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TITLE OF INVENTION	MUCOADHESIVE MICROSPHERES OF ABACAVIR SULPHATE
FIELD OF INVENTION	CHEMICAL
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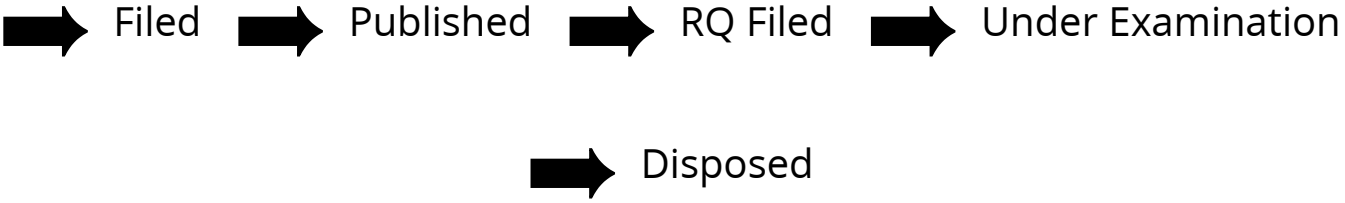

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(57) Abstract :
The present invention relates to the formulation and evaluation of abacavir sulphate mucoadhesive microspheres using sodium alginate with carbopol 934, chitosan and mucilages isolated from bhendi. The orifice ionic gelation technique was used for preparation of mucoadhesive microspheres of abacavir sulphate. The prepared batches of microspheres were evaluated for particle size, particle shape, surface morphology, FTIR study, encapsulation efficiency, swelling ratio, in vitro wash off test and in vitro drug release. The release rates were studied by using dissolution software PCP Disso V3. The optimized formulation showed controlled drug release at the end of desired period with maximum microencapsulation efficiency and excellent mucoadhesive property.

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FORM 2

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COMPLETE SPECIFICATION

(See section 10 and rule13)

TITLE OF THE INVENTION

MUCOADHESIVE MICROSPHERES OF ABACAVIR SULPHATE

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The following specification particularly describes the invention and the manner in which it is to be performed

FIELD OF INVENTION

The present invention relates to a formulation and evaluation of mucoadhesive microspheres of abacavir sulphate by Orifice ionic gelation method.

BACKGROUND OF THE INVENTION

Oral drug delivery systems have advance from immediate release to site specific delivery over a period of time. Oral drug delivery is the most acceptable and liked better technique of administering therapeutic substances for their systemic effects. The oral medication is generally considered as the first avenue investigated in the discovery and development of new drug entities and pharmaceutical formulations, mainly because of patient satisfaction, easy in administration, and inexpensive in manufacturing.

Novel drug delivery system (NDDS) can precisely limit the release rate or target drugs to a specific body site have had an maximum impact on the healthcare field. Microspheres constitute an important part of these particulate drug delivery systems by virtue of their smallest size and efficient loading characteristics. However, the success of these NDDS is limited due to their low residence time at the site of absorption. It would, therefore, be advantageous to have means for providing an intimate contact of the novel drug delivery systems with absorbing membranes. Coupling mucoadhesion characteristics to microspheres and developing novel delivery systems as mucoadhesive microspheres.

Mucoadhesive drug delivery systems (MDDS) are one of the novel drug delivery system, which utilize the property of bioadhesion of polymers that become adhesive on hydration. MDDS can be utilized for targeting a drug to a particular region of the body for controlled period of duration. Bioadhesion is an interfacial phenomenon in which two materials, at least one of which is biological, are held together by means of interfacial forces. The attachment could be between an

artificial material and biological substrate such as adhesion between a polymer and biological membrane. Mucoadhesive materials have been investigated and identified. These are generally hydrophilic macromolecules which contain maximum hydrogen bond forming groups (Ex- hydroxyl and carboxyl groups) and will hydrate and swell when placed in contact with aqueous. In many cases these materials require wetting to become adhesive.

Mucoadhesive microspheres can be tailored to adhere any mucosal tissue including those found in eye, nasal cavity, urinary and gastrointestinal tract, thus offering the feasibility of localized as well as systemic controlled release of drugs.

The following prior art is being reported:

EP3334419: The present invention describes a fixed dose oral formulation of a triple HIV antiviral combination of abacavir (notably abacavir sulphate), lamivudine and efavirenz, useful in the treatment of HIV infections. The described formulations combine a number of valuable use attributes, including reduction of mouth burning effect caused by efavirenz as well as for providing of palatable formulations for high drug loaded system that is important for a triple fixed dose combination, without however to the detriment of dissolution properties for each active ingredient. The present invention is differ from this as it involves the mucoadhesive microsphere preparation of abacavir sulphate.

CN109142723 : The invention provides an HIV (human immunodeficiency virus) human antibody and HIV antigen rapid test card, comprising a bottom plate, a sample pad, a nitrocellulose membrane, a water-absorbing pad and a fluorescent microsphere pad, wherein the fluorescent microsphere pad adsorbs type I HIV antigen-marked fluorescent microspheres, type II HIV antigen-marked fluorescent microspheres, p24 antibody-marked fluorescent microspheres and quality control protein-marked fluorescent microspheres; the nitrocellulose membrane sequentially adsorbs type I HIV antigens, II type HIV antigens, p24 antibodies and antibodies against quality control proteins. In

addition, the invention also provides a preparation method of the card herein, application of the card herein in the rapid test of HIV human antibodies and antigens, and the like.

OBJECTS OF THE INVENTION

Some of the objects of the present disclosure, which at least one embodiment herein satisfies, are as follows.

It is an object of the present disclosure to ameliorate one or more problems of the prior art or to at least provide a useful alternative

An object of the present disclosure is to provide a formulation and evaluation of mucoadhesive microspheres of abacavir sulphate.

Another object of the present disclosure is orifice ionic gelation technique was used for preparation of mucoadhesive microspheres of abacavir sulphate.

Still another object of the present disclosure is application of mucilage isolated from bhendi as natural polymer.

Another object of the present disclosure is to reduce the dosing frequency of the drug.

Still another object of the present disclosure is the prepared formulation is novel and safer and releases the drug for prolonged period of time.

Other objects and advantages of the present disclosure will be more apparent from the following description, which is not intended to limit the scope of the present disclosure.

