A Study on Design and Development of Bionanocomposites in Drug Delivery System

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Abstract - The purpose of this research is to use a bio-nanocomposite and microwave-induced diffusion technology to increase the drug's solubility and rate of dissolution. All medications that aren't very soluble in water are chosen to make them more soluble. By transforming the medicine into a bionanocomposite using the microwave-induced diffusion technique, the solubility is increased. In this study Formulation and Evaluation of BioNanocomposite is done by using MIND Method. The BioNanocomposite used is Ketoprofen, Ibuprofen and Aceclofenac. The solubility of drug is determined by taking the known excess amount of Ketoprofen drug into 150 ml of distilled water and kept for 24 hrs on magnetic stirrer at room temperature. The identification of Aceclofenac is done by the FT-IR Spectroscopy. The wavelength ranged from 400 to 4000 cm−1 with a resolution of 4 cm−1. To get better outcomes with the modified formulation than we did with the commercially available formulation, the results of this research suggest that using microwave-generated BNC to increase medication solubility, dissolution, and eventually bioavailability might be a viable option.

Keywords - Bionanocomposite, Solubility, Drug, Medicine, Delivery System, Pharmaceutical.

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INTRODUCTION

The use of nanodrug delivery devices improves drug bioavailability while decreasing hazardous side effects. These unspecific nanosized formulations are used in capsuled tablets to improve their pharmacokinetics and bioavailability. Current pharmaceutical research focuses on developing drug delivery methods with the highest possible therapeutic potential for the efficient and risk-free treatment of disease.

Polymers that break down naturally have use in medicine (for things like gene therapy and tissue engineering) in the plastics industry (including packaging and drug distribution). Biopolymers can't compete with synthetic materials in terms of mechanical rigidity, transparency, or thermal stability. However, the high drug concentration on the inorganic surface caused difficulties in recrystallization when silicon dioxide was utilised as the adsorption substrate in the first nanocomposite. Two examples of polysaccharides that might be included into a bionanocomposite are methylcellulose and hyaluronan (PLGA). However, it is essential for the filler molecules to interact with one other and with the matrix molecules in order to generate bionanocomposite. Electrospinning, double emulsion solvent evaporation, emulsion/solvent evaporation, emulsification solvent diffusion, solution intercalation, melt intercalation, and ultrasonication are only few of the methods that may be utilised to make bionanocomposite materials. [1]

Benefits of Bionanocomposites

Because of these benefits, bionanocomposites are gaining popularity, and large manufacturers are spending millions of dollars to perfect them. One of the most valuable features of bionanocomposite is the enhanced contact between the filler and matrix that is made possible by the nanoscale size of the polymer. The tensile strength of the composite increased with the addition of nanocrystalline cellulose to the chitosan matrix (up to 5% w/w), but then plateaued. This also applied to the inclusion of nanofiller. The hydrogen connections between polysaccharide nanocrystals were surprisingly strong. The end outcome is clumps of nanoparticles. These interactions may lead to the formation of a filler network inside the nanocomposite matrix. Despite its solubility in water, chitosan is a biodegradable polymer often used in medication administration. When compared to regular chitosan, the tensile strength and hydrophobicity of a composite made of chitosan and cellulose nanocrystals increased by up to 150%.

Particles of exfoliated clay stacks or mineral fibers/sheets/particles might be used as reinforcing material (e.g., carbon nanotubes or electrospun fibers). Due to the vast surface area of the reinforcement, just a very little amount is required to appreciably modify the macroscale features of the composite. Optical and dielectric characteristics, rigidity, and heat resistance are just some of the

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mechanical features that nanoparticles may enhance. [2]

Characterization of Bionanocomposite

i. X-Ray Diffraction Techniques (XRD): XRD analysis relies on the constructive interference of a monochromatic X-ray with the crystalline sample. Nano-fillers, medicines, and polymers may have their crystallinity or amorphousness identified by X-ray diffraction (XRD). It's also utilised to calculate the separation between the nanofiller and polymer phases. [3]

ii. Fourier Transfer Infra-Red Spectroscopy (FTIR):

