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DESIGN AND CHARACTERIZATION OF ACECLOFENAC BIONANOCOMPOSITE USING NATURAL SOLUBILIZERS

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Keywords:

Bionanocomposite, BCS class II, Aceclofenac, Microwave-Assisted fusion method and natural carriers

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ABSTRACT: The objective of the present research is to enhance the solubility and improve the rate of dissolution of poorly water soluble drug aceclofenac, which belongs to BCS class II. Enhancement of solubility was be achieved by converting the poorly water-soluble drugs into Bionanocomposites (BNCs) by using natural carriers, which ultimately leads to enhance the bioavailability of drug entities. Bionanocomposites (BNCs) were prepared using the microwave-assisted synthesis fusion method, where the drug entities were fused with natural carriers such as *Acacia arabica* and gond katira. Selection of carriers was done based on their wetting and surfactant properties. The FTIR, DSC studies reveal that there was no any interaction between aceclofenac and Natural carriers. Solubility dissolution studies were carried out to investigate the solubility-enhancing property of the BNCs. *In-vitro* dissolution studies of prepared aceclofenac's BNCs were characterized through DSC, SEM, XRD and FTIR. Both the gum were shown less % of swelling index, viscosity and foaming index. From the study, it was found that the developed ten batches of BNCs among which aceclofenac: *Acacia arabica* (1:4) ratio shown highest acceptable solubility *i.e.* 5.38 mg/ml and % drug release 97.22±1.1 % as compared to aceclofenac: gond katira (1:3) ratio shown acceptable solubility *i.e.* 4.72 mg/ml with drug release of 85.54%.BNCs of aceclofenac prepared with *Acacia arabica* provides significant enhancement insolubility and highlights its use in solubility and dissolution enhancement as compared to gond katira.

INTRODUCTION: Almost 40% of newer chemical entities having problems of poor water solubility and bioavailability. In the formulation and development of new dosage forms, the solubility of drug has a critical role to play.

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Low water solubility adversely affects the utilization of drug molecules and many of moieties show low absorption and poor bioavailability along adverse effects due to its low water solubility. Solubility improvement drastically improves absorption, which increases bioavailability and reduces side effects. Drug to show therapeutic response it requires adequate concentration at plasma which is achieved by a larger dose. These drugs require a high dose to attain desired plasma concentration. Aqueous form preferred at the site for oral administration [1].

As per BCS classifications and Literature survey reported that the aceclofenac was the drug that belongs to BCS-II drug which has low aqueous solubility and due to this it has poor absorption rate thus these affects their desired plasma drug concentration of a drug. Aceclofenac belong to BCS-II it has very poor water solubility and poor drug absorption it ultimately affects their desired activity [2]. Nanocomposite is a combination of two or more different materials with different properties of each and that are fused by an effort to blend the best properties of both. A composite consists of two materials of varying natures, and a combination of those shows improved in their properties greater than that of an individual. A physical mixture of drug and Natural or bio carrier in the composite by nanotechnology and their evaluating parameters as drug release profile by *in-vivo* and *in-vitro* and bioavailability in the biological system hence termed Bionanocomposite [3]. Bionanocomposite is prepared using the poorly soluble drug and a natural polymer by microwave-induced diffusion technology, resulting in complex properties of both components and accomplishing the required parameters of solubility and dissolution. This helps in overcoming the issues of solubility and dissolution [4]. The use of natural carriers in the formulation of bionanocomposite is to achieve the desired system for the dissolution enhancement of a drug that is poorly water-soluble. Some natural carriers have high viscosity property and they show limitations in their application as carrier in dissolution enhancement [5]. The objective of present investigation is to design, characterize the structural requirement for making a compound hydrophilic nature to develop bionanocomposite of aceclo-feanc. In current research work, bionanocomposites prove and competent alternative which improves therapeutic effectiveness with improved solubility in nanocrystal formulation, which drastically removes defects of current formulations.

MATERIALS AND METHODS:

Materials: Aceclofenac – Kindly gifted by Lupin Research Park Pvt. Limited Pune, *Accacia arabica* and Gond katira, and Double distilled water procured from Unique Chemicals Kolhapur, Chloroform, Ethanol, and Methanol produced from Lobachem Pvt. Ltd. Mumbai. All chemicals and reagents used in the present research work were of analytical grade.

Extraction and Purification of Natural Gums: Both the gum *viz*. *Acacia arabicaa and Gond Katira* gum respectively were dried on ground under sunlight. Dried gum was passed through Sieve No. 80. Dried gum (10gm) was added in distilled water stirred for six to eight hours; supernant was collected by centrifugation method. Supernant was precipitated by with help of acetone and dried in rotary evaporator under vacuum.[6]

Preparation of Physical mixtures (PMs): A physical mixture (PMs) of Aceclofenac with carriers of natural origin were prepared blending of Aceclofenac with natural polymers in the ratio (*i.e.*, 1:01 to 1:09 Aceclofenac: carriers) for 10 min [7].

Formulation of Bionanocomposites: Formulation of Bionanocomposite (BNCs) in two Batches such as Aceclofenac with *Acacia arabica* Gum (AFAANC), Aceclofenac with *Gond katira* Gum (AFGKNC). Aceclofenac and carrier of natural origin were mixed homogenously by mixing for each sample. Aceclofenac and carriers taken as mentioned in **Table 1**. In each formulation constant amount of water 4 ml incorporated to produce a homogeneous slurry of the Aceclofenac–carrier mixture. 5 gram of slurry kept in microwave irradiation various times at 560 volts. Using mortar and pestle, prepared samples were grounded finely and sieved to get the desired size for the preparation of bionanocomposites [8] **Table 1**.

TABLE 1: FORMULATION TABLE FOR BIONANOCOMPOSITES BATCHES

Aceclofenac + Carrier	1:1	1:2	1:3	1:4	1:5	1:6	1:7	1:8	1:9	1:10
AF-AA Gum	1:1	1:2	1:3	1:4	1:5	1:6	1:7	1:8	1:9	1:10
AF-GK Gum	1:1	1:2	1:3	1:4	1:5	1:6	1:7	1:8	1:9	1:10

*AF- Aceclofenac, AA-Acacia Arabica Gum, GK-Gond Katira Gum

Evaluation of Pure Aceclofenac:

Solubility Determination: Solubility of ACF was performed by dissolving a large amount of pure Aceclofenac to 150 ml distilled water. The mixture was stirred for 24 h at 25°C temperature by using an orbital shaker incubator. Supernatant passed

through 0.2 µ membrane filters and analyzed by UV-Visible spectrophotometer at 274 nm wave-length respectively [9].