SUMMARY OF THE INVENTION

The following presents a simplified summary of the invention in order to provide a basic understanding of some aspects of the invention. This summary is not an extensive overview of the present invention. It is not intended to identify the key/critical elements of the invention or to delineate the scope of the invention. Its sole purpose is to present some concept of the invention in a simplified form as a prelude to a more detailed description of the invention presented later.

The present invention is generally directed to the formulation and evaluation of mucoadhesive microspheres of abacavir sulphate by Orifice ionic gelation method.

An embodiment of the present invention is to formulate and evaluate abacavir sulphate mucoadhesive microspheres using sodium alginate with carbopol 934, chitosan and mucilage's isolated from bhendi. Wherein the orifice ionic gelation technique was used for preparation of mucoadhesive microspheres of abacavir sulphate, totally 5 batches of formulations viz., B-1 to B-5 were prepared

An embodiment of the present invention is prepared microspheres were evaluated for particle size, particle shape, surface morphology, FTIR study, encapsulation efficiency, swelling ratio, *in vitro* wash off test and *in vitro* drug release. The release rates were studied by using dissolution software PCP Disso V3.

Another embodiment of the invention is results revealed that by the usage of mucilage isolated from bhendi which could helpful for the controlled release of abacavir sulphate over the period of 12 hrs.

Another embodiment of the invention is the *In vitro drug* release of B-1 formulation indicate the best fit model was found to be korsemeyer peppas with 'n' value was 0.6998 suggests the release mechanism was non-fickanian

(Anomalous transport) i.e. drug released by erosion followed by diffusion mechanism and the B-1 formulation showed controlled drug release at the end of desired period with maximum microencapsulation efficiency and excellent mucoadhesive property.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1: Comparative FTIR spectra of abacavir sulphate, sodium alginate, carbopol 934, chitosan, bhendi mucilage B-1 to B-5 mucoadhesive microspheres.

Figure 2: Particle size analysis of abacavir sulphate mucoadhesive microspheres.

Figure 3: Digital photographs of B-1 to B-5 mucoadhesive microspheres and SEM photographs of B-1 formulation.

Figure 4: Swelling ratio of B-1to B-5 mucoadhesive microspheres formulations.

Figure 5: *In vitro* wash off test for B-1 to B-5 mucoadhesive microspheres formulations.

Figure 6: Comparative *In vitro* drug release for B-1 to B-5 formulations.

DETAILED DESCRIPTION OF THE INVENTION

The following description is of exemplary embodiments only and is not intended to limit the scope, applicability or configuration of the invention in any way. Rather, the following description provides a convenient illustration for implementing exemplary embodiments of the invention. Various changes to the described embodiments may be made in the function and arrangement of the elements described without departing from the scope of the invention.

BIOLOGICAL SOURCES

Bhendi was purchased from local market, Raichur, Karnataka.

Acquired immune deficiency syndrome (AIDS) is a degenerative disease of the immune system caused by the human immunodeficiency virus (HIV). Abacavir sulphate is a nucleoside analog reverse transcriptase inhibitor. It performs by lowering the growth of HIV. Abacavir sulphate has short half life of about 1.54 ± 0.63 hour and hence, required multiple administration doses. To decrease the dosing frequency of drug, it's necessary to revising a newer and safer formulation which release drug to the body for complete and prolonged duration.

EXAMPLE 1: Preparation of bhendi mucilage

The mucilage from the selected parts of the plants was isolated by conventional method. The 50g of dried bhendi powder was soaked in 150 ml distilled water for 24 hrs in a RB flask. Further, it was boiled for 1 hrs under reflux with occasional stirring and kept aside for 2 hrs for the release of mucilage into distilled water. The material was filtered through a muslin bag and hot distilled water (25 ml) was added through the sides of the marc and squeezed well in order to remove the mucilage completely. Concentrate the aqueous filtrate to 1/3rd of its volume then to this added equal volume of ethanol to precipitate the mucilage. The obtained precipitate is kept in a refrigerator for overnight for effective settling. After complete settling of the precipitate it was filtered and dried the residue at 37º C. The obtained dried powder was subjected for identification test to confirm its identity.

EXAMPLE 2: Preparation of mucoadhesive microspheres by Orifice ionic gelation method

Sodium alginate and mucoadhesive polymer carbopol 934 and chitosan were dissolved in purified water (10ml) separately. Then both the solutions were mixed to form homogeneous polymer solution. The drug was added to the polymer solution and mixed thoroughly with help of mortar and pestle to form viscous dispersion. The resulting dispersion was added drop wise into 10% w/v calcium

chloride solution (100ml) through a syringe with needle no 24 with continuous stirring at 500 rpm. The added droplets were retained in the calcium chloride solution for 15 minutes to produce spherical rigid microspheres. The microspheres were collected by decantation and the product thus separated was washed repeatedly with distilled water and dried at 45^0 C for 12 hrs and stored in desiccators. Similarly, mucoadhesive microspheres prepared by dissolving required quantity of sodium alginate and mucoadhesive polymer mucilage isolated from the natural source in distilled water. Then drug is added to polymeric solution and mixed thoroughly with help of mortar and pestle to get viscous dispersion. Then follow the procedure as mentioned above. The various formula is listed in table 1.

Table 1: Formula for abacavir sulphate mucoadhesive microspheres.

Batches	**Abacavir sulphate (mg)**	**Sodium alginate (mg)**	**Carbopol 934 (mg)**	**Chitosan (mg)**	**Bhendi (mg)**
B-1	500	500	500	--	--
B-2	500	500	--	500	--
B-3	500	500	--	--	500
B-4	500	500	250	--	250
B-5	500	500	--	250	250

EXAMPLE 3: **Production yield**

The dried microspheres of each batch are weighed separately and percentage yield is calculated by using following equation.

$$\% \textbf{ Yield} = \frac{\textbf{Practical weight}}{\textbf{Theoretical weight}} \times \textbf{100}$$

The production yield of all the batches were shown in table.2. The production yields were in the range of 95.30 ± 0.730 to 97.47 ± 0.78 for B-1 to B-5

formulations. The production yield was manageable with little loss of drug during the formulation stage. The method found to be reproducible

EXAMPLE 4: Estimation of drug content

50 mg of mucoadhesive microspheres were weighed and powdered. This was dissolved or extracted in methanol in 100 ml volumetric flask and made up to volume. The solution was shaken occasionally for 1hrs and filtered. From this 1ml of solution was diluted up to 100 ml with pH 7.2 phosphate buffer solution in 100 ml volumetric flask. The drug content was analyzed by measuring absorbance in a UV spectrophotometer at 217 nm using pH 7.2 phosphate buffer as a blank. The studies were carried out in triplicate.

