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FORMULATION AND EVALUATION OF ALBENDAZOLE NANOSPONGES

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ABSTRACT

This paper describes the development and evaluation of albendazole nanosponges as an implicit strategy to enhance drug dissolution and increases the bioavailability of drug to the specific point of action. Nanotechnology interceded drug delivery has been reported to enhance the drug effectiveness, bioavailability, reduced poison and meliorate patient compliance by nanoparticles. The main end of the study was to formulate and estimate Albendazole loaded nanosponges. The FTIR test is conducted as the primary test, by this test there was no commerce between the drug and polymers. Also Nanosponges (NS) were estimated for flyspeck size, poly dispersive index (PDI), zeta eventuality, ruse effectiveness and Invitro drug release. The flyspeck size ranged from 111.7nm to 200nm, zeta eventuality from -17.7mv to 25.0mv and ruse effectiveness was ranged from 75.00% to 80.00%. Through logical system for albendazole absorbance at λmax 294nm ranges between 0.464 to 2.502 while the attention ranges between 10 to 50(µg/ml). This study appears to be a promising step in perfecting the delivery and effectiveness of albendazole using nanotechnology.

KEYWORDS

Albendazole (ABZ), Nanosponges, Emulsion solvent diffusion, Lipophilic and Hydrophilic.

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INTRODUCTION

Nanosponges are the modern category of material and it is made up of tiny particles with a narrow cavity of few nanometers. These narrow cavities can be filled with various types of substances these tiny particles are having capability due to which it is able to carry both hydrophilic and lipophilic drug substances[1].

Release the medicine at specific target point rather of circulates through the body it'll more effective for particular given lozenge[2,3].

The invention of nanosponges has come significant step towards prostrating the complexity associated with the recently developing systems. The small size and pervious nature of nanosponges can bind inadequately water-answerable medicines within the matrix and ameliorate their solubility and bioavailability[4].

Nanosponges are suitable to entrap both hydrophilic as well as lipophilic medicine motes because of their inner hydrophobic depressions and external hydrophilic branching, thereby offering unequaled inflexibility. Nanosponge attained by using suitable cross-linking agent also by different organic and inorganic accoutrements[5].

The trouble to ameliorate dissolution and solubility of inadequately and virtually water undoable medicines remains one of the most grueling tasks in medicine development. Several styles have been introduced to increase dissolution rate and thereby oral immersion and bioavailability of similar medicines. Among colorful approaches, Nanosponges has shown promising results in perfecting solubility, wettability, dissolution rate of medicine and latterly its bioavailability[6].

Nanosponges are bitsy mesh- suchlike structures that may revise the treatment of numerous conditions and early trials suggest this technology is over to five times further effective at delivering medicines for bone cancer than conventional styles[7].

Nanosponge shows a implicit future in the coming times due to its variety of pharmaceutical operations like, extended- release, better product performance, fineness, bettered physical, thermal and chemical stability, and reduced vexation[8].

Nanosponges are characterized by being largely stable and having the capability to carry both hydrophilic as well as hydrophobic medicines[6].

Nanosponges are solid in nature and are small patches with pervious face can be formulated as oral, parenteral, topical or inhalational lozenge forms. For oral administration, these may be dispersed in a matrix of excipients, diluents, lubricants and anti riming agents which is suitable for the medication of tablets or capsules and the major benefits of these capsules or tablets are reduction of total cure, retention of lozenge form, reduction in toxin and perfecting patient compliance by prolonged release[9,10].

MATERIAL AND METHODS

Characterization of active ingredient

Characterization of Active Pharmaceutical Ingredient (API) is one of the essential steps involved in any formulation development. Drug characterization step involves identification and confirmation of the drug by infra-red spectroscopy.

PHYSICOCHEMICAL CHARACTERIZATION

Melting point determination

The Melting Point of drug was determined using Microprocessor melting and boiling point apparatus.

FT-IR Spectroscopy

Fourier Transform Infrared (FT-IR) is a supportive tool for characterization of pharmaceutical ingredients. IR spectrum obtained for the drug sample was compared with standard spectrum of pure drug and checked for any prominent shift in functional peaks and non-involvement of functional group.