When exposed to infrared light, every functional class has a unique resonance frequency. The degree to which functional groups have altered in bionanocomposite materials is used as a proxy for their capacity to execute a given function. Mixing various polymers and medicines during manufacture may easily be detected as causing a shift in chemical composition. The reliability, purity, and composition of the sample, as well as the presence of a hitherto undiscovered metal, are all laid bare.

iii. Transmission Electron Microscopy (TEM): Recognition and amplification of electron interactions during transmission create the picture. It was used to determine the internal quality of the structure and the global distribution of the different phases. In addition, information on the nanofiller's distribution in the polymer matrix is provided.

iv. Scanning Electron Microscopy (SEM):

By letting accelerated electrons collide with the material, secondary electrons and backscattered electrons are created, both of which may be utilised to create three-dimensional pictures. assess the create three-dimensional pictures. assess the likelihood of morphological transitions in nanocomposites. If you want to make better fillers, you need to know how uniformly the nanofiller is dispersed in the polymer. A bionanocomposite's surface may readily be broken and clumped particles can be seen.

v. Thermal Gravimetric Analysis (TGA):

The effect of time and temperature changes on a sample's weight is quantified. There are commonalities. To lose weight, composites and single polymers go about it in various ways. Physical mechanisms, such as melting, as well as chemical ones that contribute to weight loss are noted. [4]

Method for Preparation of Bionanocomposite

i. Solvent Evaporation: Drugs that don't dissolve in water may be administered effectively using this method. The dissolvable polymer is the water part. Then, an oil-in-water emulsion is formed by repeatedly agitating the oil phase in the water phase using a sonicator or by swirling the two phases together. To make the paclitaxel-loaded PLGA/MMT nanocomposite, dichloromethane (DCM) is used as the solvent. In DCM, dissolving 5 mg of paclitaxel and 110 mg of PLGA produced a transparent oil phase solution. Mixing 2% w/v PVA with either 0%, 0.046%, or 0.092% w/v MMT results in aqueous solutions. After that, the aqueous phase is sonicated for 120 seconds to emulsify the oil phase. In order to harden the particles, the resultant emulsion was allowed to evaporate at room temperature for a whole night. [5]

Figure 1: solvent evaporation

ii. Emulsification Solvent Diffusion: We created the PLA/MMT bionanocomposite emulsion using solvent diffusion emulsification. In various ways, ethyl acetate was used to make both the PLA solution and the MMT dispersion. Then, an oil phase was made by combining the PLA solution, clay dispersion, and lauryl alcohol. In order to create the aqueous phase, we dissolved PVA and surfactants in sterile water. Magnetic stirring is used to combine the oil and water phases after homogenization.

Figure 2: Emulsification solvent diffusion

iii. Ultrasonication: The high-frequency ultrasonic vibrations used here cause the material to shrink to nanoscale dimensions. This technique for producing bionanocomposites involves combining two polymers with an agent and then treating those using ultrasonic waves. To flush out any remaining solvent, the size and shape of the bionanocomposite are controlled by the radiation's frequency, duration, and power supply.

Figure 3: Ultrasonication

iv. Electrospinning: This method is used in the production of bionanocomposite fibre. It consists of a high-voltage power source, a pump, a conductive collecting plate, and a flat-tipped needle. The polymer is blended with organic solvents like dimethylformamide (DMF) and chloroform. The material is fed into the electrospun needle, and high voltage is utilised to spin the material into composite fibre.

Figure 4: Electrospinning

v. Melt Intercalation: Melting the polymer involves simultaneously heating layers of stacked silicate. The next step is to mix it with a high shear rate. Matrix is intercalated with the silicate phase. Single- and twinscrew extruder tools use melt intercalation. The galleries between the silicate layers serve as a dispersal mechanism for polymer chains. [6]