The percentage drug content of all the batches were shown in table.2. The percentage drug content were in the range of 91.54 ± 0.069 to 98.25 ± 0.661 for B-1 to B-5 formulations with low SD value indicating uniform distribution of drug within the various batches of microspheres prepared with a negligible loss during the formulation stage.

EXAMPLE 5 : Encapsulation efficiency

100 mg of mucoadhesive microspheres were accurately weighed. They were powdered and extracted with 100 ml of methanol. Further it was serially diluted with pH 7.2 phosphate buffer solution. The resulting solution was analyzed for abacavir sulphate drug content by measuring absorbance in a UV spectrophotometer at 217 nm using pH 7.2 phosphate buffer as a blank. The studies were carried out in triplicate. Encapsulation efficiency (%) was calculated using the formula.

$$\textbf{Encapsulation efficiency} = \frac{\textbf{Actual drug content}}{\textbf{Theoretical drug content}} \times \textbf{100}$$

The percentage encapsulation efficiency of all the batches were shown in table.2. The percentage encapsulation efficiency were found in the range 75.44 ± 0.370 to

91.99 ± 0.267 for B-1 to B-5 formulations found within the specified limits. The mucoadhesive microspheres prepared with synthetic polymer carbopol 934 and natural polymer chitosan and mucilage isolated from bhendi. Chitosan showed higher drug encapsulation efficiency than the mucilages isolated from natural source bhendi. This could be attributed due to formation of larger microspheres with synthetic polymer than the natural polymers, thus entrapping more amount of drug table 2

Table 2: Evaluation data of abacavir sulphate mucoadhesive microspheres.

Batches	**Percentage of production yield**	**Percentage of drug content**	**Percentage of encapsulation efficiency**
B-1	97.47 ± 0.728	98.26±0.661	85.51±0.085
B-2	95.30 ± 0.730	91.54±0.069	91.99±0.267
B-3	95.40 ± 0.980	96.08±0.144	75.44±0.370
B-4	96.58 ± 0.856	97.84±0.288	79.25±0.259
B-5	97.47 ± 0.783	95.92±0.260	85.18±0.295

EXAMPLE 6; FTIR studies

The FTIR spectra of pure drug abacavir sulphate, polymers viz., sodium alginate, carbopol 934, chitosan, mucilage isolated from *hibiscus esculantus L* and compatibility between pure drug and polymers measured at 4000 cm^{-1} to 500 cm^{-1} using BRUKER-FTIR spectrophotometer. Small amount of finely ground solid samples under the study were added to 100 times of its weight of KBr and

compressed using hydraulic press to get a thin transparent pellet. These pellets are transferred to FTIR instrument to determine the spectra.

The characteristic abacavir sulphate FTIR bands are -OH stretching at 3351.68 cm^{-1}, -NH stretching at 3103.85 cm^{-1}, -NH bending at 1663.00 cm^{-1} and -C-N stretching at 1344.00 cm^{-1}. The characteristics FTIR stretching bands of B-1 to B-5 were shifting towards lower/higher wavelength and few were superimposed with that of abacavir sulphate indicate the no interaction or minor at molecular level suggest the polymers added were compatible with the drug. Figure 1shows the Comparative FTIR spectra of abacavir sulphate, sodium alginate, carbopol 934, chitosan, bhendi mucilage

EXAMPLE 7: Size analysis of microspheres

The microspheres were analyzed for its size and distribution by sieving method**.** Different sizes in a batch are separated by sieving using a range 16/22, 22/44 of standard sieves and the quantity retained on different sieves were weighed. Studies were carried out in triplicate. The average sizes of the microspheres were calculated by using the equation.

$$\mathbf{D_{Avg}} = \frac{\sum \mathbf{Xifi}}{\mathbf{fi}}$$

Where,

$\mathbf{X_i}$**-** is the mean size of the range

$\mathbf{F_i}$-is the percent material retained on the smaller sieve in the size range.

The microspheres were distributed for B-1 to B-5 in the range of 787.27 to 800.17μm formulations found within the specified sizes (figure 2). The size of microspheres is depending upon concentration of sodium alginate and polymers used in the formulation.

EXAMPLE 8: Scanning electron microscopy

The particle size, shape and surface morphology of microspheres were examined by scanning electron microscopy (SEM). Microspheres were fixed on aluminium

studs and coated with gold using a sputter coater SC 502, under vacuum [0.1 mm Hg]. The microspheres were then analyzed by SEM. The scanning electron microscopy reveals that the microspheres were spherical, discrete with smooth to rough texture which were shown in figure 3.

EXAMPLE 9: Swelling studies by weight method

A known weight (50mg) of microspheres were placed in basket assembly of dissolution apparatus rotated at 500 rpm in 500 ml of pH 7.2 phosphate buffer solution maintained at 37 ± 0.5^0 C and allowed to swell for the required period of time. The microspheres were periodically removed, blotted with filter paper and their changes in weights were measured during the swelling until equilibrium was attained. Finally, the weight of the swollen microspheres was recorded after a period of 6 hrs, and the swelling ratio (SR) was then calculated from the formula.

$$\textbf{Swelling ratio} = \frac{(\textbf{Mass of swollen microspheres} - \textbf{Mass of dried microspheres})}{\textbf{Mass of dried microspheres}}$$

The swelling depends upon the polymer concentration, ionic strength as well presence of water. The swelling ratio of all the batches were shown in figure 4. The swelling ratio was found in the range of 1.8 to 2.0 for B-1 to B-5 formulations at the end of 6 hrs

EXAMPLE 10: *In vitro* wash off test

The mucoadhesive property of microspheres was evaluated by an *in vitro* adhesion testing method known as wash off method**.** Freshly excised piece of intestinal mucosa (2 x 2 cm) from sheep were mounted onto glass slides (3 x 1 inch) with cyanoacrylate glue. Two glass slides were connected with a suitable support, about 50 microspheres were spread on to each wet rinsed tissue specimen and immediately thereafter the support was hung onto the arm of a USP tablet disintegrating test machine. When the disintegrating test machine was operated, the tissue specimen was given slowly, regular up and down moment in the test

fluid (500ml pH 7.2 phosphate buffer) maintained at 37º C. At the end of 30 min, 1 hrs and hourly intervals upto 6 hrs, the number of microspheres adhering to tissue were counted.