Analytical method for Albendazole

Determination of max and construction of calibration curve Albendazole standard powder was accurately weighed to prepare a solution of known concentration (10µg/mL). This solution was prepared by dissolving an appropriate amount of Albendazole standard powder in a DMSO and then diluting it to the desired volume by using buffer solution. Using a UV-Visible spectrophotometer, the prepared Albendazole solution was scanned over a range of wavelengths from 200 to 400nm. The absorbance spectrum was recorded, and the wavelength at which the highest absorbance occurred was identified as the λ max for Albendazole was found to be at 294nm. Standard solutions of Albendazole were prepared by diluting

the Albendazole stock solution to concentrations of 10, 20, 30, 40 and 50µg/ml. Absorbance measurements of these standard solutions were taken at the λ max of 294nm using the UV-Visible spectrophotometer.

Preparation of Albendazole nanosponge

The Albendazole Nanosponge is prepared by emulsion solvent diffusion method. In this method the organic phase and aqueous phase where, the organic phase is slowly added into aqueous phase and it is stirred for one or more hours. Nanosponges collected were filtered, washed and then air dried at room temperature or in vaccum oven for 40°C for 24 hours.

CHARACTERIZATION OF ALBENDAZOLE NANOSPONGES

Drug Content (%)

Drug content was performed by indirect method. Accurately weighed 10mg of prepared Albendazole are transferred into 100ml volumetric flask dissolved and made upto the volume upto 100ml with buffer solution. 10ml solution was transferred into 100ml volumetric flask and the volume made upto 100ml with buffer solution. Pipetted out 1ml of above solution into 10ml volumetric flask and made up the volume upto the 10ml with buffer solution. The absorbance of the above solution was measured at 294nm by using UV visible spectroscopy. For the centrifuged sample (Albendazole Nanosponge) supernatant was taken and diluted to the standard concentration then measured at 294nm by using UV Spectroscopy.

Drug content = concentration of sample/concentration of standard * 100

Entrapment Efficiency

Taken 25mg drug Albendazole nanosponge is dispersed in 100ml water sonicate for 20 min. Dispersion was filtered through a whatman filter paper. Analysed the filtered solution by U.V spectrophotometer at 275nm. The drug entrapment efficiency was determined by following equation.

Drug entrapment efficiency = (Total drug conc-supernatant drug conc)/ total drug cone x 100

Particle Size

Albendazole Nanosponges is characterized in terms of particle size, PDI and zeta potential using the Nano size analyser at 25°C. Unentrapped drug is removed by dialysis of the formulations. Briefly, the shape and form of the optimized formulation is confirmed with transmission electron microscopy.

PDI

Albendazole Nanosponges is characterized in terms of PDI using the Nano size analyser at 25°C. Unentrapped drug is removed by dialysis of the formulations. Briefly, the shape and form of the optimized formulation is confirmed with transmission electron microscopy.

Zeta Potential

Albendazole Nanosponges is characterized in terms of particle size, PDI and zeta potential using the Nano size analyser at 25°C. Unentrapped drug is removed by dialysis of the formulations. Briefly, the shape and form of the optimized formulation is confirmed with transmission electron microscopy.

POLYMERS USED IN NANOSPONGES PREPARATION[11]

There are colorful polymers and cross linkers are used in the medication of nanosponges:

Polimers

Hyper cross linked polystyrenes, cyclodextrines and its derivatives like Alkyloxycarbonyl Cyclodextrins, Methyl β-cyclodextrines, Hydroxy Propyl β Cyclodextrins.

Copolimr

Poly (valerolactoneallyl valerolactone), Poly (valerolactoneallylvalero- lactone oxepanedione), Ethyl Cellulose, Poly vinyl alcohol.

Cross linker

Carbonyl dimidazoles, Carboxylic acid dianhydrides, Diarylcarbonates, Dichloromethane, Diisocyanates, Diphenyl Carbonate, Epichloridine, Gluteraldehyde, Pyromellitic anhydride, 2, 2-bis (acrylamido) Acetic acid.

CHARACTERIZATION OF NANOSPONGES

Particle size determination

The sizes of patches are maintained during polymerization for the conformation of free-

following maquillages having fine aesthetic appearance. Flyspeck size analysis of loaded and disburdened nanosponges can be carried out by ray light diffractometry or Malvern zeta sizer[12].

Determination of lading effectiveness

The lading effectiveness of set nanosponge is determined by abating the un- entangled medicine from the total quantum of medicine. The un-entrapped medicine must be estimated by any suitable system of analysis. The system used for separation of un-entrapped medicine by gel filtration, dialysis and ultra centrifugation. The lading effectiveness is calculated as:

Lading effectiveness factual medicine content in nanosponge/ Theoretical medicine content × 100

Compatibility studies

The medicine should be compatible with the polymers which are used for the medication of nanosponges. The comity of medicine with adjuvant can be determined by thin layer Chromatography (TLC) and Fourier Transform Infrared Spectroscopy (FTIR). Liquid characteristics can be studied by greasepaint X-ray diffraction (XRD) and Differential Scanning Colorimetry (DSC)[13].