Figure 5: Melt intercalation

Multifunctionality of Drug Carriers

Intravenous injection is a common method of drug administration, although this may cause systemic dispersion, breakdown by plasma proteins, and decreased effectiveness. If a drug stays in the circulation for a longer period of time after administration, its pharmacological effects may persist for a longer period of time as well. Synergistic integration of therapeutic and diagnostic activities would be possible if many functional nanostructure materials could be integrated in a single organism. Using either passive targeting owing to their nanosize or active targeting due to the adsorption of bioactive ligands on the particle surface, nanoparticles constructed on multifunctional drug carriers will offer targeted delivery of bioactive chemicals to target tissues. In the battle against pathological disorders, these nanosystems' noninvasive real-time monitoring of the body's response to therapies might be vital. [7]

i. Drug loading and release: Medications and bioactive chemicals need delivery mechanisms to protect them from deterioration and increase their therapeutic efficacy. Safeguarding devices may prevent the degradation of drug molecules, halt the diffusion of drugs out of the device, and regulate the release of drug solutions. There are a various options for getting the drugs into DDS. To create a polymer-based DDS, the drug and polymer chain might establish a covalent connection, creating a polymer-drug conjugate complex. Medication may also be loaded in a polymer matrix by dissolving or dispersing it in the matrix. This loading technique results in a monolithic matrix system. The composition, molecular weight, and layer thickness of a polymer coating, such as that used to encapsulate a medication core, may alter the rate at which the medicine is absorbed by the body.

ii. Targeting: The primary objective of DDS is to effectively and precisely transport the drug molecules to the target diseased location. To go to the heart of the action, you may go either directly or indirectly. The carrier system must be covalently coupled to the cellspecific ligand in order for active targeting to take place. Enhanced permeability and retention effect of the carrier system may allow the drug to passively target the tumour (EPR). Drug carriers may also have target ligands attached, including as antibodies, peptides, folate, sugar moieties, and others. Potentially treating liver cancer using pharmacological nanocarriers with glucosamine saccharide moieties on their surfaces is now under investigation. Nanocarriers loaded with folate are often utilised to precisely target tumours due to the fact that most human cancer cells overexpress the folate receptor. Different nanocarrier systems, such as polymeric NPs, iron oxide NPs, quantum dots (QDs), and mesoporous silica NPs, have had folic acid attached to their surfaces.

iii. Visualization: Real-time imaging of biological molecules including DNA, peptides, and proteins, as well as inside organs, is much sought after for use in medical research. Numerous imaging techniques have been used. 104 Iron oxide nanoparticles and quantum dots are used as contrast probes in MRI and fluorescence imaging, respectively. The increased soft tissue contrast, the high spatial resolution, and the non-invasive nature of MRI make it a potent imaging tool. 105, 106 Recently, researchers have demonstrated a great deal of enthusiasm for the idea of using MRI signals to create medication delivery systems. To be used in magnetic resonance imaging (MRI), polymeric nanoparticles encasing SPION are created. 107 SPION with a mesoporous silica coating and MRI are being developed for theranostic DDS. [8]

iv. Magnetic resonance imaging: When it comes to the clinical imaging of cancer, magnetic resonance imaging (MRI) is essential. The non-invasive imaging method of magnetic resonance imaging (MRI) offers a clear image of cellular processes. Nuclear magnetic resonance (NMR) is the basis of MRI technology, and it was discovered independently by two groups of scientists in 1946. The interaction between a proton and a magnetic field produces an NMR scan. In a static magnetic field (B0), the torque produced by the field causes the B0 field to precess. As can be seen in Figure 1.6, the precession frequency scales as a function of the gyromagnetic ratio and B0 (also known as the Larmor frequency). All the protons in the magnetic field will be in resonance if they precess at the same Larmor frequency. For protons, the B0 field is aligned when their energy is lowest.

Figure 6: Larmor precession of a spinning nucleus about the axis of an applied magnetic field.

A magnetic moment undergoes resonant precession into the perpendicular plane when a transverse pulse of radio frequency (RF) is applied in a direction perpendicular to B0. Once the radio transmission is cut, the magnetic moment gradually returns to B0, establishing equilibrium. [9]

LITERATURE REVIEW

Kushare SS, Gattani SG (2016) a range of bionanocomposites consisting of PLA nanoparticles and shark gelatin hydrogels with varied nanostructures were designed to construct multifunctional drug delivery systems with the customised release rates required for individualised treatment techniques. The overall design of the systems took into account everything from the desired customization of the drug release to the viscoelastic properties needed for their convenience during storage and subsequent local administration as well as their biocompatibility and cell growth capability for the successful administration at the biomolecular level. The hydrogel matrix serves as the basis for the creation of a direct thermal approach to change the kinetically trapped nanostructures present in standard formulations while avoiding the detrimental nanoparticle aggregation that lessens their therapeutic efficacy. [10]

