



Formulation Development and Optimization of Ceramic Nanoparticle for Delivery of Anticancer Drug

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ABSTRACT

Nanoparticles in drug-delivery systems are generated by a variety of research survey. Unique physicochemical characteristics of nanostructured biomaterials include their very small and structural adaptability, high surface area to mass ratio, high reactivity, and controlled size. It enables molecularly focused cancer treatment, targeted administration of early detection of cancer lesions, early detection of cancer lesions, imaging agents, and anticancer medications, identification of tumor molecular factors by non-invasive imaging. These characteristics may be used in medicine to get around some of the drawbacks of conventional treatments. They are employed in vivo to protect the drug entity in the systemic circulation, limit drug access to the targeted areas, and deliver the drug to the site of action at a regulated and sustained pace. It reduces adverse side effects and enables more effective drug use. It must be active and therapeutically effective while in circulation and present at the target location in the right amounts. We will now go through several elements of nanoparticle formulation, the impact of their properties, characterization, and the potential of nanomedicine, improving targeted delivery of therapeutic agents, applications in drug molecule delivery, the development of novel, more powerful diagnostic and screening techniques to expand the boundaries of

molecular diagnostics, and difficulties in synthesis nanoparticle platforms for dispensing various drugs.

Key Words: Ceramic nanoparticles, Dendrimers, Liposomes, Microbes, Polymeric nanoparticles, Solid lipid nano particles.



INTRODUCTION

Materials in the nanoscale range are used as diagnostic instruments or to administer therapeutic compounds to specific targeted regions in a leashed way in the relatively young but quickly evolving field of Nano medicine and Nano delivery systems. These systems are through the targeted and site-specific administration of precise medications. Nanotechnology for several benefits in the treatment of chronic human illnesses. Recent advances in nanomedicine (including, immunotherapeutic agents, biological agents, and chemotherapeutic medicines) for the treatment of different illnesses include several unique applications. The most common ways to give a drug are by mouth or through an IV. The drug is expected to move through the body and affect both unhealthy and healthy cells and organs. It could cause bad things to happen. Trying to find a way to give a drug to an animal so that it has the most effectiveness while causing the fewest side effects is hard to do. The capacity of drugs to get to the site of therapeutic action limits their potential to have an impact.

METHODS

Solubility:

Quantitative solubility tests are performed as a test for purity [1]. Solubility of drug was determined in water and methanol. 10 mg sample was taken in a clean dry test tube and solvent was added gradually in aliquots of 0.1 ml with continuous shaking until it dissolved completely [2].

Melting point:

Melting point is one of the identification test method for organic substances. Hence, it was determined for the sample by capillary method using melting point apparatus (VMP-D, Veego). Small amount of the sample was filled in a capillary tube (closed at one end) and placed in the melting point apparatus.

Infrared Absorption:

Fourier Transform Infrared (FT-IR) is an important complementary tool for the solid-state characterization of pharmaceutical solids [3]. Identification of drug was done by infrared spectroscopy technique using Alpha Bruker FTIR spectrophotometer. The sample was prepared by disc method.

UV- Spectrophotometric

UV spectrophotometric methods have been reported for the estimation of Doxorubicin in formulations [4, 5]. Calibration curves were plotted in methanol: water (50% v/v) and in methanolic phosphate-buffered saline (PBS) (pH 6.4, 40%v/v) as solvents using UV-1800 spectrophotometer (Shimadzu) at 247 nm.

Calibration curve in methanol: water (50 %v/v) as solvent:

The calibration curve of the drug in methanol: water (50 %v/v) as solvent was useful to determine the entrapment efficiency and for analyzing the stability samples.

Calibration curve in methanolic phosphate-buffered saline (pH 6.4, 40%v/v):

The calibration curve was also plotted in methanolic phosphate-buffered saline (pH 6.4, 40%v/v) and regression equation was determined for the release studies of drug from the formulations. The pH was selected based on the nasal mucosal pH (5.5-6.5) and methanol being added to maintain the sink condition [6, 7].

Preparation of Phosphate-buffered saline pH 6.4 [8]:

1.79 g of disodium hydrogen phosphate, 1.36 g of potassium dihydrogen phosphate and 7.02 g of sodium chloride was dissolved in sufficient water to produce 1000 ml. Preparation of stock solutions:

EVALUATION OF OPTIMIZED FORMULATION

Particle size

The average particle size, PDI and zeta potential of the solid lipid nanoparticles were determined using Zetasizer Nanoseries Nano-ZS, Malvern Instruments, Malvern, UK. In-built dynamic light scattering, DLS, and Laser Doppler Electrophoresis were used for the determinations of particle size and for zeta potential.