The percentage of microspheres retained on everted intestinal mucosa after 6 h was found in the range of 62 % to 66 % for B-1 to B-5 formulations. The results of all the batches were shown in figure 5. The *in vitro* wash off test results suggests that in all formulations the mucoadhesive property increases/decreases due to the presence of sodium alginate and mucoadhesive polymers. The results clearly showed better mucoadhesive property in mucoadhesive microspheres prepared with mucilage isolated from natural source when compared to synthetic polymers.

EXAMPLE 11: Dissolution studies

In vitro drug release studies were carried out for abacavir sulphate mucoadhesive microspheres using USP type I apparatus (basket). In each case mucoadhesive microspheres equivalent to 100 mg of abacavir sulphate, filled in hard gelatin capsules were used for estimation. Initially the dissolution is carried out in 900 ml of 0.1N HCl for 4 hrs, replace the dissolution medium with pH 6.8 buffer solution and continue the dissolution studies for 6 hrs and then replace the dissolution medium with pH 7.2 buffer solution and continue the dissolution studies for 12 hrs at 60 RPM and temperature is 37 ± 0.5º C maintained throughout the dissolution period. A sample of 5 ml was withdrawn at different intervals of time and transfers same with fresh fluid to maintain the sink condition. The drug release at different time intervals was measured at 217 nm using a double beam UV spectrophotometer. The *in vitro* dissolution data of oral mucoadhesive microspheres were tabulated and computed by using dissolution software viz., **PCP DISSO V 3.0.**

The *in vitro* drug release rate from all the formulations were shown in table 3 and figure 6. The *in vitro* drug release rate from all the formulations was found to be

optimum. Among all formulations B-1 formulation showed controlled and better release with respect to the time when compared to remaining all formulations. The dissolution profiles suggest there is significant difference in the release rate of all these formulations. Further dissolution data were subjected for model fitting by using dissolution software PCP Disso V3. The results of model fitting dissolution software were shown in table 4.

Table 3: *In vitro* dissolution profile for B-1 to B-5 formulations.

Cumulative percentage drug release* ± SD					
Time (h)	**B-1**	**B-2**	**B-3**	**B-4**	**B-5**
0.25	5.02 ±0.37	4.34 ±0.18	7.98±0.21	6.06±0.12	4.78±0.14
0.5	8.09 ±0.07	9.44 ±0.18	11.56±0.21	12.50±0.18	9.44±0.14
0.75	11.57 ±0.24	14.47 ±0.14	15.55±0.27	17.79±0.25	15.37±0.07
1	13.94 ±0.30	18.63 ±0.07	17.60±0.25	23.49±0.25	19.99±0.12
1.5	20.27 ±0.27	22.30 ±0.24	20.35±0.12	27.04±0.20	23.44±0.07
2	23.58 ±0.07	26.64 ±0.12	24.25±0.12	31.32±0.20	27.43±0.13
2.5	31.10 ±0.24	30.14 ±0.18	29.62±0.18	34.85±0.12	30.94±0.07
3	34.07 ±0.20	33.40 ±0.18	34.41±0.12	39.22±0.07	35.38±0.07
3.5	37.24 ±0.96	37.58 ±0.07	39.34±0.46	44.57±0.24	37.73±0.13
4	38.35 ±0.20	41.65 ±0.30	42.78±0.46	48.64±0.07	41.16±0.13
4.5	40.13 ±0.17	44.13 ±0.23	47.15±0.40	52.70±0.66	46.09±0.07
5	42.56 ±0.13	48.07 ±0.07	49.84±0.45	55.47±0.52	49.35±0.17
5.5	45.96 ±0.11	51.60 ±0.28	53.81±0.47	59.32±0.28	54.17±0.06
6	48.29 ±0.28	56.41 ±0.06	56.53±0.23	63.64±0.26	58.64±0.06
7	56.99 ±0.45	64.07 ±0.06	64.09±0.61	70.93±0.23	66.69±0.06
8	61.31 ±0.55	69.08 ±0.06	70.48±0.40	74.58±0.17	71.02±0.13
9	65.23 ±0.35	73.21 ±0.13	75.21±0.33	79.37±0.35	76.49±0.06
10	67.26 ±0.33	76.35 ±0.06	80.52±0.33	82.69±0.55	81.60±0.25
11	71.56 ±0.44	81.53 ±0.12	84.07±0.32	87.44±0.12	86.21±0.19

12	75.77 ±0.12	85.25 ±0.37	87.09±0.11	93.80±0.34	90.01±0.16

Table 4: Model fitting values for B-1 to B-5 formulations.

Batch Code	Zero order	1st order	Matrix	Hix. Crow	Peppas	n	Best fit model
B-1	0.9393	0.9956	0.9847	0.9871	0.9966	0.6998	Peppas
B-2	0.9519	0.9948	0.9815	0.9962	0.9933	0.7146	Hix Crow
B-3	0.9548	0.9927	0.9803	0.9976	0.9968	0.6433	Hix Crow
B-4	0.9226	0.9800	0.9907	0.9928	0.9933	0.6537	Peppas
B-5	0.9578	0.9855	0.9789	0.9968	0.9937	0.7108	Hix Crow

The formulation B-1 best fit model were found to be korsemeyer peppas with exponent `n` value was found to be 0.6998. From the kinetic studies reveals that the best fit model was found to be korsemayer peppas exponential $n<0.5$ and $n>1.0$ indicate the release mechanism was non-fickanian (Anomalous transport) i.e. drug released by erosion followed by diffusion mechanism

While considerable emphasis has been placed herein on the specific features of the preferred embodiment, it will be appreciated that many additional features can be added and that many changes can be made in the preferred embodiment without departing from the principles of the disclosure. These and other changes in the preferred embodiment of the disclosure will be apparent to those skilled in the art from the disclosure herein, whereby it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the disclosure and not as a limitation.

We Claim,

1. A method of preparation of mucoadhesive microsphere of Abacavir sulphate comprising of:

i. preparation of bhendi mucilage; and
ii. preparation of mucoadhesive microspheres.

2. The method of preparation of bhendi mucilage as claimed in claim 1, wherein the method comprising of:

i. soaking of 50 g of dried bhendi powder in 150 ml of distilled water;
ii. boiling the contents for 1hr under reflux;
iii. keeping it aside for 2hrs;
iv. filtering the contents through a muslin bag;
v. precipitating the contents with the help of ethanol from the concentrated aqueous filtrate;
vi. refrigerating the precipitate for overnight; and
vii. finally, precipitate was filtered followed by drying the residue at 37C.