FTIR Studies: The identification of Aceclofenac performed by FT-IR Spectroscopy. The FT- IR spectrum was achieved by a spectrophotometer (Agilent Corp., Germany). The wavelength of rang from 400 to 4000 cm^{-1} was used. Characteristic peaks of the Aceclofenac, Acacia Arabica, and Gond Katira gum were also compared with the formulated BNCs to check the inter-reaction of Aceclofenac [10].

Characterization of Natural Gum Carriers: Viscosity is determined by Brookfield viscometer; density was measured using settling apparatus; angle of repose and Loss on drying, total ash, insoluble matter, PH and solubility calculated by the standard Pharmacopoeial Procedure *i.e.,* Indian Pharmacopoeia1985. [11]

Solubility of Gum: Acacia Arabica gum and Gond Katira gum forms a viscous solution in water due to its solubility. Practically these are insoluble in alcohol, acetone, and ether [12].

Angle of Repose: The powder was poured in to funnel and allow to flow freely on the surface. The heap diameter was measured further used to measure it by using the following formula.

$$\theta = \tan^{-1} H/R$$

Bulk Density: Calculated by pouring the powder into the cylinder the volume of bulk (Vb) and weight (M) was measured fused to calculate bulk density using following formula.

$$B.D. = M/Vb$$

Tapped Density: Cylinder with powder tapped for fix time volume lowest in the cylinder (Vt) and M weight of blend was determined. Tapped density was calculated by using formula *i.e.*

$$T.D. = M/Vt$$

Compressibility Index (CI): CI determines the flow of free powder, which determines powder flow from hopper into die cavity during the compression in manufacturing of tablet dosage form.CI can be calculated by formula [13]

$$CI = (T.D\text{-}B.D/T.D) \times 100$$

CI value >15% good whereas above 25% indicate poor flowability of powder.

Evaluation of Prepared BNCS:

Drug Content Analysis: The amount of Aceclofenac incorporated into the BNCs such as AFAA and AFGK were identified by extracting Aceclofenac from Bionanocomposite into adequate 25 ml methanol. The solution was filtered by 0.2µ membrane filter and determined by a UV-Visible spectrophotometer (UV- Carry 60, Agilent) at the wavelength of 274 nm. [14]

Solubility Study: Solubility of AFAANC and AFGKNC was performed by dissolving a large amount of pure Aceclofenac and BNCs to 150 ml distilled water. The mixture was stirred for 24 h at 25 °C temperature by using orbital shaker incubator. Supernatant passed through 0.2 µ membrane filters and analyzed by UV-Visible spectrophotometer at 274 nm wavelength respectively. The ratio optimization (Aceclofenac: carrier) was performed by best solubility observed.

Characterization of Bionanocomposites:

Fourier-Transform Infrared Spectroscopy (FT-IR): FTIR of Aceclofenac, Acacia Arabica, and Gond Katira gum and BNCs of Aceclofenacs with the individual (Acacia Arabica and Gond Katira gum) was performed to check compatibility. BNCs of Aceclofenac with each polymer homogeneously added with KBr in the ratio of 1:100. Samples scanned using FT-IR Spectrophotometer (Agilent Corp., Germany). They were scanned through a range from 400 to 4000 cm^{-1}. Characteristic peaks of the Aceclofenacs, Acacia Arabica, and Gond Katira gum compared to BNCs to conform compatibility of Aceclofenac-polymer [15].

Differential Scanning Calorimetry (DSC): DSC of Aceclofenac, Acacia Arabica, and Gond Katira gum and BNCs of Aceclofenac with an individual (Acacia Arabica and Gond Katira gum) were performed to check improved solubility of Aceclofenac. DSC thermos-gram was obtained using DSC (DSC 60; Shimadzu) at a heating rate of 11°C/min from temperature 0 °C to 250 °C in inert condition. The DSC gives information related to melting point and polymer, which helps determine

and predict the solubility of BNCs by Hansen Solubility Parameter [16].

X-Ray Diffraction Studies (XRD): XRD of Aceclofenac, pure polymers (*Acacia arabica* and Gond Katira gum), and BNCs of Aceclofenac with individual polymers (*Acacia arabica* and Gond Katiragum) were checked to know modification in the crystalline nature after mixing and converting into the BNCs. The XRD patterns of the Aceclofenac, polymers, and BNCs were recorded using (Bruker, D8) and Cu-kα radiation. The scanning angle ranged from 1° to 42° of 3θ.[17]

Particle Size Determination: The particle size of the Aceclofenac bionanocomposites was measured by (Malvern Zetasizer Ver. 7.11 UK). PDI of the bioonanocomposites particles was determined through particle size analysis with a wet sampling system [18].

Surface Morphology (SEM): Morphology surface of Aceclofenac and BNCs performed by surface morphology by SEM. SEM sample holder holds the sample for surface morphology was recorded at the desired magnification at acceleration voltage 15 kV and at distance of 08 mm on XL30-SFEG Philips (Lab exchange, Germany) [19].

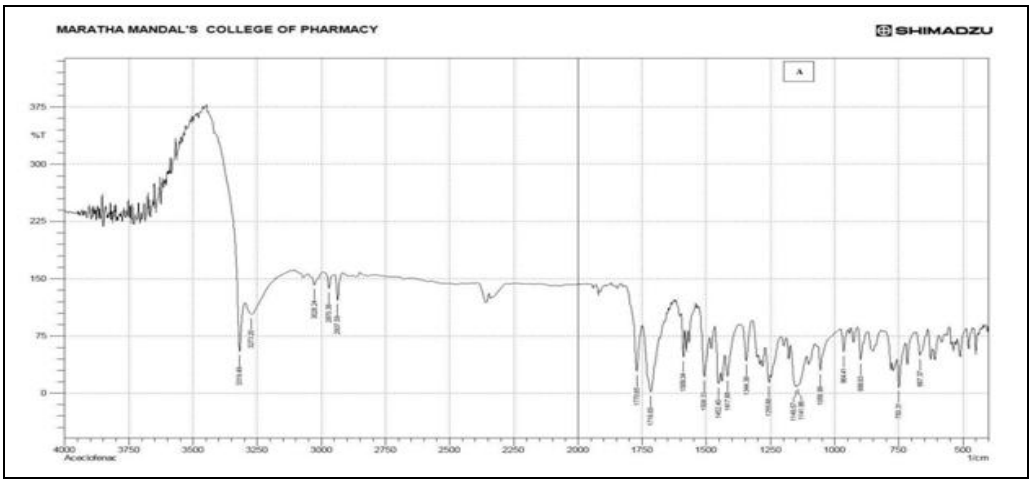
RESULTS AND DISCUSSION:

Physical Characterization of *Acacia arabica* and Gond Katira: By using Rheometer R/S-CPS+ Rheometer (7030107) with the Measuring system: C75- 2 the viscosity and thixotropic analysis was carried out. From the study, it was found that *Acacia arabica* has lesser viscosity as compared to Gond Katira. Hence, both the gum (Polymer) revels the stability and helps in enhancement of solubility for optimization poorly water soluble drugs by preparing its Bionanocomposite and can withstand in microwave radiation. Viscosity of *Acacia arabica* and Gond Katira Gum was found to be 0.5740± 0.085 and 1.5442±0.145 Pascal respectively.