Zeta implicit

Zeta eventuality is a measure of face charge. The face charge of nanosponge can be determined by using Zeta sizer[14].

Solubility studies

The most extensively used approach to study addition complexation is the phase solubility system described by Higuchi and Connors, which examines the effect of a nanosponge, on the solubility of medicine. Phase solubility plates indicate the degree of complexation[15].

Medicine release kinetics

To probe the medium of medicine release from the nanosponge the release data was anatomized using Zero order, First order, Higuchi, Korsemeyer Peppas models. The data can be anatomized using DD solver software. The software estimates the parameters of anon-linear function that provides the closest fit between experimental compliances and non-direct function[16].

***In vitro* release studies**

In vitro release kinetics trials are carried out using a multi cube rotating cell. A waterless dissipation of nanosponges (1ml) containing the medicine is placed in the patron cube, while the receptor cube separated by a hydrophilic dialysis membrane is filled with phosphate buffer of requires pH. The trial is carried out for 24 hr. At fixed time intervals, the receptor buffer is fully withdrawn and replaced with fresh buffer. The quantum of medicine in the medium is determined by the suitable logical system and medicine release is calculated to determine the release pattern [16].

Microscopy studies

Scanning Electron Microscopy (SEM) and Transmission Electron Microscopy (TEM) can be used to study the bitsy aspects of the nanosponges. The difference in crystallization state of the raw accoutrements and the product seen under electron microscope indicates the conformation of the addition complexes[17].

ADVANTAGES OF NANOSPONGES[18,11]

Increase waterless solubility of the unwell water-answerable medicine.

Nanosponges can release the medicine motes in a predictable fashion.

Because of their bitsy severance size (0.25µm), bacteria cannot access the nanosponges and they act like a tone- sterilizer.

DISADVANTAGES OF NANOSPONGES[19]

Nanosponges have the capacity of recapitulating small motes, not suitable for larger motes.

Cure jilting may do at times.

FACTORS AFFECTING MEDICINE RELEASE FROM NANOSPONGES

Physical and chemical parcels of entangled active pharmaceutical constituents.

Physical parcels of sponger system similar as severance periphery severance volume, and resiliency External triggers similar as pressure, temperature, and solubility of actives.

Temperature

Some entangled actives can be too thick at room temperature to flow spontaneously from bloodsuckers onto the skin but increased skin or terrain temperature can affect in increased inflow rate and eventually medicine release[13].

PREPARATION OF NANOSPONGES

Nanosponges are set substantially on the criteria of delivery system, polymer and nature of medicine and detergents.

NANOSPONGES PREPARED FROM hyperactive- CROSS LINKED β-CYCLODEXTRINS

β- Cyclodextrin nanosponges were prepared by placing 100ml of dimethyl formamide (DMF) in a round bottomed beaker and 17.42g of anhydrous β-CD was poured and shaken to get full dissolution. Also 9.96g of carbonyl diimidazole (61.42m mol) was added and the result was allowed to reply for 4hrs at 1000°C. Once condensation polymerization was complete, the block of hyperactive cross linked cyclodextrin was roughly base and an excess of deionised water was added to remove DMF. Eventually residual by- products or unreacted reagents were fully removed by soxhlet birth with ethanol[20].

The white greasepaint therefore attained was dried overnight in a roaster at 600°C. The fine greasepaint attained was dispersed in water.The colloidal region that remained suspended in liquid were recovered and lyophilized. The attained nanosponges are sub-micron in dimension and with a globular shape[17].

EMULSION SOLVENT DIFFUSION METHOD

Nanosponges can be produced by using the involvement of different proportion of ethyl cellulose and polyvinyl alcohol. The dispersed phase containing ethyl cellulose and medicine was dissolved in 20ml dichloromethane and sluggishly added to a definite quantum of polyvinyl alcohol in 150ml of waterless nonstop phase. The response admixture was stirred at 1000rpm for 2 hrs in a glamorous stirrer. The nanosponges formed were collected by filtration and dried in roaster at 40°C for 24 hrs. The dried nanosponges were stored in vaccum desiccators to insure the junking of residual detergents[10].

