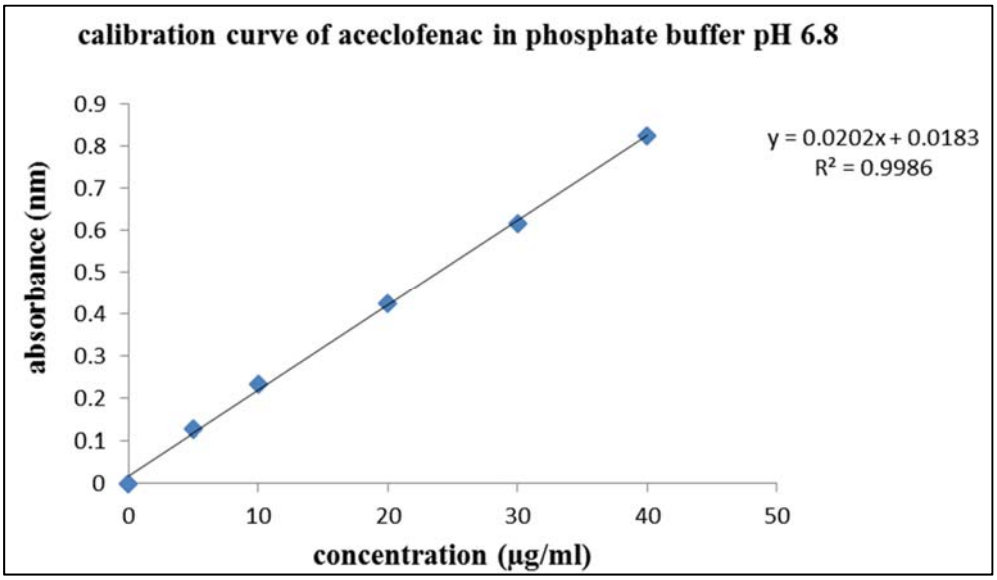


Fig 6: Calibration curve of aceclofenac in phosphate buffer solution pH 6.8

Table 12: Optical characteristics and statistical data of the regression equation

S. No.	Parameters	Value (PBS pH 6.8)	Value (PBS pH 7.4)	Value (Methanol)
1.	Absorption maximum	273(nm)	276(nm)	276(nm)
2.	Beer's law limit	5-40 (µg/ml)	5-40 (µg/ml)	5-40 (µg/ml)
4.	Coefficient of correlation (R^2)	0.998	0.991	0.991
5.	Regression equation	y = 0.020x + 0.018	y = 0.017x + 0.040	y = 0.016x + 0.014
6.	Intercept	0.018	0.017	0.014
7.	Slope	0.020	0.040	0.016

Preparation of Calibration Curves

Estimation of Aceclofenac in Phosphate Buffer pH 7.4: Spectrophotometric method of USP was used for estimation of Aceclofenac. The method is based on the measurement of absorbance at 276nm in phosphate buffer of pH 7.4.

Table 13: Calibration curve of Aceclofenac in Phosphate Buffer pH 7.4

Conc. (µg/ml)	Absorbance (nm)			
	1	2	3	MEAN ± SD (n=3)
5	0.1552	0.1549	0.1542	0.1548 ± 0.000513
10	0.2295	0.2280	0.2289	0.2289 ±0.000458
20	0.4110	0.4088	0.4098	0.4098 ± 0.000569
30	0.5875	0.5880	0.5887	0.5887 ± 0.000656
40	0.7317	0.7297	0.7309	0.7309 ± 0.000802