Organoleptic and Physical Characterization of Gum: % swelling and foaming index were represented in **Table 2**. The swelling property and viscosity of Gond Katira and Acacia Arabica gum was low. Due to the less viscosity of Gond Katira and *Acacia arabica* gum, they were considered for solubility and dissolution enhancement of selected BCS class-II drugs. Hence both the gums were more suitable and conveniently useful for the enhancement of solubility and dissolution rate of aceclofenac.

TABLE 2: ORGANOLEPTIC AND PHYSICAL CHARACTERIZATION OF NATURAL GUM

S. no.	Parameters/ Particulars	Acacia Arabica	Gond Katira
1	Swelling Index	18.3 ± 1.21	21.5 ± 1.3
2	Foaming index	19 ± 2.4	15 ± 1.6
	* All values are represented as means ± SD, n = 3.		
3	Angle of Repose	36°	30°
4	Bulk density (gm/ml)	0.76gm/ml	0.63gm/ml
5	Tapped density (gm/ml)	1.21gm/ml	1.26gm/ml
6	Compressibility index (%)	45.22%	53.51%
7	Swelling Index (ml/gm)	19.7	20.3
8	pH	5.5	6.5



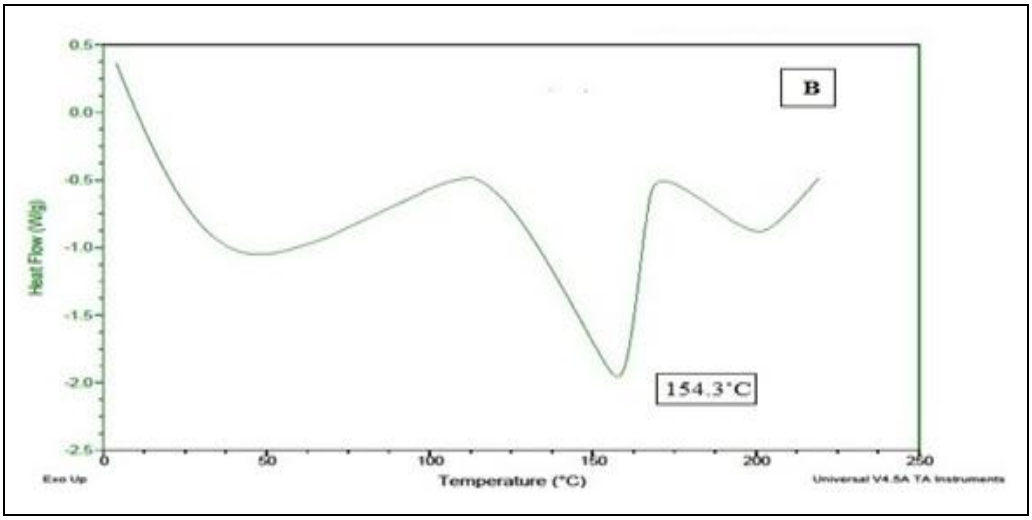


FIG. 1: PURE ACECLOFENAC A) FTIR B) DSC

Compatability Study: Aceclofenac sample was analyzed by infrared spectroscopy for knowing purity and to characterize the probable structural modification of the drug sample. Principle peak N-H str.- 3319.49, C-H str.- 2937.59, C=O str.- 1716.65, C-C str.- 1452.40, C-Cl str.-750.31. **Fig. 1A** Principle peaks were found in the range corresponding to a functional group of standard drug. Appearance of the principal peak in spectrum confirmed that the tested sample was Aceclofenac.

