

# Securing Bone Health with Bisphosphonates during COVID-19 Pandemic

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## Abstract

The work is based on the precision engineering methodology based drug delivery design and nanoformulation development of pamidronate and sesame oil for the treatment of osteoporosis. It is in this context that the COVID-19 pandemic has brought unprecedented disruption to the provision of health care globally, including near universal requirements for social distancing. We provide evidence, where available, regarding the general care of patients with osteoporosis in the COVID-19 era and provide clinical recommendations based primarily on expert opinion when data are absent.

**Keywords:** Postmenopausal osteoporosis • Pamidronate • Complex precision engineering • Nanoformulation • Drug delivery

## Introduction

Osteoporosis emerged as a chronic disease of skeleton system leading to weaken bones and hip fractures making it a burden to the society. During lifetime, one out of every three women and one out of every six males will experience an osteoporotic fracture. Every minute, eight new fracture cases are reported in the EU. In the European Union, it is projected that over 23 million men and women are at high risk of osteoporotic fractures. According to estimates from 2019, osteoporosis and the 4.3 million fragility fractures it generates cost Europe's health care systems more than €56 billion every year. However, numbers alone do not tell the whole story. The stories of those who suffer fractures as a result of the condition are personal. Long term disability, pain, impairment, and reduced movement are very much frequent. Furthermore, some osteoporosis related fractures result in mortality [1].

## Description

### Current scenario of post-menopausal osteoporosis

Currently, it is recognized as a chronic musculoskeletal disease causing reduced bone density and pain due to weaken bones and reduced mobility in elderly patients. In Europe, about a quarter of a million people die each year as a result of hip or spine fractures. Osteoporosis is a chronic, multifaceted condition that can be treated and managed in a variety of ways. During the last 30 years, advances in pharmaceutical and diagnostic procedures have enabled highly effective ways to lower the incidence of osteoporotic fractures. However, research in Europe has revealed significant variety in country

approaches to disease management. Practically in every European country, the expenditures of osteoporosis and fragility fractures have increased dramatically in the last ten years when compared to 2010. The absolute cost rise in several nations was mostly due to greater populations: Germany (+€ 4.8 billion), Italy (+€ 2.4 billion), and France (+€ 2.1 billion) [2].

### Underlying mechanism of bisphosphonates in osteoporosis treatment

The mechanism of osteoporosis treatment is laying on the origin of bones cells in bone marrow. Bisphosphonates are regarded as the first line medicinal therapy for osteoporosis. They come in a variety of forms, but their primary activity is to adhere to the bone and cause osteoclast death, hence slowing bone resorption and boosting Bone Mineral Density (BMD). Basically, they are stable pyrophosphate analogues with a P-C-P bond that offers hydroxyapatite binding ability. As osteoclasts begin to resorb bisphosphonate coated bones, the released bisphosphonates impair osteoclasts capacity to establish wrinkled borders and make protons, which are required for bone resorption [3].

## Hypothesis

### Complex precision engineering approach of nanoformulation development

Here a novel precision engineering approach was employed for the complex nanoformulation development using the phospholipid 90G tagged pamidronate with sesame oil functionalized self-nanoemulsion development with enhanced drug loading and improved gut permeation. Rational design was hypothesized from the results obtained after preparation of Job's plot. Precisely, the ratios of 1 to 9 of pamidronate and phospholipid 90G were taken for the selection of optimized concentrations suitable for the development of complex. After careful investigation, 1:1 ratio of pamidronate and phospholipid 90G were selected for further optimization using pseudo ternary phase diagram with nanoformulation development and drug loading leading to optimized SNEDDS development with the help of Box Behnken Design (BBD) under response surface methodology [4].

### Evaluation of hypothesis

**The evaluation of hypothesis is based on the experimental proof of concept:** This research work was based on the previous literature supported hypotheses development followed by evidence based outcomes leading to a successful nanoformulation development. Precisely, the complex was prepared via method adopted by Singh, et al. 2011 with slight modifications. Briefly equimolar ratios (1:1) of disodium pamidronate hydrate and phospholipid mixture were poured into Round Bottom Flask (RBF). 50 ml of organic solvent (methanol) was added to the RBF. This mixture was placed on water bath sonicator (Model-LeelaSonic-50, ultrasonic power-50 W, size-1.5 L \* W \* H, electric supply 170-245 V) for 30 min at 25°C temp. The round bottom flask was then assembled with reflux assembly for 4 hrs. When reflux was completed, round bottom flask was taken out and attached to the rotary evaporator. This was done for easy and fast evaporation of methanol under reduced pressure with the help of advanced digital model APS-192, semi-automatic machine. The semi solid complex was further process for lyophilization with the help of Labfreez FD-10-R instrument. The thin dried film of complex was prepared and loaded into solid Self Nanoemulsifying Drug Delivery System (SNEDDS) with the help of vortex mixing and ultra sonication method. The developed nanoformulation was successfully prepared and characterized for particle size, zeta potential, DSC, TGA, XRD and FTIR [5-9].

**Evidence based drug delivery outcome:** The developed nanoformulation was administered to wistar rats for determination of bone density.

**Empirical data and future experiments:** Presently, osteoporosis is a challenge to our society which became even worse during pandemics like COVID-19.

## Conclusion

This nanoformulation delivery system has proven benefits in osteoporosis treatment leading to increased bone density and normalization of bone architecture.

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## Consent statement/Ethical approval

Animal ethical approval was taken prior to conducting research therefore this project was approved by institutional animal ethical committee, Jamia Hamdard University, New Delhi-110062 wide project file no. 1726

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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