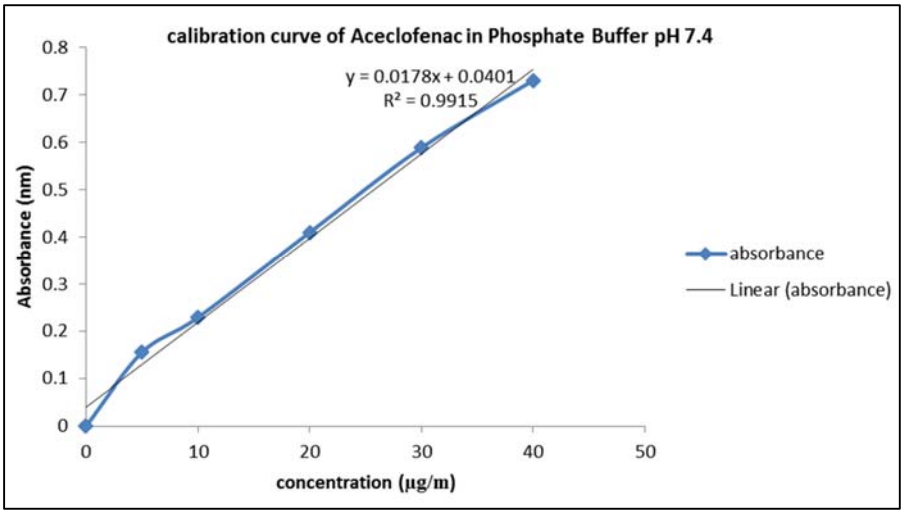


Fig 7: Calibration curve of Aceclofenac in Phosphate Buffer pH 7.4

Preparation of calibration curve in methanol

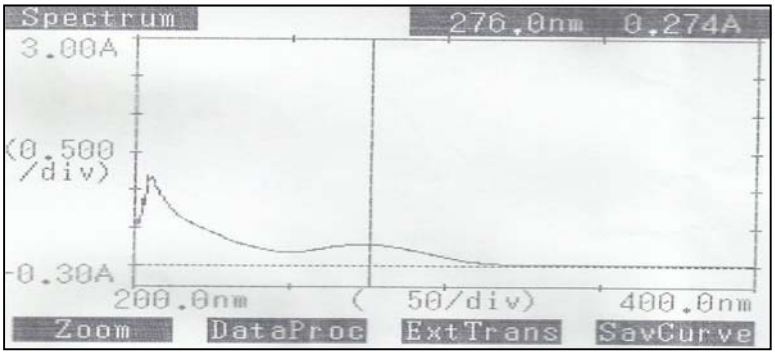


Fig 8: UV Scan of Aceclofenac in methanol

A calibration curve for Aceclofenac was obtained by measuring the absorbance at the max of 276 nm. Statistical parameters like the slope, Intercept, coefficient of correlation, standard deviation, Relative standard deviation, and error was determined.

Table 13: Calibration curve data of aceclofenac in Methanol

S. No.	Concentration (µg/ml)	Absorbance (nm)			MEAN ± SD (n=3)
1.	0	0	0	0	0
2.	5	0.1198	0.1186	0.1175	0.1186 ±0.0012
3.	10	0.2076	0.2066	0.2088	0.2077 ± 0.0011
4.	20	0.3198	0.3178	0.321	0.3195 ± 0.0006
5	30	0.5087	0.5076	0.5076	0.5080 ± 0.0016
6.	40	0.7089	0.7075	0.7095	0.7086 ± 0.0010

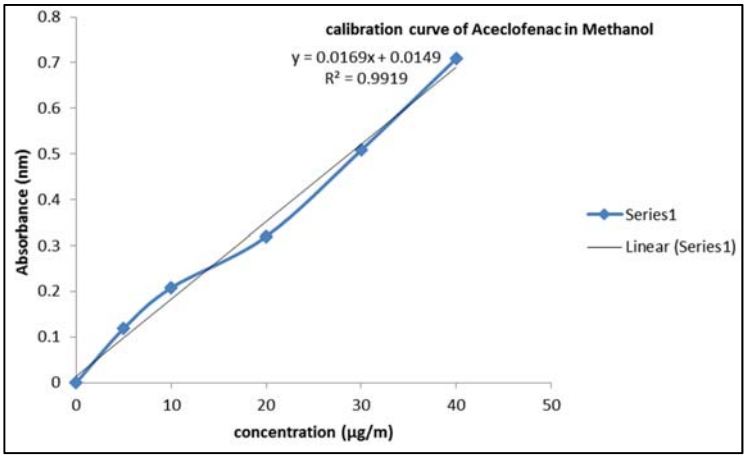


Fig 9: Calibration curve data of aceclofenac in Methanol

Drug Stability Studies

Solid State Stability: The primary objective is to identify the stable storage conditions for API in solid state and identify the possible deterioration of drug on storage conditions the solid state study may be affected by changes in purity and Crystallinity during storage by various Organoleptic and FTIR study.

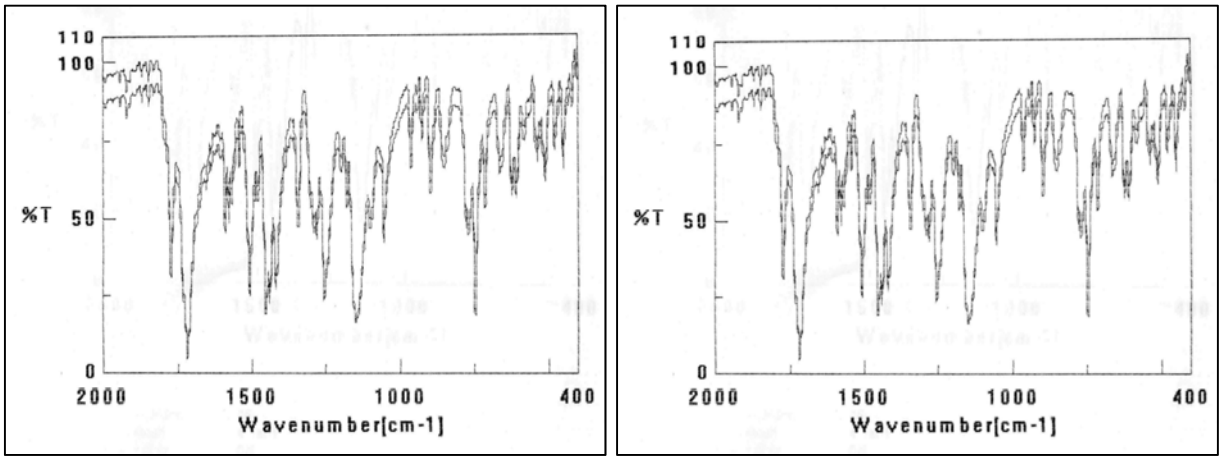
Photo stability Studies: For photo stability studies drug samples were further analysed for Organoleptic studies, FTIR and UV absorbance