3. The method of preparation of mucoadhesive microspheres claimed in claim 1, wherein the amounts comprising of:

i. abacavir sulphate is 500 mg;
ii. sodium alginate is 500 mg;
iii. carbopol 934 is 250 to 500 mg;
iv. chitosan is 250 to 500 mg; and
v. bhendi mucilage is 250 to 500 mg.

Dated this 6 September 2021

Dr. Amrish Chandra

Agent of the applicant

IN/PA No: 2959

TITLE: MUCOADHESIVE MICROSPHERES OF ABACAVIR SULPHATE

ABSTRACT

The present invention relates to the formulation and evaluation of abacavir sulphate mucoadhesive microspheres using sodium alginate with carbopol 934, chitosan and mucilages isolated from bhendi. The orifice ionic gelation technique was used for preparation of mucoadhesive microspheres of abacavir sulphate. The prepared batches of microspheres were evaluated for particle size, particle shape, surface morphology, FTIR study, encapsulation efficiency, swelling ratio, in vitro wash off test and in vitro drug release. The release rates were studied by using dissolution software PCP Disso V3. The optimized formulation showed controlled drug release at the end of desired period with maximum microencapsulation efficiency and excellent mucoadhesive property.

FORM 5
THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENTS RULES, 2003
DECLARATION AS TO INVENTORSHIP
[*See* section 10 (6) and rule 13 (6)]

NAME OF APPLICANT(S)

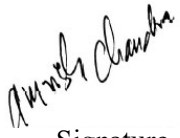
Name in Full	Dr. Srikanth
Nationality	Indian
Country of Residence	India
Address of the Applicant	Assistant Professor, Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin code: 584103, Karnataka, India.
Name in Full	Dr. Shubhrajit Mantry
Nationality	Indian
Country of Residence	India
Address of the Applicant	Associate Professor, HOD, Department of pharmaceutics, Sharadchandra Pawar College of pharmacy, Dumberwadi, Khamundi, Pune, Pin Code: 410504, Maharashtra, India.
Name in Full	Mr. Basangouda Malipatil
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Prashant Chitralu
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Ms. Meghana VKodler
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutical Chemistry, V.L. College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Saket Pathak
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, ISF College of Pharmacy, NH 95, Ghal Kalan, Moga, Punjab, Pin Code: 142001, India.

hereby declare that the true and first inventor(s) of the invention disclosed in the complete specification filed in pursuance of my/our application numbered dated is/are

INVENTOR(S)

Name in Full	Nationality	Address of the Inventor
Dr. Srikanth	Indian	Assistant Professor, Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin code: 584103, Karnataka, India.
Dr. Shubhrajit Mantry	Indian	Associate Professor, HOD, Department of pharmaceutics, Sharadchandra Pawar College of pharmacy, Dumberwadi, Khamundi, Pune, Pin Code: 410504, Maharashtra, India.
Mr. Basangouda Malipatil	Indian	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Mr. Prashant Chitralu	Indian	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Ms. Meghana V Kodler	Indian	Department of Pharmaceutical Chemistry, V.L. College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Mr. Saket Pathak	Indian	Department of Pharmaceutics, ISF College of Pharmacy, NH 95, Ghal Kalan, Moga, Punjab, Pin Code: 142001, India.

Dated this 6 September 2021



Signature
Name: Amrish Chandra
(IN/PA 2959)

3. DECLARATION TO BE GIVEN WHEN THE APPLICATION IN INDIA IS FILED BY THE APPLICANT(S) IN THE CONVENTION COUNTRY:—

We the applicant(s) in the convention country hereby declare that our right to apply for a patent in India is by way of assignment from the true and first inventor(s).

Dated this **NOT APLICABLE**

Signature

Name:

4. STATEMENT (to be signed by the additional inventor(s) not mentioned in the application form)
I /We assent to the invention referred to in the above declaration, being included in the complete

specification filed in pursuance of the stated application.

NOT APLICABLE
Dated
Signature of the additional inventor(s):
Name:

To,
The Controller of Patents
The Patent Office, at Chennai

Dr.Srikanth
Dr. Shubhrajit Mantry
Mr. Basangouda Malipatil
Mr. Prashant Chitralu
Ms. Meghana V Kodler
Mr. Saket Pathak

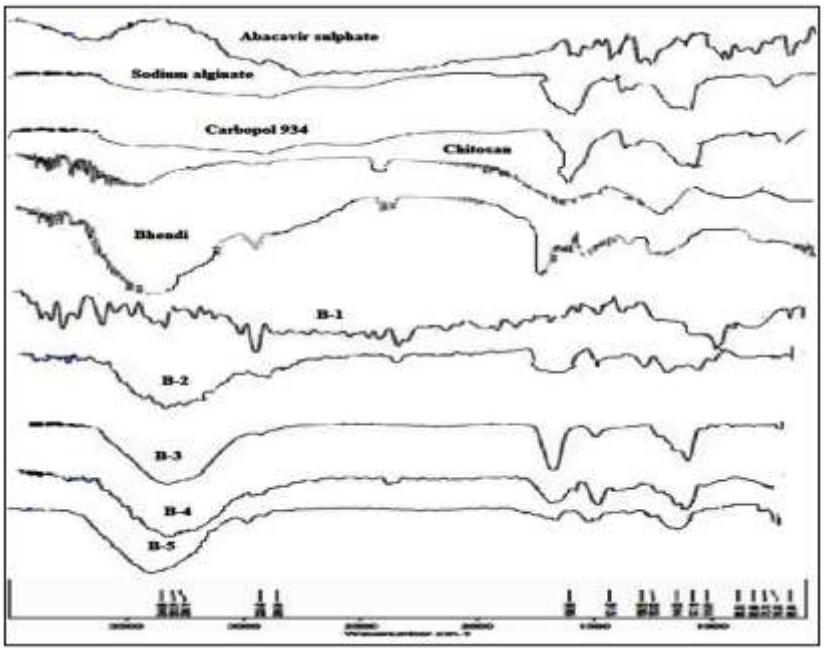


Figure 1

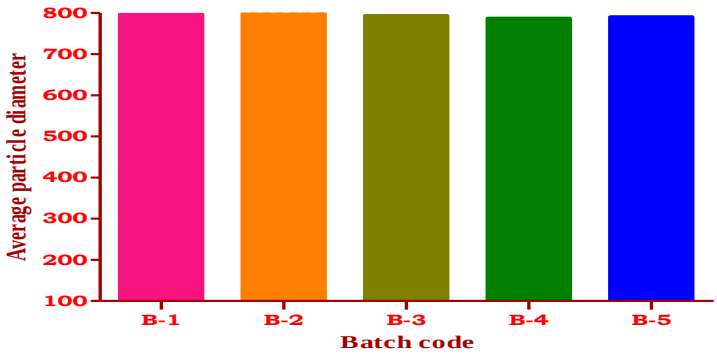


Figure 2

Amrish Chandra
Agent of the Applicant
IN/PA-2975

Dr.Srikanth
Dr. Shubhrajit Mantry
Mr. Basangouda Malipatil
Mr. Prashant Chitralu
Ms. Meghana V Kodler
Mr. Saket Pathak