Prabu L, Ravikumar G (2016) shows how gelformed Chi/GO bionanocomposite beads may be made using a simple process. This study is the first to employ Chi/GO beads as a medication carrier for oral drug delivery to assess the metronidazole (MTD) antibiotic release pattern over an extended period of 84 hours. It is possible to build MTD-Chi/GO bionanocomposites by putting MTD into both its surface and its interior cavities. The MTD drug loading was found to be 683 mg/g. In addition, the in vitro release patterns of the pure drug and the drug encapsulated in Chi/GO beads are examined in simulated gastric and intestinal fluids using phosphate-buffered saline (PBS) of pH 1.2 and 7.4, respectively. [11]

Bhat MR, Payghan SA (2017) A type of smart materials called magnetic nanocomposites has recently received attention for use in medical implants or as drug delivery systems. A novel method for creating biocompatible nanocomposites that can be melted remotely is demonstrated. Magnetite nanoparticles (MNPs) may be embedded in a matrix using biocompatible thermoplastic dextran esters. That's why researchers developed thermostable dextran fatty acid esters with melting points ranging from 30 to 140 degrees Celsius. Polysaccharide esterification by activating the acid as iminium chlorides provided moderate reaction conditions that resulted in high-quality products, as shown by gel permeation chromatography, Fourier-

transform infrared, nuclear magnetic resonance, and FTIR spectroscopy (GPC). [12]

Chimkode RM (2018) Nanotechnology and nanomaterials are now at the centre of technological and scientific research. An overview of bionanocomposite and cutting-edge drug delivery methods is given in this review paper. Nanoscience, in its most basic sense, is the study of materials in which a crucial characteristic can be attributed to an underlying structure having at least one dimension smaller than 100 nanometers. The definition of bionanocomposites has greatly expanded to include a wide range of systems, including one-, two-, three-, and amorphous materials, composed of distinctively different components and blended at the nanoscale scale. [13]

Parthasarathi V, Thilagavathi G. (2019) Materials in the nanoscale range are used as diagnostic instruments or to administer therapeutic compounds to particular targeted regions in a controlled way in nanomedicine and nano delivery systems, which is a relatively young but fast emerging discipline. By delivering precise medications to specified locations and targets, nanotechnology provides several advantages in the treatment of chronic human illnesses. The use of Nano medicine (including chemotherapeutic medicines, biological agents, immunotherapeutic agents, etc.) in the treatment of different illnesses has recently seen a number of notable applications. [14]

METHODOLOGY

Materials

- **Characterizations:** Physicochemical characterization of Ketoprofen.
- **Particle Size & Surface Morphology:** The particle size was analysed using a Particle Size Analyzer, a Transmission Electron Microscope, and a Scanning Electron Microscope.
- **Melting Point:** The melting point was calculated using a digital melting point apparatus.
- **Purity of Drug:** FTIR and DSC analysis verify the drug's purity.
- **Solubility Determination:** Melting the polymer involves simultaneously heating layers of stacked silicate. The next step is to mix it with a high shear rate. Matrix is intercalated with the silicate phase. Singleand twin-screw extruder tools use melt intercalation. The galleries between the silicate layers serve as a dispersal mechanism for polymer chains. Bionanocomposites may be intercalated or exfoliated depending on

how deeply their polymer chains are embedded in the silicate matrix.

 FT-IR Spectrophotometric Analysis: Ketoprofen's identity was confirmed by FT-IR spectroscopy. The spectral range ranged from 400 to 4000 cm1, and the resolution was 4 cm1.

Characterization of Polymers

 Swelling Index (SI): The elasticity of the gums was measured by determining their swelling index. Acacia and Ghatti gum, each weighed at 10 grammes, were placed in separate 100 millilitre cylinders. Early evidence of gum impressions was recorded.

$$
SI = H_f - H_i / H_i \times 100
$$

Determination of Viscosity

Acacia gum and Ghatti gum, each weighing 1 gramme, were mixed with 100 millilitres of distilled water (1% w/v) to determine their respective viscosities.