QUASI-EMULSION SOLVENT DIFFUSION

The inner phase is prepared using Eudragit RS.100 and added to a suitable detergent. Medicine to be incorporated is made into a result and dissolved under ultrasonication at 35°C. This inner phase added into external phase containing polyvinyl alcohol which acts as emulsifying agent. The admixture is also stirred at 1000- 2000rpm for 3 hr at room temperature and dried in an hot air roaster at 40°C for 12 hr[17].

ULTRA SOUND- ASSISTED SYNTHESIS

In this system, polymers reply with cross-linkers in absence of detergent and under Sonication. Then, the polymer and cross-linker are mixed in a beaker. Place the steins in an ultrasound bath filled with water and hotted to 90°C and also sonicate for 5 hrs. It was also allowed to cool and washed with water to remove the unreacted polymer. So the product under vacuum and store at 250°C[17].

CRITICAL ANALYSIS

CHARACTERIZATION OF NANOSPONGES

Flyspeck size determination

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RESULTS AND DISCUSSION

Characterization of active ingredients

Melting point determination

FT-IR Spectroscopy

Analytical method for Albendazole

CHARACTERIZATION OF ALBENDAZOLE NANOSPONGES

Drug Content (%)

Drug content= concentration of sample/concentration of standard*100=76.84%

Entrapment Efficiency

Drug entrapment efficiency= (Total drug conc-supernatant drug conc)/total drug conc × 100=79.52%

Composition of Albendazole Nanoparticles formulations

Table No.1: Composition of Albendazole Nanoparticles formulations

S.No	Ingredients	i1	i2	i3	i4	i5	i6	i7	i8
1	Albendazole(mg)	20	20	20	20	20	20	20	20
2	Stearic acid (mg)	150	150	100	100	150	150	110	110
3	Bees Wax (mg)	100	100	120	120	150	150	130	130
4	Polaxamer (mg)	200	200	200	200	200	200	200	200
5	Span 80 (ml)	0.5	0.75	1.0	1.25	0.5	0.75	1.0	1.25
6	Ethanol (ml)	10	10	101	10	10	10	10	10

Analytical method for Albendazole

Table No.2: Analytical methods for Albendazole

S.No	Concentration(µg/mL)	Absorbance at max λ294nm
1	10	0.464
2	20	0.972
3	30	1.515
4	40	1.98
5	50	2.502