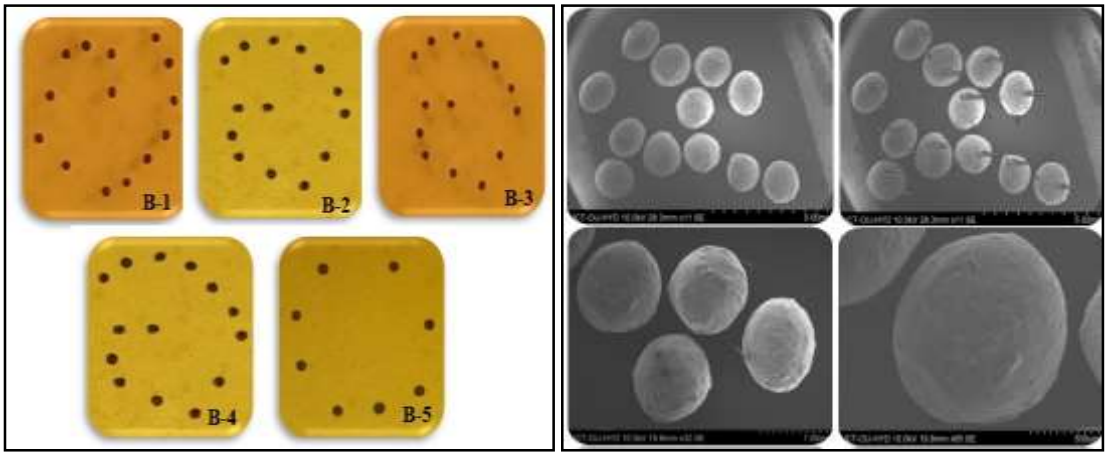


Figure 3

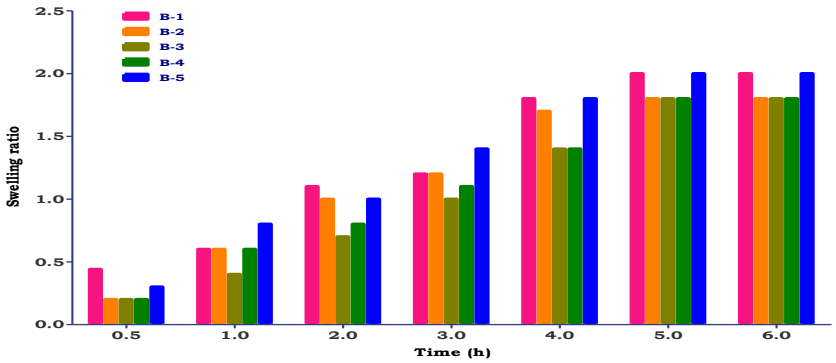


Figure 4

Amrish Chandra
Agent of the Applicant
IN/PA-2959

Dr.Srikanth
Dr. Shubhrajit Mantry
Mr. Basangouda Malipatil
Mr. Prashant Chitralu
Ms. Meghana V Kodler
Mr. Saket Pathak

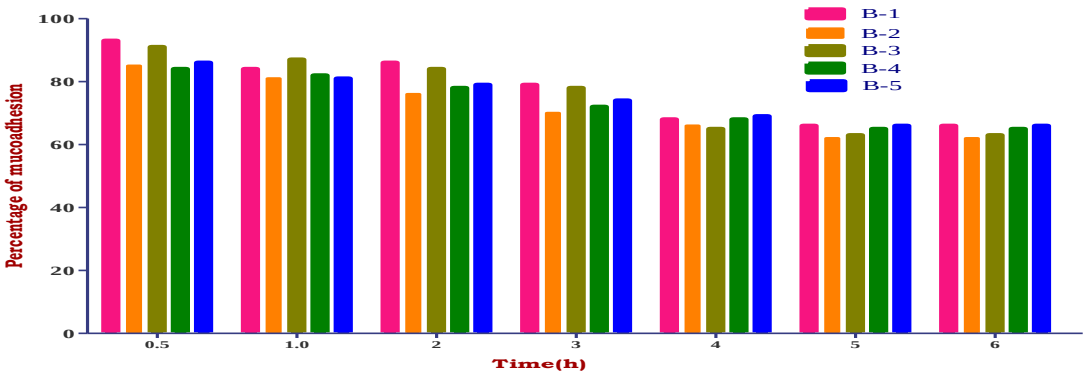


Figure 5

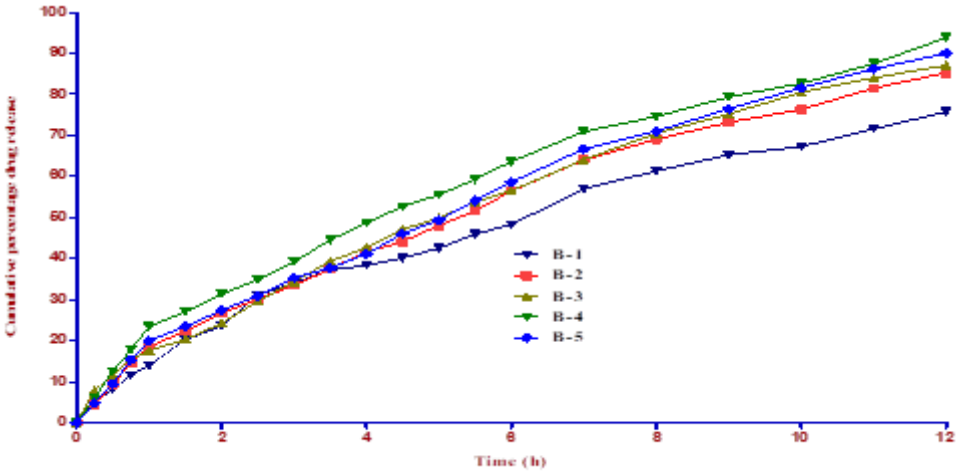


FIGURE 6

Amrish Chandra
Agent of the Applicant
IN/PA-2959

"**FORM 1** THE PATENTS ACT 1970 (39 of 1970) and THE PATENTS RULES, 2003 **APPLICATION FOR GRANT OF PATENT** (See section 7, 54 and 135 and sub-rule (1) of rule 20)	(FOR OFFICE USE ONLY)