Foaming index

Making a foaming index for gum allowed us to calculate its surfactant capacity. One gramme of gum was carefully measured and placed to a 250 ml cylinder. To make the dispersion, 100 ml of distilled water was added to the measuring cylinder.

Foaming index $=$ $\rm Hf - Hi$

Preparation of Physical Mixture

Ketoprofen was physically combined with the polymers AC and GG at a 1:1:3 ratios (drug: gum). Drug-polymer physical pairings were denoted by the symbols KEACP (1-3) and KEGGP (1-3).

Preparation of Nanobiocomposite

Acacia and Ghatti gum were used as transporters while the weight of the active ingredient, ketoprofen, was maintained consistent by meticulous weighing. A ceramic glass mortar and pestle were used to properly combine the medication and carrier.

Drug Content Analysis

Dissolving the mixture in 25 cc of methanol allows one to measure the extent to which medication has been incorporated into the nanobiocomposite. The resulting solution was analysed in a UV visible spectrophotometer at 258 nm against methanol as a blank after being filtered via a 0.2 micron membrane.

Solubility Study

In order to determine whether or not the nanobiocomposite was soluble, For this experiment, we used an excessive amount of ketoprofen that had been diluted in 150 cc of distilled water. The mixture was then magnetically swirled at 100 revolutions per minute and 25 degrees Celsius for a full 24 hours. In order to examine the recovered supernatant fluid, a 0.2 m membrane was used to filter it. The fluid was then exposed to UV visible light at a wavelength of 262 nm for analysis.

In-vitro Dissolution test of nanobiocomposite Powder

The USP XXIV apparatus 2 (paddle) protocol was used to conduct an in-vitro dissolution test. Around 900 mL of phosphate buffer solution (pH 6.8) was used. Powder containing 100 mg of ketoprofencontaining nanobiocomposite was added, and the dissolving medium was kept at 37 0.5 oC while the paddle rotated at 50 rpm. At 5, 10, 15, 30, 45, and 60 minutes, five millilitres of sample were removed from the dissolving medium and replaced with five millilitres of buffer solution. The materials were filtered through a 0.5 membrane filter before being analysed by spectrophotometry at 258 nm.

Characterization of Nanobiocomposite

- Fourier-Transform Infrared Spectroscopy (FT-IR)
- Differential Scanning Calorimeters (DSC)
- X-ray Diffraction Studies (XRD)
- Scanning Electron Microscopy (SEM)
- Transmission Electron Microscopy (TEM)

Preparation of Immediate Release Tablet

Solubility and dissolution were optimised by using a nanobiocomposite in the development of an instant release tablet. The nanobiocomposite used in the production of the fast-acting pill contains acacia fibres at a ratio of 1:3, while the ketoprofen component contains 600 milligrammes. The ingredients and components of the utilised pills are listed in the table below. A #60 mesh screen is used to sift the whole mixture. Direct compression with a 10 mm punch yielded a tablet.

Evaluation of Immediate Release Tablet

- Precompression Evaluation
- Post compression Evaluation
- Weight Variation
- Disintegration Test
- **Friability**
- **Hardness**
- In-Vitro Dissolution Test

Drug Content Analysis

Dissolving the Nanobiocomposite mixture in the 25 cc of methanol may help determine how much medication is added to the tablet. The resulting solution was analysed in a UV visible spectrophotometer at 258 nm against methanol as a blank after being filtered via a 0.2 micron membrane.

- In vivo evaluation
- Stability studies

RESULT

Formulation and Evaluation of Ketoprofen Bionanocomposite

Physical Characterization of Carriers

Results demonstrate that both acacia and ghatti gum have low viscosity and swelling potential. Acacia and ghatti gum are utilised to enhance medicine solubility and dissolution due to their low viscosity. While Ghatti gum has a reduced viscosity and better foaming index, acacia has none of those qualities. For this reason, acacia gum is preferable than Ghatti gum for enhancing the dissolving rate and solubility of medications.