Entrapment Efficiency

Entrapment efficiency was determined by determining the amount of free drug spectrophotometric ally at 247 nm in the supernatant after centrifugation of the known amount of nanoparticulate dispersion at 10000 RPM using freeze centrifuge (BL – 135 R) for 15 minutes.

**pH:**

pH of the nasal formulations are also important for avoiding the irritation to the nasal mucosa. Hence, the pH of the formulation was determined using pH meter (Li 615, Elico India, Hyderabad) and was compared with the reported pH in nasal cavity.

Viscosity:

Viscosity is also one of the parameter to be evaluated for the in-situ gels. The viscosity of the formulations should be such that it remains convenient during their administration by the patient. Viscosity of the formulation was determined at 25°C (ambient temperature) and 34°C (nasal temperature) using Brookfield viscometer (DV-I Prime).

Mucoadhesive Strength:

The mucoadhesive force was determined using modified two-pan balance method [37]. As per the literature review, in spite of numerous studies concerning the in-vitro and in-vivo performance of mucoadhesive drug delivery systems, surprisingly, there has not been any standard technique designed for mucoadhesive measurement or any analytical method that can be employed to qualify mucoadhesive strength.

RESULT AND DISCUSSION**Major peaks observed and reported for doxorubicin in IR spectra:**

Observed (cm ⁻¹)	Reported (cm ⁻¹)	Inferences [3]
3319.64	3500-3100	N-H stretching
2249.39	2250-2100	C≡C (Alkyne)
1750.06	1750-1730	C=O of ester
1602.59	1680-1630	C=O of amide
1498.33	1350-1000	C-N
1036.16	1300-1000	C-O