FT-IR Spectroscopy

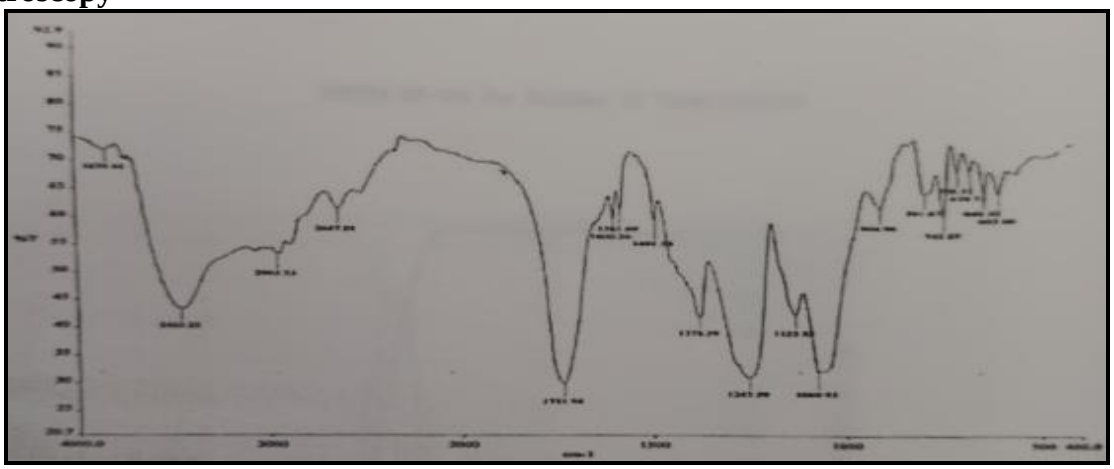

Figure No.1: FT-IR Spectroscopy

Particle Size

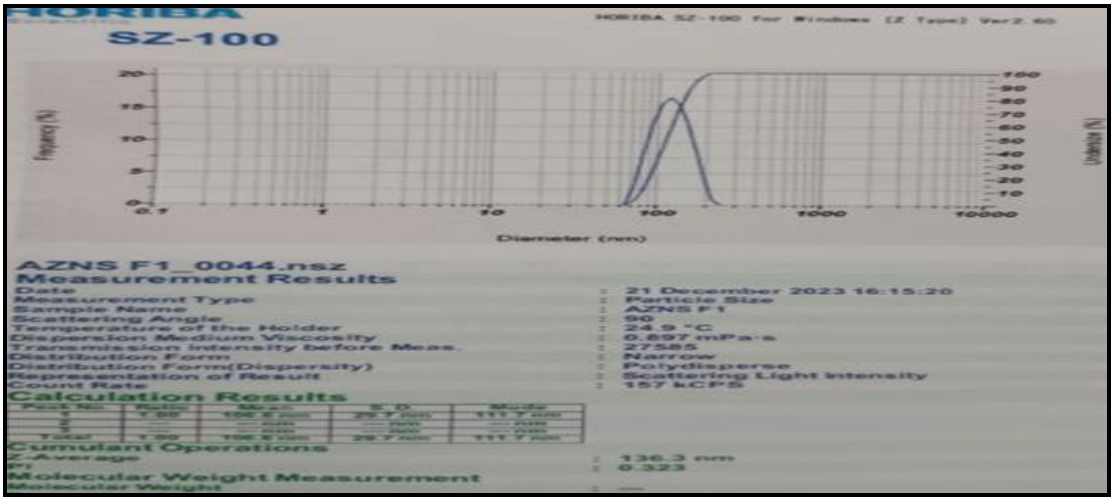

Figure No.2

PDI

Zeta Potential

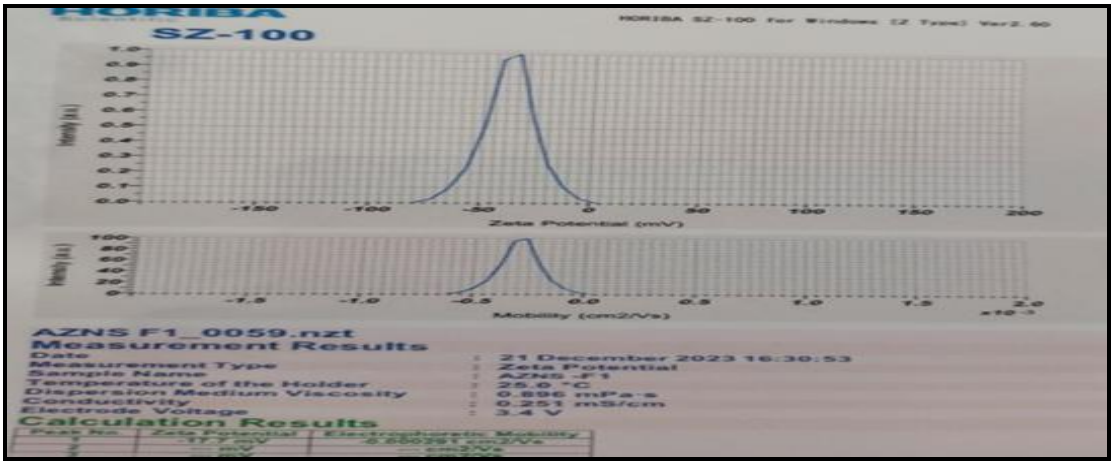

Figure No.3

SUMMARY AND CONCLUSION

Nanosponges are microscopic particles with a few nanometers wide cavities, in which a large variety of substance can be encapsulated. These particles possess the ability to carry both lipophilic and hydrophilic substance and thereby improving the solubility of poorly water soluble molecules. Drugs encapsulated within the nanosponge pores are within the nanosponge pores are shielded from premature destruction and stability of drug is enhanced.

Albendazole is a broad-spectrum antihelminthic and antiprotozoal agent of the benzimidazole type. It is used for the treatment of a variety of intestinal parasite infections.

Main objective of this study was to formulate Albendazole loaded nanosponges using different polymers to target the cells and release the drug in a controlled manner.

Preformulation study was carried out to find out the melting point and FTIR spectroscopic study of the Albendazole drug.

IR spectrum obtained for the drug sample was compared with standard spectrum of pure drug and checked for any prominent shift in functional peaks and non involvement of functional group.

Drug dissolution studies were performed and comparing F1, F2 and F3. F3 was found be shown the best release.

FUTURE PERSPECTIVES

The future plan of the study to carry out the Accelerated Stability studies, release kinetics and also to conduct the animal studies and formulating solid dispersions into liquid dosage form and examining its features might be the future scope of this study.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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