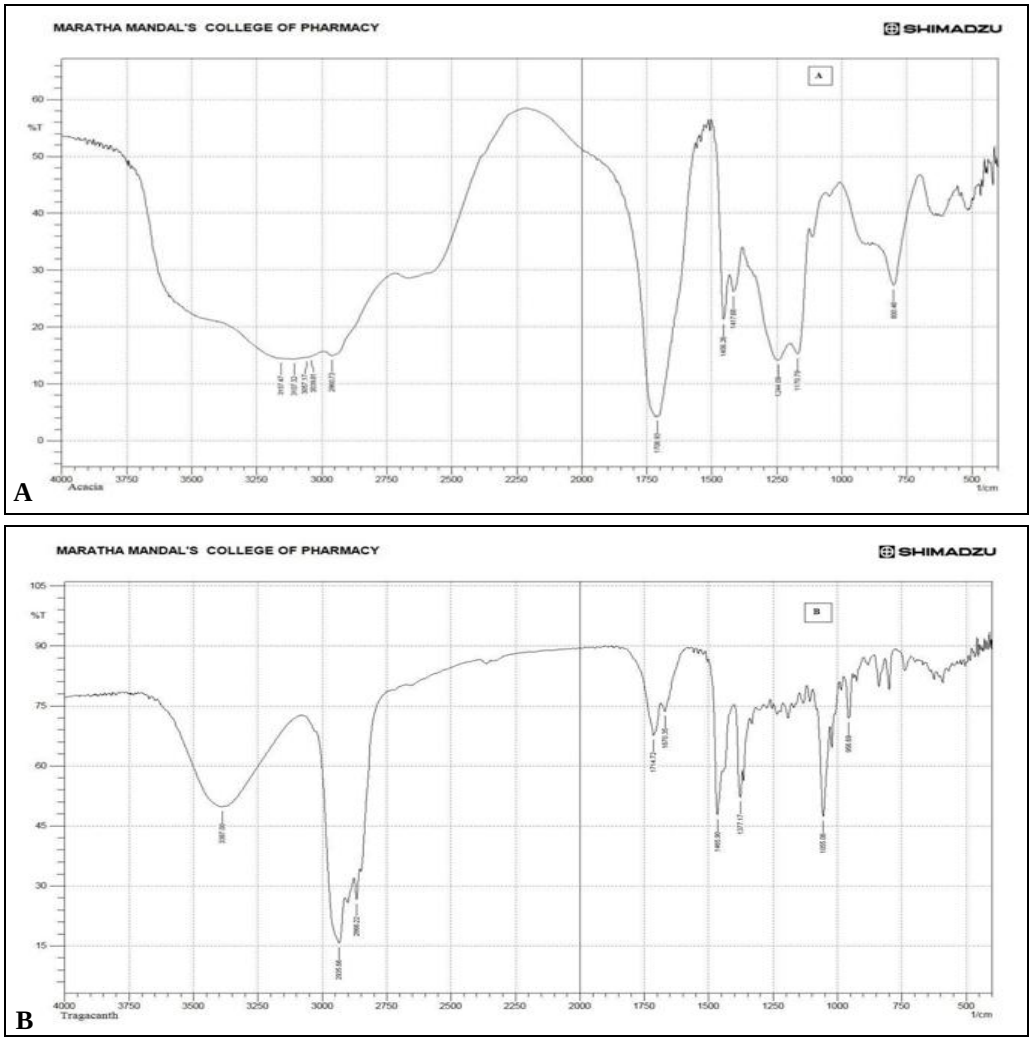


FIG. 2: FTIR SPECTRA OF PURE A) ACACIA ARABICA B) GOND KATIRA

FTIR of *Acacia arabica* and Gond Katira: *Acacia arabica* and Gond katira was analyzed by infrared spectroscopy for knowing purity and to characterize the probable structural modification. *Acacia arabica* shows Principle peak at O-H str. -3157.47, 3107.32, C-H str.- 2960.73, C=O str.-1708.93, C-H Deformation-1244.09, C-O Str. Ether-1170.79, C-H-640.38 **Fig. 2A** and Gond katira shows Principle peak at C-H str.- 2935.66, Glycopyranose str. belongs to galactose and mannose-1670.35, C-O 1055.06 **Fig. 2B**. Principle peaks were found in the range corresponding to the functional group of standard drugs. The appearance of the principle peak in spectrum confirmed that the tested sample was *Acacia arabica* and Gond katira respectively.

FTIR of AFAANC and AFGKNC Bionano Composite: Further, study after the BNCs formulation by FTIR spectrum all the peaks showed in the pure Aceclofenac was unchanged in the FT-IR spectra of AFAANC and AFGKNC. It indicates that there is no chemical reaction between aceclofenac and polymer after microwave irradiation of Aceclofenac. AFAANC shows characteristic peaks at N-H str.- 3318.28,. C-H str.-2888.01, C=O str.-1715.72, C-C str.-1451.91, C-Cl str.-748.33 and OH Str at 3387.00 **Fig. 3A**. AFGKNC shows characteristic peaks at N-H str.-3318.52,. C-H str.-2880.58, C=O str.-1716.09, C-C str.-1452.01, C-Cl str.-715.72 **Fig. 3B**.

Overlain of FT-IR spectrums of pure aceclofenac and *Acacia arabica*, Gond katira, AFAANC, and AFGKNC formulation of shown in **Fig. 3**. It revealed that the fundamental peaks of the aceclofenac are retained in the formulation. Results showed that there exists no chemical interaction between aceclofenac and excipients used in the formulation.