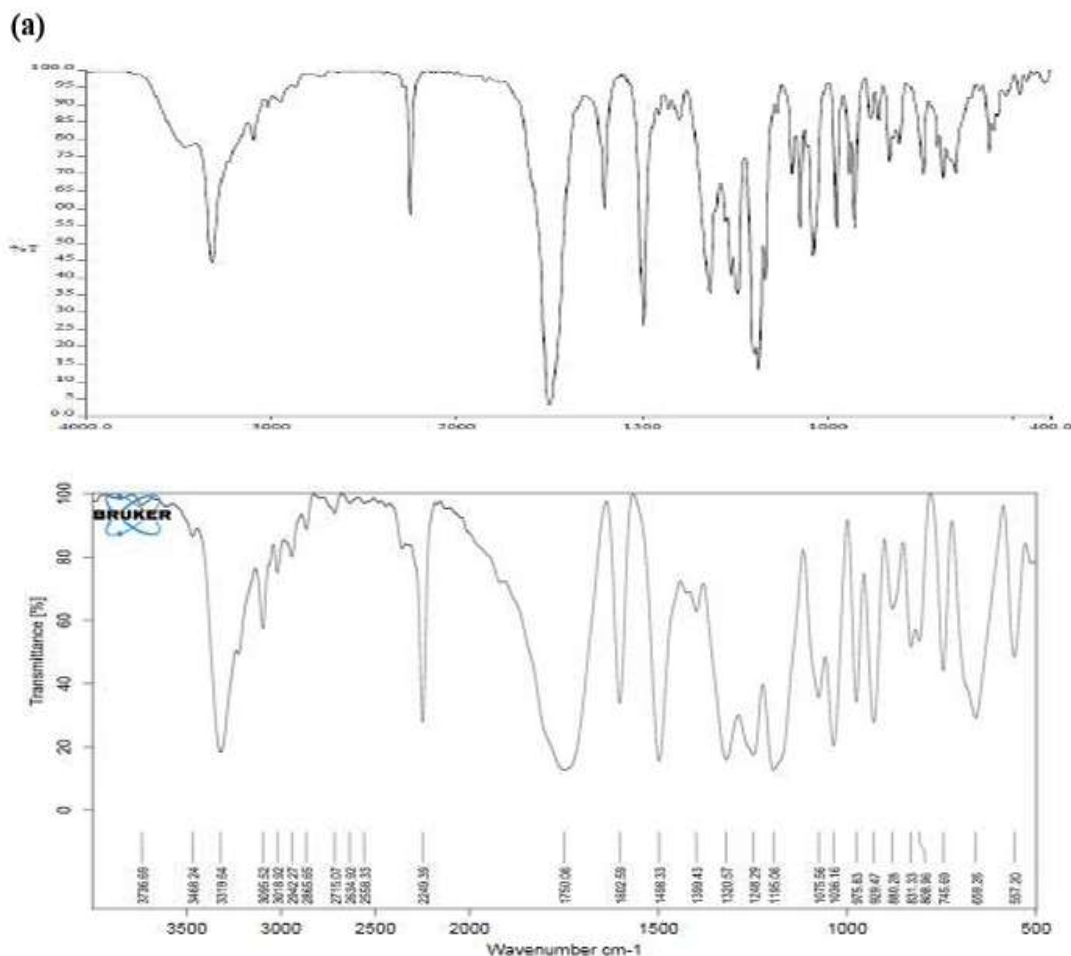


Figure 4.1: IR Spectra (A) Observed Spectra of Doxorubicin (B) Reported Spectra of Doxorubicin

4.2 Analytical Methods

Simple, rapid and reliable analytical methods for the estimation of drug content were required to determine the entrapment efficiency of the formulation, which in turn was needed for selection of right material, optimization of their concentrations, characterization of the optimized formulation and for stability testing. The analytical methods were also needed for the in-vitro and ex-vivo drug release studies and for estimation of drug in plasma and brain post-administration of the formulations.

4.2.1 UV- Spectrophotometric estimation of Doxorubicin

Simple, sensitive, accurate, precise and rapid ultraviolet (UV) spectrophotometric methods have been reported to be developed and validated for the estimation of Doxorubicin in pure form, its formulations and stability samples [4, 5]. Hence, calibration curves were obtained using methanol:water (50% v/v) and methanolic phosphate buffer saline (PBS) (pH 6.4, 40%v/v) as solvents respectively for determining the entrapment efficiency and in-vitro drug release studies.

4.2.1.1 Calibration curve in methanol:water:: 50:50 %v/v as solvent :

Calibration curves were plotted in methanol:water (50% v/v) at 247 nm in the concentration range of 3-18 µg/ml of Doxorubicin using UV- spectrophotometer (UV-1800, Shimadzu) for determining the entrapment efficiency and for analysing the stability samples. The data obtained for calibration curve is shown in Table 4.3 and the overlay spectra of EFV at different concentrations and the calibration curve is shown in Figure 4.3 respectively.



TABLE 4.3: Calibration data for Doxorubicin in methanol: water (50% v/v)

S.No.	Concentration ($\mu\text{g/ml}$)	Mean Absorbance* $\pm$ S.D.
1	3	0.152 ± 0.009
2	6	0.309 ± 0.008
3	9	0.461 ± 0.009
4	12	0.634 ± 0.007
5	15	0.785 ± 0.005
6	18	0.951 ± 0.013