Test Results for Accelerated Stability Study

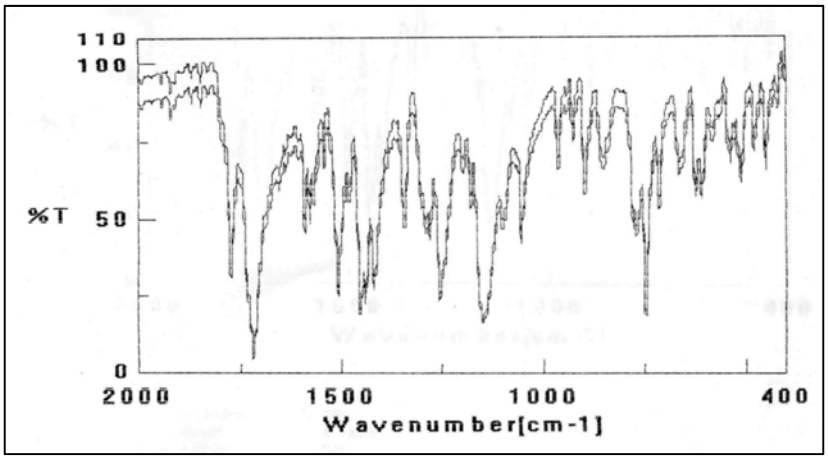
Storage condition: Temperature 40±2 ℃, RH 75±5%

Package condition: Two layers PE bags

S. no		4 weeks	8 weeks	12 weeks
1	Organoleptic Properties			
	Colour	White powder	White powder	White powder
	Taste	Slightly bitter in taste	Slightly bitter in taste	Slightly bitter in taste
	Odour	Odourless	Odourless	Odourless
2	Chemical Identification	A blue color was developed and a precipitate was formed.	A blue color was developed and a precipitate was formed.	A blue color was developed and a precipitate was formed.
3	Melting Point	149 ºC	150 ºC	149ºC
4	FTIR	Complies	Complies	Complies



4 weeks **8 weeks**



12 weeks

Fig: Test Results for Solid state Accelerated Stability Study

Test Results for Accelerated Stability Study Package condition: Two layers PE bags
Storage condition: Room Temperature

S. No		4 weeks	8 weeks	12 weeks
1	Organoleptic Properties			
	Colour	White powder	White powder	White powder
	Taste	Slightly bitter in taste	Slightly bitter in taste	Slightly bitter in taste
	Odour	Odourless	Odourless	Odourless
2	Chemical Identification	A blue color was developed and a precipitate was formed.	A blue color was developed and a precipitate was formed.	A blue color was developed and a precipitate was formed.
3	Melting Point	148 ºC	151 ºC	149ºC
4	FTIR	Complies	Complies	Complies

Test Results for Accelerated Stability Study Package condition: Two layers PE bags
Storage condition: Refrigerator

S. No		4 weeks	8 weeks	12 weeks
1	Organoleptic Properties			
	Colour	White powder	White powder	White powder
	Taste	Slightly bitter in taste	Slightly bitter in taste	Slightly bitter in taste
	Odour	Odourless	Odourless	Odourless
2	Chemical Identification	A blue color was developed and a precipitate was formed.	A blue color was developed and a precipitate was formed.	A blue color was developed and a precipitate was formed.
3	Melting Point	148 ºC	151 ºC	149ºC
4	FTIR	Complies	Complies	Complies

Liquid State Stability: the primary objective is to identify the stable storage conditions for API in solution form and identify the possible deterioration of solution form of drug on storage conditions by UV Spectroscopic study.

Test Results for Accelerated Stability Study **Package condition:** Two layers PE bags
Storage condition: Room Temperature

S. No		4 weeks	8 weeks	12 weeks
1	Organoleptic Properties			
	Colour of solution	Transparent	Transparent	Transparent
	Visual appearance	No visual change	No visual change	No visual change
	Microbial growth	None	None	None
	Odour	Odourless	Odourless	Odourless
2	Absorbance at UV	Λmax at 274 nm	Λmax at 275 nm	Λmax at 274 nm

Conclusion

The current aim of the work was to perform various characteristic Preformulation test for Aceclofenac API and it was found that the API had variable solubility and other properties that could be used for incorporating it in various dosage forms including oral, dermal and Parenteral route of administration the drug was also found to be stable at various conditions

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