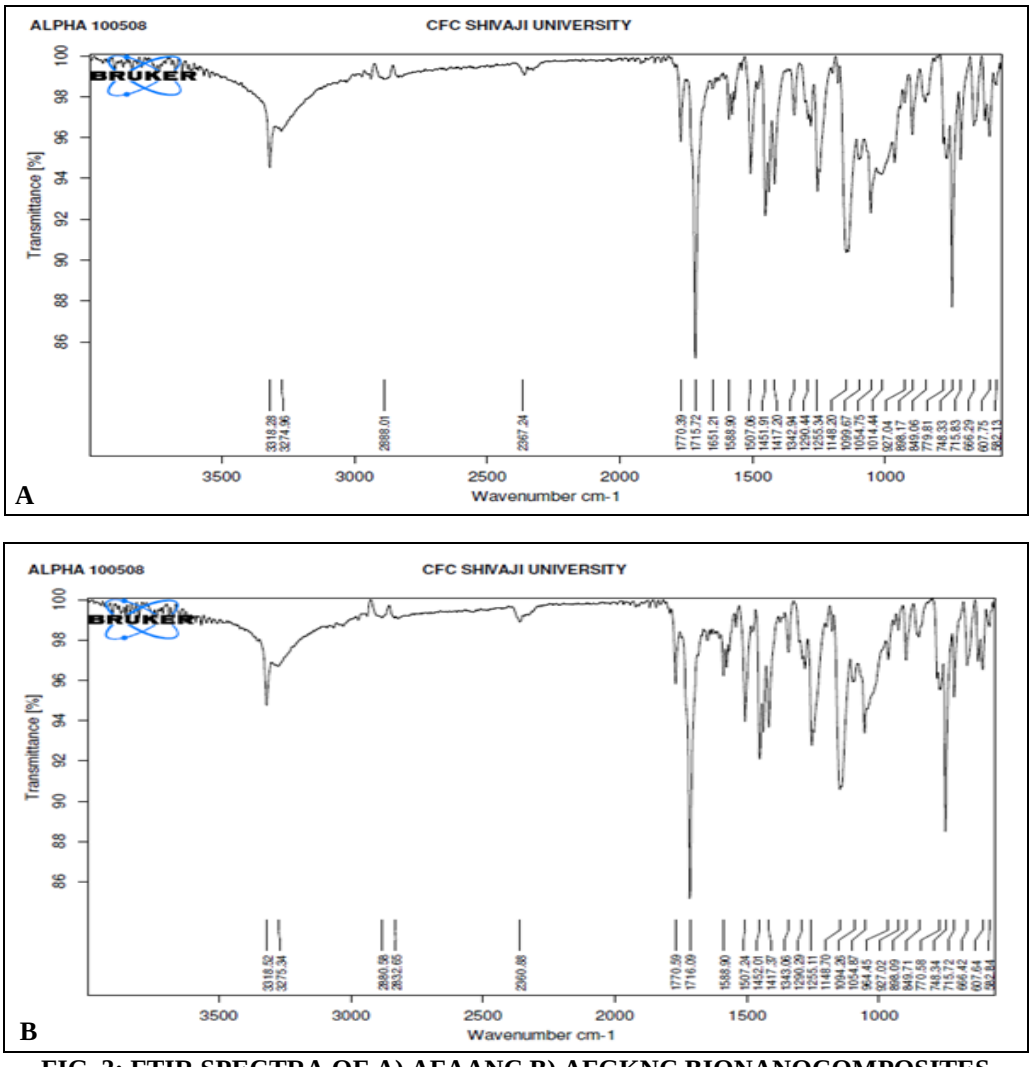


FIG. 3: FTIR SPECTRA OF A) AFAANC B) AFGKNC BIONANOCOMPOSITES

DSC of Aceclofenac: DSC gives information about transition temperature. By comparing DSC spectra of aceclofenac showed that the exothermic and endothermic melting temperatures for extract were 112.6°C and 154.3°C, respectively **Fig. 1B**. By comparing DSC spectra of aceclofenac, AFAANC and AFGKNC Bionanocomposites for possible interactions are studied. The results of DSC analysis showed that the exothermic melting temperature for aceclofenac 154.3°C **Fig. 1B**. The integrity of the aceclofenac was remained unaffected after formulation into bionanocomposite, this is confirmed by DSC of formulation where the composite melting peaks of AFAANC were found to be at 152.82 °C and 245.24°C **Fig. 4A** and DSC of formulation where the composite melting peaks of AFGKNC were found to be at 152.47°C and 232.74°C **Fig. 4B** indicating compatibility between aceclofenac and *Acacia arabica*, gond katira, and processing conditions. The details of DSC thermograms are shown in **Fig. 4**.

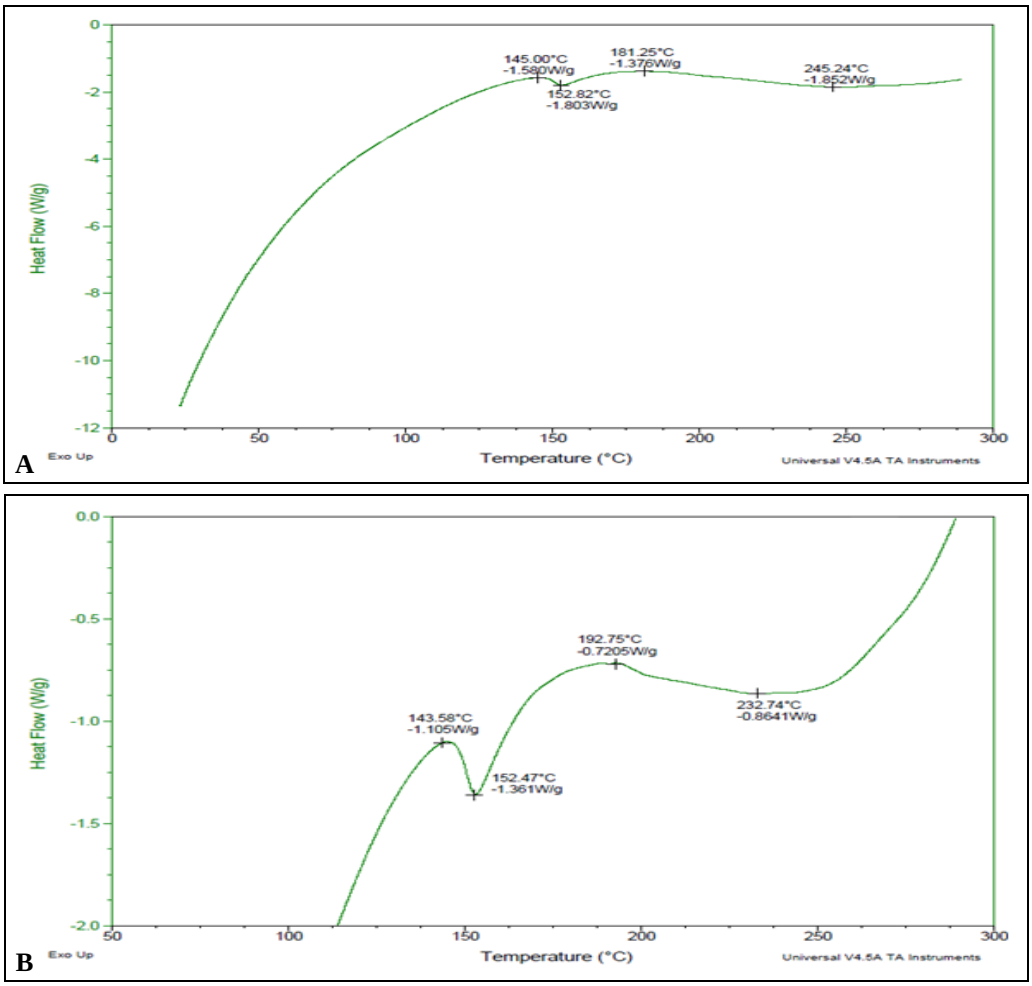


FIG. 4: DSC THERMOGARM OF A) AFAANC B) AFGKNC BIONANOCOMPOSITES

XRD Study: PXRD analysis gives information about the crystallographic structure and composition of materials.

XRD was performed to check the physical state of aceclofenac and its BNCs. XRD pattern of pure drug aceclofenac and its bionanocomposites AFAANC and AFGKNC were shown in the following **Fig. 5**. The XRD pattern of pure Aceclofenac showed a crystalline peak. It demonstrated characteristic diffraction peaks indicating crystalline nature of Aceclofenac **Fig. 5A**. XRD pattern of AFAANC and AFGKNC showed reduced peak intensity due to decreased crystallinity.

Reduced peak intensity of bionanocomposites might be due to reduction in the drug size and converted in to amorphous form .It revealed that there is no such interaction was observed. Results were shown in **Fig. 5B** and **5C**.