	Application No.	
	Filing date:	
	Amount of Fee paid:	
	CBR No:	
	Signature:	
1. APPLICANT'S REFERENCE / IDENTIFICATION NO. (AS ALLOTTED BY OFFICE)		

2. TYPE OF APPLICATION [Please tick (√) at the appropriate category]

Ordinary (√)		Convention ( )		PCT-NP ( )	
Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )

3A. APPLICANT(S)			
Name in Full	**Nationality**	**Country of Residence**	**Address of the Applicant**
Dr. Srikanth	Indian	India	Assistant Professor, Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin code: 584103, Karnataka, India.
Dr. Shubhrajit Mantry	Indian	India	Associate Professor, HOD, Department of pharmaceutics, Sharadchandra Pawar College of pharmacy, Dumberwadi, Khamundi, Pune, Pin Code: 410504, Maharashtra, India.
Mr. Basangouda Malipatil	Indian	India	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.

Mr. Prashant Chitralu	Indian	India	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Ms. Meghana V Kodler	Indian	India	Department of Pharmaceutical Chemistry, V.L. College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Mr. Saket Pathak	Indian	India	Department of Pharmaceutics, ISF College of Pharmacy, NH 95, Ghal Kalan, Moga, Punjab, Pin Code: 142001, India.

3B. CATEGORY OF APPLICANT [Please tick (√) at the appropriate category]

Natural Person (√) Small Entity ( ) Start up ( ) Others ( )

4. INVENTOR(S) [Please tick (√) at the appropriate category]

Are all the inventor(s) same as the applicant(s) named above? YES

Name in Full	Nationality	Country of Residence	Address of the Inventor
Dr. Srikanth	Indian	India	Assistant Professor, Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin code: 584103, Karnataka, India.
Dr. Shubhrajit Mantry	Indian	India	Associate Professor, HOD, Department of pharmaceutics, Sharadchandra Pawar College of pharmacy, Dumberwadi, Khamundi, Pune, Pin Code: 410504, Maharashtra, India.
Mr. Basangouda Malipatil	Indian	India	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Mr. Prashant Chitralu	Indian	India	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Ms. Meghana V Kodler	Indian	India	Department of Pharmaceutical Chemistry, V.L. College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.

Mr. Saket Pathak	Indian	India	Department of Pharmaceutics, ISF College of Pharmacy, NH 95, Ghal Kalan, Moga, Punjab, Pin Code: 142001, India.

5. TITLE OF THE INVENTION

MUCOADHESIVE MICROSPHERES OF ABACAVIR SULPHATE

6. AUTHORISED REGISTERED PATENT

AGENT(S)
IN/PA No. IN/PA 2959
Name AMRISH CHANDRA
Mobile No. 9971117009

IN/PA No. IN/PA 2700
Name RAMANPREET WALIA

7. ADDRESS FOR SERVICE OF APPLICANT IN INDIA

Name AMRISH CHANDRA
Postal Address T21/1602, PARAS TIEREA, SECTOR 137, NOIDA 201301
Mobile No. 9971117009
E-mail ID info@lexgin.com

8. IN CASE OF APPLICATION CLAIMING PRIORITY OF APPLICATION FILED IN CONVENTION COUNTRY, PARTICULARS OF CONVENTION APPLICATION

Country	Application Number	Filing date	Name of the applicant	Title of the invention	IPC (as classified in the convention

9. IN CASE OF PCT NATIONAL PHASE APPLICATION, PARTICULARS OF INTERNATIONAL APPLICATION FILED UNDER PATENT CO-OPERATION TREATY (PCT)

International application number	International filing date

10. IN CASE OF DIVISIONAL APPLICATION FILED UNDER SECTION 16, PARTICULARS OF ORIGINAL (FIRST) APPLICATION

Original (first) application No.	Date of filing of original (first) application

11. IN CASE OF PATENT OF ADDITION FILED UNDER SECTION 54, PARTICULARS OF MAIN APPLICATION OR PATENT

Main application/patent No.	**Date of filing of main application**

12. DECLARATIONS

(i) Declaration by the inventor(s)

(**In case the applicant is an assignee**: the inventor(s) may sign herein below or the applicant may upload the assignment or enclose the assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period).

I/We, the above named inventor(s) is/are the true & first inventor(s) for this Invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

Surname Name	**Signature**
Dr. Srikanth	
Dr. Shubhrajit Mantry	
Mr. Basangouda Malipatil	
Mr. Prashant Chitralu	
Ms. Meghana V Kodler	
Mr. Saket Pathak	

Date 6 September 2021

(ii) Declaration by the applicant(s) in the convention country

(In case the applicant in India is different than the applicant in the convention country: the applicant in the convention country may sign herein below or

applicant in India may upload the assignment from the applicant in the convention country or enclose the said assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period)

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

(a) Date
(b) Signature(s) **NOT APPLICABLE**
(c) Name(s) of the signatory

(iii) Declaration by the applicant(s)

I/We the applicant(s) hereby declare(s) that: -

√ I am/ We are in possession of the above-mentioned invention.

√ The ~~provisional~~/complete specification relating to the invention is filed with this application.

√ The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us.

√ There is no lawful ground of objection(s) to the grant of the Patent to me/us.

√ I am/we are the true & first inventor(s).

x I am/we are the assignee or legal representative of true & first inventor(s).

x The application or each of the applications, particulars of which are given in Paragraph-8, was the first application in convention country/countries in respect of my/our invention(s).

x I/We claim the priority from the above mentioned application(s) filed in convention country/countries and state that no application for protection in respect of the invention had been made in a convention country before that date by me/us or by any person from which I/We derive the title.

x My/our application in India is based on international application under Patent Cooperation Treaty (PCT) as mentioned in Paragraph-9.

x The application is divided out of my /our application particulars of which is given in Paragraph-10 and pray that this application may be treated as deemed to have been filed on DD/MM/YYYY under section 16 of the Act.

x The said invention is an improvement in or modification of the invention particulars of which are given in Paragraph-11.

13. FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION

(a) Form 2

Item	Details	Fee	Remarks
Complete/ ~~provisional~~ specification)#	No. of pages: 14	1600 INR	

No. of Claim(s)	No. of claims: 3 No. of pages: 2		
Abstract	No. of pages: 1		
No. of Drawing(s)	No. of drawings: 6 No. of pages: 3		

In case of a complete specification, if the applicant desires to adopt the drawings filed with his provisional specification as the drawings or part of the drawings for the complete specification under rule 13(4), the number of such pages filed with the provisional specification are required to be mentioned here.

(b) Complete specification (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).

(c) Sequence listing in electronic form

(d) Drawings (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies).

(e) Priority document(s) or a request to retrieve the priority document(s) from DAS (Digital Access Service) if the applicant had already requested the office of first filing to make the priority document(s) available to DAS.

(f) Translation of priority document/Specification/International Search Report/International Preliminary Report on Patentability.

(g) Statement and Undertaking on Form 3

(h) Declaration of Inventorship on Form 5

(i) Power of Authority

I/We hereby declare that to the best of my/our knowledge, information and belief the fact and matters slated herein are correct and I/We request that a patent may be granted to me/us for the said invention.

Dated this 6 September 2021

Signature: 

Name: Amrish Chandra
IN/PA2959

To,
The Controller of Patents
The Patent Office, at
Chennai

FORM 9

THE PATENTS ACT, 1970 (39 of 1970)

&

THE PATENTS RULES, 2003

REQUEST FOR PUBLICATION

[*See* section 11A (2); rule 24A]

I /We

Name in Full	Dr. Srikanth
Nationality	Indian
Country of Residence	India
Address of the Applicant	Assistant Professor, Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin code: 584103, Karnataka, India.
Name in Full	Dr. Shubhrajit Mantry
Nationality	Indian
Country of Residence	India
Address of the Applicant	Associate Professor, HOD, Department of pharmaceutics, Sharadchandra Pawar College of pharmacy, Dumberwadi, Khamundi, Pune, Pin Code: 410504, Maharashtra, India.
Name in Full	Mr. Basangouda Malipatil
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Prashant Chitralu
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Ms. Meghana VKodler
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutical Chemistry, V.L. College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Saket Pathak
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, ISF College of Pharmacy, NH 95, Ghal Kalan, Moga, Punjab, Pin Code: 142001, India.

hereby request for early Publication of my/our Patent application No. dated under section 11A(2) of the Act.

Dated this 6 September 2021

Signature……

Dr. Amrish Chandra

IN/PA 2959

To

The Controller of Patents,

The Patent Office, Chennai

Signature Not Verified

Digitally Signed.
Name: AMRISH CHANDRA
Date: 06-Sep-2021 15:31:41
Reason: Reason : Testing
Location: DELHI

FORM 9

THE PATENTS ACT, 1970 (39 of 1970)

&

THE PATENTS RULES, 2003

REQUEST FOR PUBLICATION

[*See* section 11A (2); rule 24A]

I /We

Name in Full	Dr. Srikanth
Nationality	Indian
Country of Residence	India
Address of the Applicant	Assistant Professor, Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin code: 584103, Karnataka, India.
Name in Full	Dr. Shubhrajit Mantry
Nationality	Indian
Country of Residence	India
Address of the Applicant	Associate Professor, HOD, Department of pharmaceutics, Sharadchandra Pawar College of pharmacy, Dumberwadi, Khamundi, Pune, Pin Code: 410504, Maharashtra, India.
Name in Full	Mr. Basangouda Malipatil
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Prashant Chitralu
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Ms. Meghana VKodler
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutical Chemistry, V.L. College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Saket Pathak
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, ISF College of Pharmacy, NH 95, Ghal Kalan, Moga, Punjab, Pin Code: 142001, India.

hereby request for early Publication of my/our Patent application No. dated under section 11A(2) of the Act.

Dated this 6 September 2021

Signature……

Dr. Amrish Chandra

IN/PA 2959

To

The Controller of Patents,

The Patent Office, Chennai

Signature Not Verified

Digitally Signed.
Name: AMRISH CHANDRA
Date: 06-Sep-2021 15:29:44
Reason: Reason : Testing
Location: DELHI

FORM 3

THE PATENTS ACT, 1970

(39 of 1970) AND
The Patents Rules, 2003

STATEMENT AND UNDERTAKING UNDER SECTION 8

[See section 8; rule 12]

I/We,

Name in Full	Dr. Srikanth
Nationality	Indian
Country of Residence	India
Address of the Applicant	Assistant Professor, Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin code: 584103, Karnataka, India.
Name in Full	Dr. Shubhrajit Mantry
Nationality	Indian
Country of Residence	India
Address of the Applicant	Associate Professor, HOD, Department of pharmaceutics, Sharadchandra Pawar College of pharmacy, Dumberwadi, Khamundi, Pune, Pin Code: 410504, Maharashtra, India.
Name in Full	Mr. Basangouda Malipatil
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Prashant Chitralu
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, V.L.College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Ms. Meghana VKodler
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutical Chemistry, V.L. College of Pharmacy, Raichur, Pin Code: 584103, Karnataka, India.
Name in Full	Mr. Saket Pathak
Nationality	Indian
Country of Residence	India
Address of the Applicant	Department of Pharmaceutics, ISF College of Pharmacy, NH 95, Ghal Kalan, Moga, Punjab, Pin Code: 142001, India.

hereby declare:

(i) that We have not made any application for the same/substantially the same invention outside India

OR

(ii) ~~that we who have made this application No. dated , alone/jointly, made for the same/substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:~~

Name of the Country	Date of Application	Application number	Status of the application	Date of publication	Date of grant

Not applicable

(iii) ~~that the rights in the application(s) has been assigned to~~ NOT APPLICABLE

That I/We undertake that up to the date of grant of patent, by the Controller, I/We would keep him informed in writing the details regarding corresponding applications for patents filed outside India within three months from the date of filing of such application.

Dated this 6 September 2021

Amrish Chandra (IN/PA 2959)
Patent Agent for the Applicant

To,
The Controller of Patents
The Patent Office at Chennai