Table 2: Physical Characterization of carriers

***Data are means +/- SD, n=3**

Powder Dissolution Test

Powder dissolution tests and solubility and dissolution experiments for ketoprofen and ketoprofen BNCs were done to assess the materials' capacities to enhance solubility. There was a significant increase in the dissolution rate of ketoprofen BNCs as compared to pure ketoprofen, as seen by the dissolution profile. BNCs of ketoprofen with Acacia have showed good effects, releasing 81% after 60 minutes, while pure ketoprofen only released 61%. Results from solubility and dissolution tests informed the tablet's final composition. As shown in Figure 4.1, the dissolution profile of both regular ketoprofen and BNCs for ketoprofen is shown. While only 61% of the drug is released in a solution from pure drug, 81% is liberated from KEACNC powder. In this way, we can say that the use of BNCs has improved the solubility of the pharmaceutical ketoprofen.

Figure 7: Powder dissolution studies of pure ketoprofen, KEACNC and KEGGNC powder

Formulation and Evaluation of Ibuprofen Bionanocomposite by using Mind Method

Physical Characterization of Polymer

Table 3: Physical Characterization of Polymer

***Data are n=3, means +/- SD**

Both acacia and ghatti gum were found to have low viscosity and swelling properties. Because of their decreased viscosity, acacia and Ghatti gum are utilised to increase medication solubility and dissolution. When compared to Ghatti gum, acacia has a slightly greater foaming index and lower viscosity. As a result, acacia gum is preferable to Ghatti gum for improving the solubility and rate of dissolution of medicinal ingredients.

Table 4: Comparison of solubility

In comparison to Ibuprofen on its own, the bionanocomposition IBUAC generated had a solubility that was 10.24 times higher.

Drug Content Analysis

Ibuprofen distribution uniformity in a bio nanocomposite might be evaluated using a drug content analysis. Homogeneous drug dispersion was shown by the fact that 95–99% of the ibuprofen was incorporated into the bio nanocomposite.

Table 5: Drug content analysis

IBUAC_{NBC}

Formulation and Evaluation of Aceclofenac Bionanocomposite by using Mind Method

Physical Characterization of Polymer

Table 6: Physical Characterization of Polymer

***Data are means +/- SD, n=3**

Both acacia and ghatti gum are shown to have minimal swelling and viscosity in this study. Acacia gum and Ghatti gum are used to improve drug solubility and dissolution because of their low viscosity. Acacia lacks the lowered viscosity and improved foaming index of Ghatti gum. As a result, acacia gum is preferable to Ghatti gum for improving the solubility and rate of dissolution of medicinal ingredients.

Table 47: Comparison of solubility

Solubility of the resultant ACEAC bionanocomposition was 25.24 times higher than that of aceclofenac alone.

Powder Dissolution Test

The drug BNCs had much higher solubility rates compared to the pure drug, as seen by their dissolution profiles.

Table 8: Powder dissolution study of pure Aceclofenac, ACEACNBC, and ACEGGNBC

Figure 8: Powder Dissolution Study of Pure Aceclofenac, ACEACNBC, ACEGGNBC

ACEACNBC powder released 87.72% of the medicine in solution, but the pure medication only released 76.21%. The release rate of ACEGGNBC powder is 85.54 percent. When comparing ACEACNBC with ACEGGNBC, the medication dissolution rate is better in ACEACNBC. The disintegration rate may have been sped up by the use of bio-nanocomposite.

CONCLUSION

This study Conclude that microwave-generated BNCs might benefit from the addition of natural carriers like AC and GG, which would aid in the solubility and dispersion of the active pharmaceutical component. Its dissolving ability was much enhanced, and the drug's solubility was increased by a factor of two. According to the findings of FT-IR, XRD, DSC, SEM, and TEM, the enhancement in solubility and dissolution is due to the medication's transformation into BNCs. Drugs and

polymers are demonstrated to have no detectable interactions. The optimized tablet performed just as well as the reference drug indomethacin in in vivo testing. The enhanced formulation produced better results than the commercially available product. The findings suggest that microwave-generated BNC is a viable method for increasing drug bioavailability via enhanced solubility and dissolution.

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