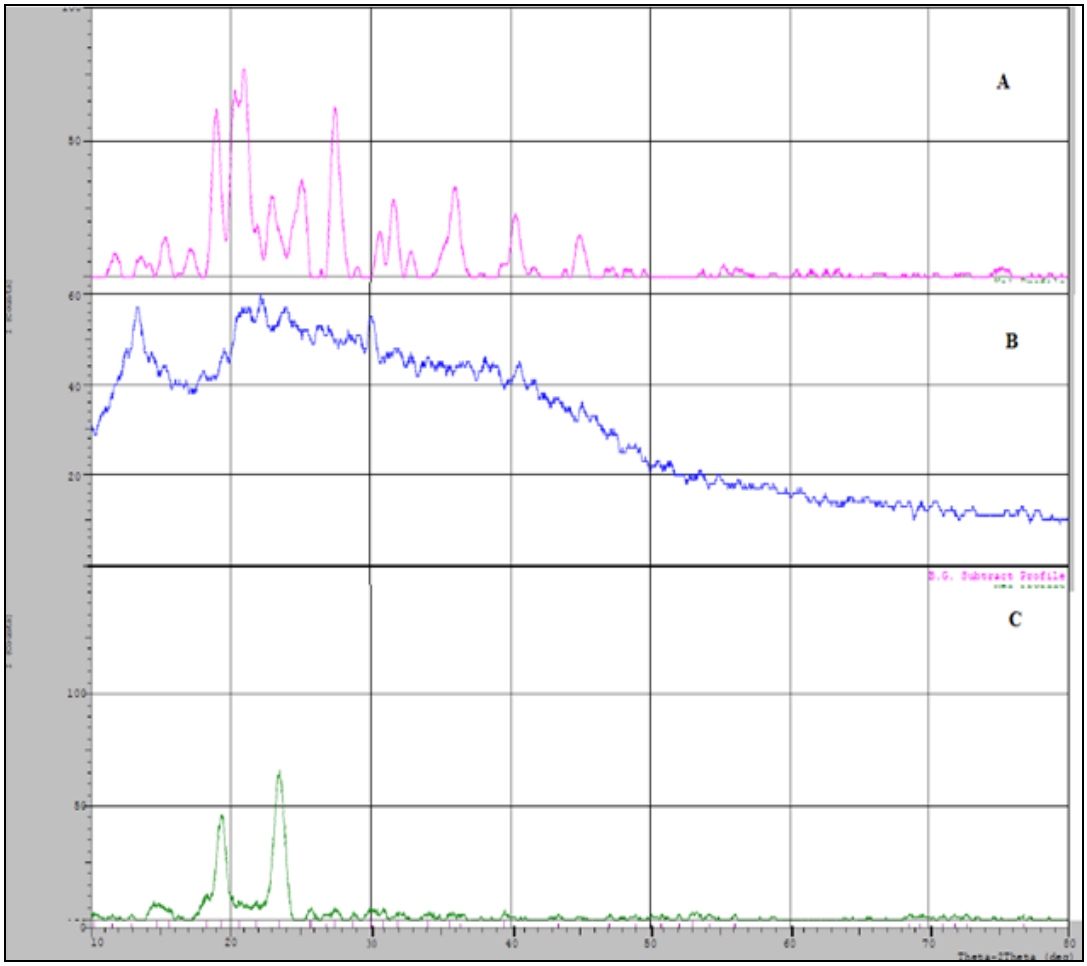


FIG. 5: XRD SPECTRA OF A) ACECLOFENAC B) AFAANC C) AFGKNC BIONANOCOMPOSITE

Solubility Study: Solubility study performed in mg/ml for of Physical Mixture of aceclofenac. Solubility of AFAAPM was found to be in the range of 1.25 to 4.23 mg/ml ratio 1:3 having highest solubility 4.23 mg/ml and AFGKPM having highest solubility 3.55 mg/ml ratio 1:4 having highest solubility 3.55 mg/ml. The solubility (mg/ml) of Prepared BNCS of Aceclofenac with Gond Katira and *Acacia arabica*, respectively, as reported in **Table 3**. It was observed that the Optimized ratio for AFAANC (1:3) shows solubility **5.38** mg/ml, AFGKNC (1:4) shows solubility **4.72** mg/ml. This optimized ratio was then confirmed with powder dissolution and found to be increase insolubility. Enhancement of solubility was mainly due to less foaming index and viscosity profile of Gond Katira and *Acacia arabica* gum, aceclofenac diffused in the gum in the form of its Bionanocomposite with structural modification *i.e.* it was made to hydrophilic form of aceclofenac which get enriched with possible hydrogen bonding and this hydrogen bonding helps the molecule to go under dispersion and ring-opening for the drugs by reveling molar volume without affecting its parent activity of drugs. This hydrophilic nature is obviously utilized for solubility enhancement of aceclofenac.

TABLE 3: COMPARATIVE SOLUBILITY STUDY OF ACECLOFENAC BNCS AFAANC AND AFGKNC

	Solubility in mg/ml			
Ratio	**AFAAPM**	**AFAANC**	**AFGKPM**	**AFGKNC**
1:01	1.25	1.90	0.95	1.10
1:02	3.41	3.28	1.51	2.26
1:03	4.23	5.38	2.47	3.20
1:04	2.85	3.32	3.55	4.72
1:05	2.61	3.40	2.24	2.85
1:06	2.58	3.48	2.30	2.95
1:07	2.71	3.50	2.35	2.90
1:08	2.68	3.45	2.28	2.88
1:09	2.65	3.41	2.39	2.75
1:10	2.70	3.35	2.33	2.85

Powder Dissolution Test for Physical Mixture and BNCs: The powder dissolution test was carried out to check solubility enhancing properties of the natural gems. The dissolution profile of the Physical Mixture showed remarkable improvement in the dissolution rate when compared with the pure

Aceclofenac their physical mixture with natural carriers. Physical Mixture of Aceclofenac with both the gum demonstrated appropriate result. % CDR of Aceclofenac was observed 54. 69±4 and % CDR of Physical mixture of AFAAPM and AFGKPM observed 70.2±7.5 and 61.1±7.5 respectively after 60min. **Fig. 6A** % CDR of BNCS such as AFAANC observed 97.22±1.1, for AFGKNC it was 70.21±1.9 after 60 min. **Fig. 6B**. From the result observed it was clearly indicated that the prepared BNCs of both the aceclofenac (Optimized batches) showed good drug release when it was compared with its pure form and its physical mixture form; it was concluded from the study that the natural polymer used for the preparation of BNCs with microwave-induced diffusion technique the dissolution rate has been enhanced for prepared BNCs.