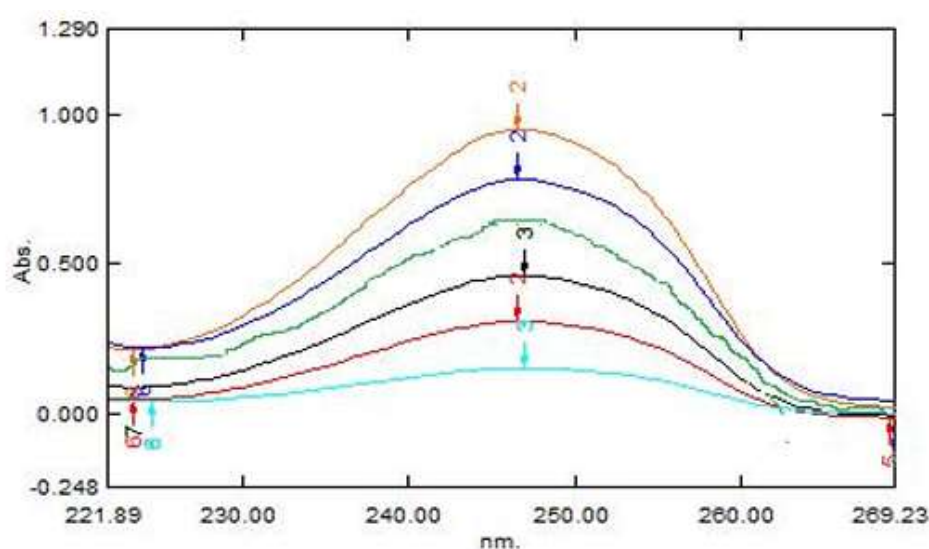


FIGURE 4.3(a): Overlay spectra of Doxorubicin at different concentrations

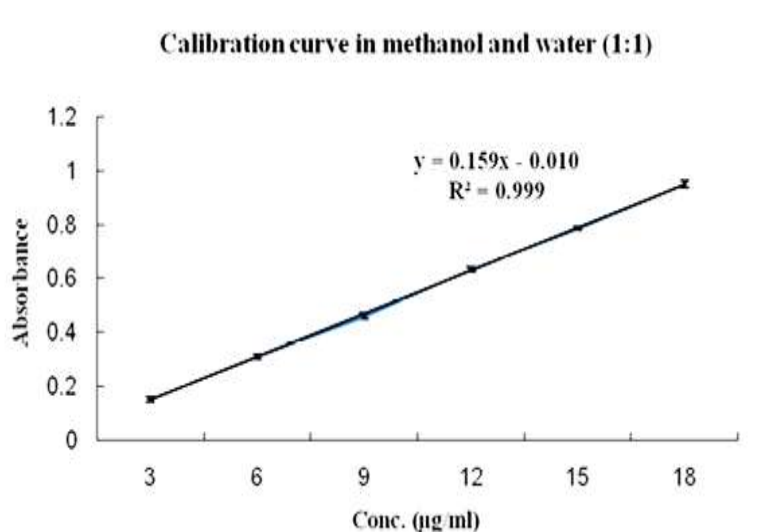


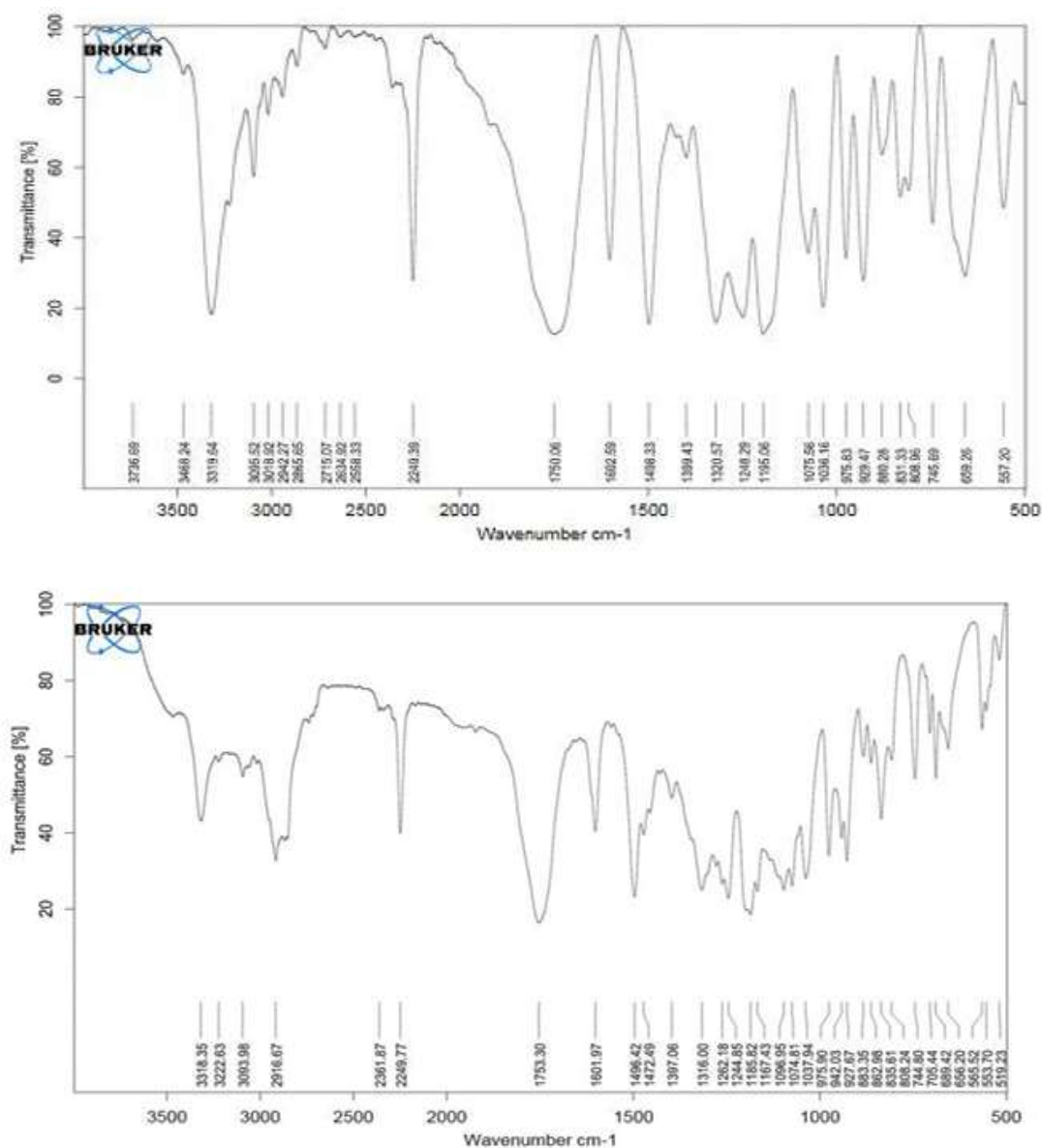
FIGURE 4.3

The calibration curve was found to be linear in the concentration range of 3 – 18 $\mu\text{g/ml}$ with correlation coefficient (R^2) value of 0.999.



Drug-Excipient Compatibility Study

IR spectra of pure drug doxorubicin and the physical mixtures of doxorubicin, tripalmitin and poloxamer 188 are shown in Figure 4.21.



IR spectra of drug and physical mixture of drug and excipients. (a) IR spectrum of drug (doxorubicin) (b) IR spectrum of drug (doxorubicin) + Lipid (Tripalmitin) + Surfactant (Poloxamer 188)

It was observed from Figure 4.21, that all major peaks of the drug were obtained in the IR spectra as shown in Table 4.2 and no significant change was observed in the IR spectra of drug-excipients mixture (Figure 4.21(b)) indicating the compatibility of the drug with the selected excipients [36].



Zero order release:

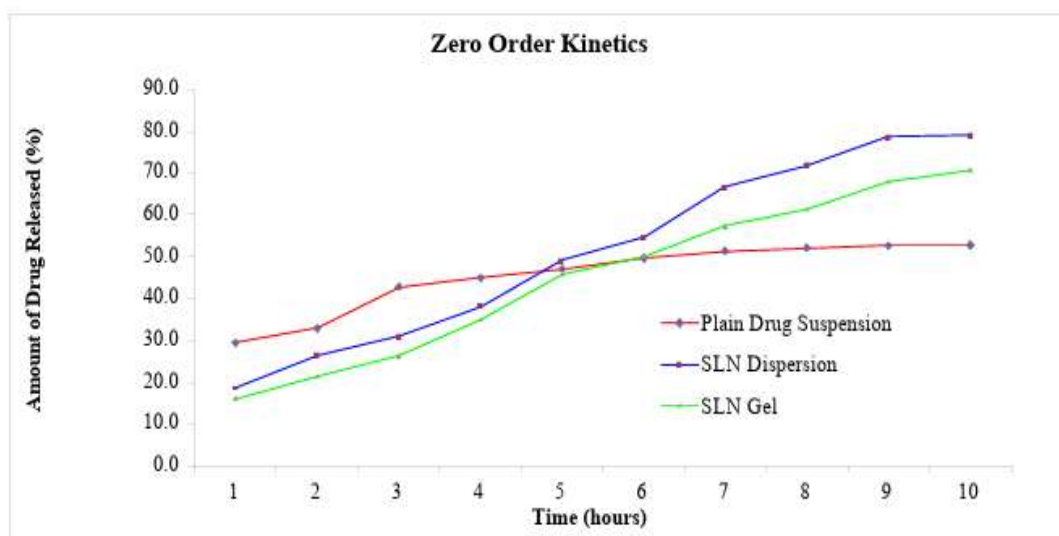


FIGURE 4.31(a): Zero order release kinetics.

SUMMARY

Thus, the main aim of the present investigations were to design and develop nanoparticles of EFV with the objectives of providing increased permeability and protection to drug with biocompatible lipid content, avoid first-pass metabolism and efflux-mechanisms, and select the route of administration to deliver EFV to brain/CNS in order to increase the bioavailability of EFV at the reservoir site of HIV. Suitable analytical methods were selected/developed and validated for determining the entrapment efficiency, in-vitro, ex-vivo drug release profiles and for estimation of EFV in brain and plasma respectively.

CONCLUSION

Nanoparticles in drug-delivery systems are generated by a variety of research survey. Unique physicochemical characteristics of nanostructured biomaterials include their very small and structural adaptability, high surface area to mass ratio, high reactivity, and controlled size. It enables molecularly focused cancer treatment, targeted administration of early detection of cancer lesions, early detection of cancer lesions, imaging agents, and anticancer medications, identification of tumor molecular factors by non-invasive imaging.

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