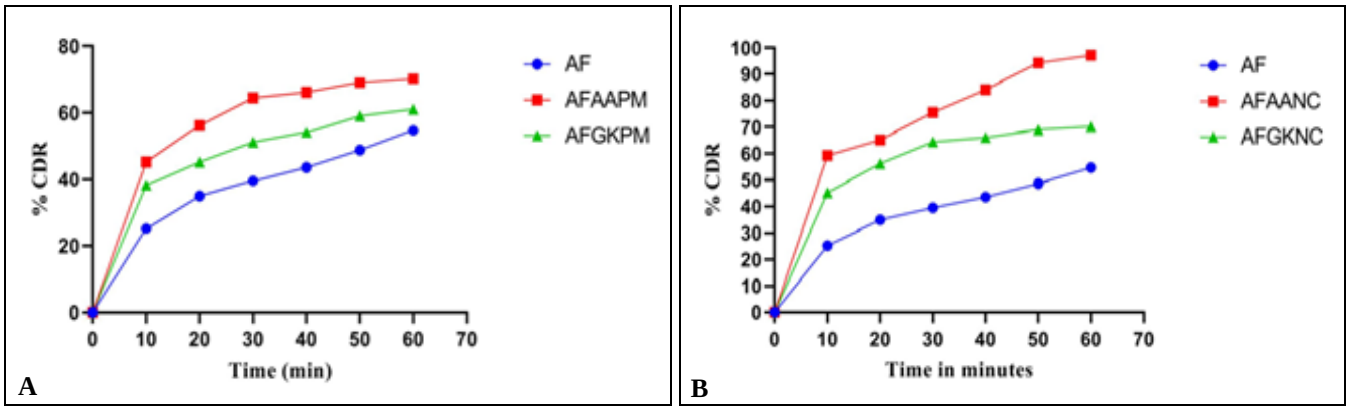


FIG. 6: % CDR OF A) PHYSICAL MIXTURE B) AFAANC AND AFGKNC BIONANOCOMPOSITES

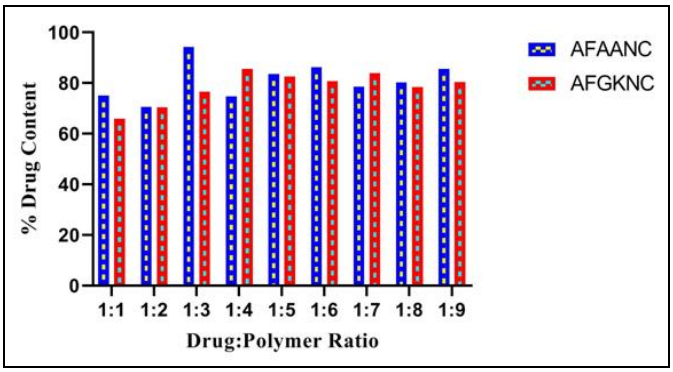


FIG. 7: DRUG CONTENT OF AFAANC AND AFGKNC BIONANOCOMPOSITES

Drug Content Analysis: Uniform dispersion of drugs in the BNCs was determined by drug content analysis. It was found that for AFAANC for (1:3) ratio 94.22% and for AFGKNC (1:4) ratio 85.54% aceclofenac was entrapped in the BNCs showing uniform dispersion of drug for both the gums.

Particle Size and Surface Morphology: Average particle size of developed AFAANC and AFGKNC bio-nanocomposites optimized formulation was found to be in 1214 nm **Fig. 8A** and 1632 nm **Fig. 8B** respectively.

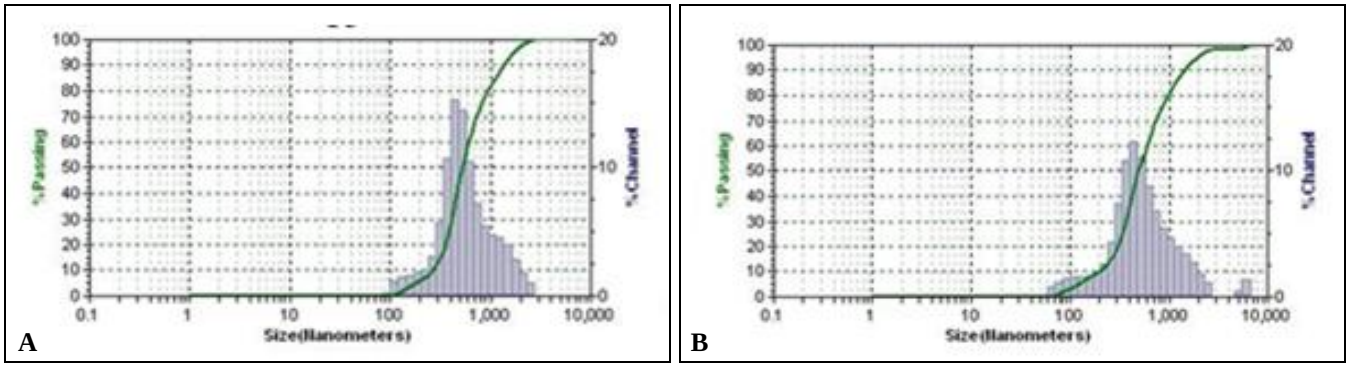


FIG. 8: AVERAGE PARTICLE SIZE RANGE OF A) AFAANC B) AFGKNC BIONANOCOMPOSITES

The SEM study was done to check the surface morphology of the drug particles. The SEM of polymer (AA) and its BNCs are shown in **Fig. 9**. Aceclofenac particles were variable shaped with a rough surface **Fig. 9A**. From the surface morphology, it was clearly demonstrated crystal shape of Aceclofenac was completely changed in amorphous form in AFAANC and AFGKNC shown embedded Aceclofenac crystals in the matrix **Fig. 9B** and **9C**.

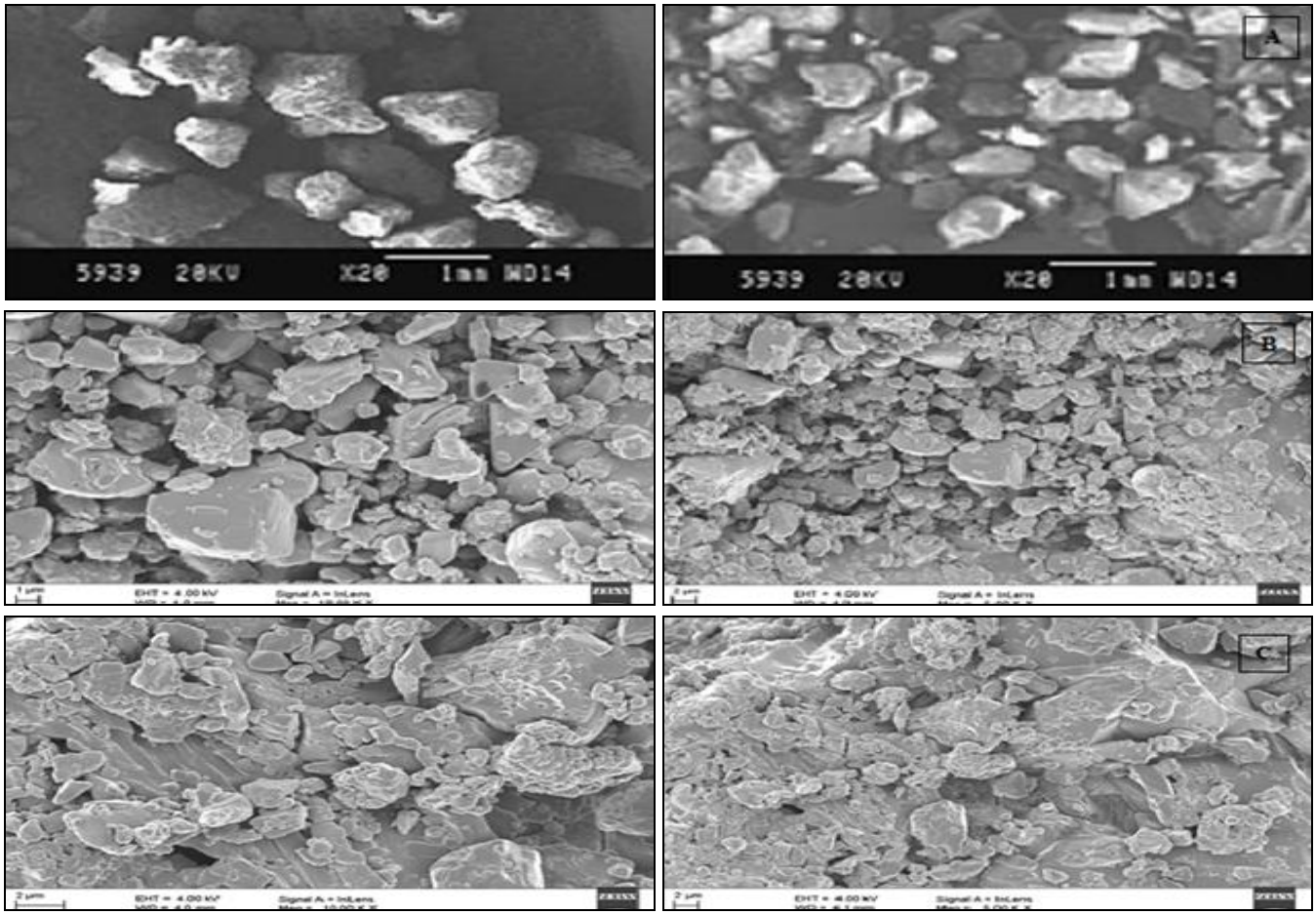


FIG. 9: SEM OF A) ACECLOFENAC B) AFAANC C) AFGKNC BIONANOCOMPOSITES

Proposed Structure of Prepared Bionano-composites: From the study, it was found that, the Hydrogen bonding with a molecule of Aceclofenac proposed feasibility towards solubility enhancement. As the structure influence, the BNCs formed would correspond to the need of study. More covalent bond and hydrogen bonds formed when drugs are entrapped into their BNCs with natural carriers. From the obtained structure -O-OH bond of indicating hydrogen bond and CH- O-H stating the Alcoholic Covalent bond and because of such interaction between aceclofenac and gums which was held into covalent bond and stated the intermolecular hydrogen bonding and less energy is required to break such bond. Further, weak van-der Waals force found in the prepared BNCs hence the solubility of molecule enhanced through the proposed mechanism. Following are the possible 3D structure for prepared BNCs from Aceclofenac by using natural carriers such as Acacia Arabica and Gond Katira **Fig. 10A** and **10B**.

Aceclofenac Bionanocomposites:

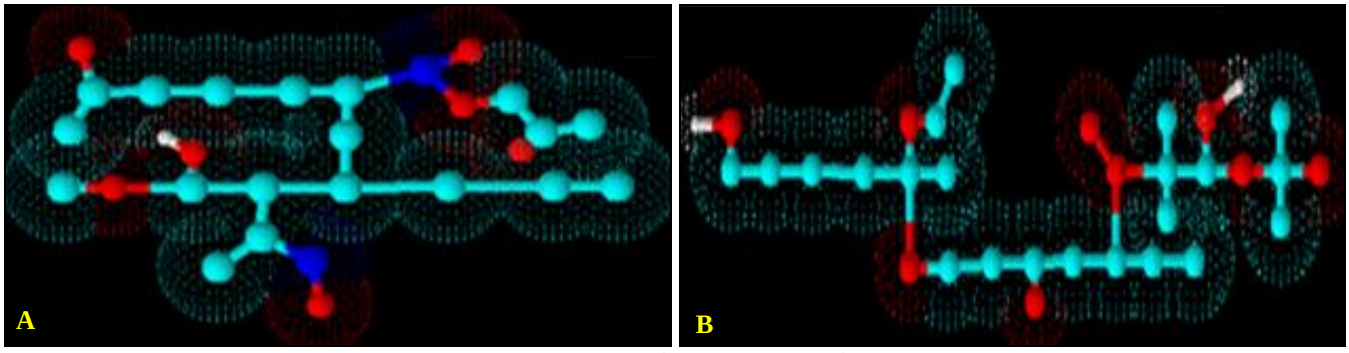


FIG. 10: POSSIBLE INTERACTION BETWEEN A) AFAANC A B) AFGKNC BIONANOCOMPOSITES

CONCLUSION: From the results we concluded that, use of newer natural polymers Arabica and Gond Katira Gum for the generation Bionanocomposite influences physicochemical characteristics of aceclofenac. Microwave induced diffusion technique which provides shown promising approach increase rate of solubility of prepared BNCs. Results reported for FT-IR, XRD, and DSC and SEM that aceclofenac generated into the BNCs showed significant liability, which increases the rate of solubility. Results show the newer natural carrier or polymer were shown good Compatibility with aceclofenac. Furthermore, the gum was shown less % of swelling index, less viscosity, and less foaming index. The % CDR of pure aceclofenac was 54.69± 4.5 and for Optimized BNCs *i.e.* (AFAANC) (1:04) 97.22±1.1 and AFGKNC (1:03) 85.54% respectively. There was drastic increase in solubility of optimized ratios. *In vitro* evaluation of conforms Suitability of BNCs for optimization in the enhancement of the rate of solubility of aceclofenac.

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