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# Development of self-nano emulsifying drug delivery system of *Boswellia serrata* extract for enhanced bioavailability

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Osteoarthritis (OA) is the commonest form of inflammatory joint disease characterized by articular cartilage degradation with accompanying pre-articular bone response. Because of high incidence of adverse effect associated with both non selective and cyclooxygenase II NSAID therapy, effective and safer alternative treatments for OA are urgently needed. In Indian Ayurvedic medicine Boswellia serrata has been used for hundreds of years for treating Arthritis. In recent years the gum resin extracted from ancient herb boswellia serrata has gained much attention as a potent anti inflammatory, antivarthritic, and analgesic action. Patients receiving AKBA treatment reported decrease in knee pain, increased knee flexion and increased walking distance. The frequency of swelling in the knee joint was decreased. AKBA proved to be the most potent 5-lipoxygenase inhibitor acted by 5 -lipoxygenase directed non-redox, non competitive mechanism and there for less toxicity and limited side effect compared with other anti inflammatory drugs. The four major pentacyclic triterpenic acids present in the acidic extract of Boswellia serrata gum resin are: β-boswellic acid (I), Acetyl- β -Boswellic Acid (II), keto- β -Boswellic Acid (III), Acetyl-11-keto- β -Boswellic Acid (IV). Here SNEDDS of boswellia serrata extract were prepared for the treatment of osteoarthritis as it suffers from poor water solubility and ultimately poor oral bioavailability issues. Firstly, the analytical methodology for AKBA was validated on UV and HPLC. The stress degradation studies on AKBA were carried out by HPTLC technique. In SNEDDS formulation development, screening of various components like oil, surfactant, co-surfactant and co-solvent was done by solubility studies. After that drug-excipient compatibility studies were carried out at 4, 25 and 40 C. Various drug and components combinations were tried using pseudo-ternary plots. Eventually, four formulations (C3, D1, D2, and F3) from various Smix ratios which passed dispersibility tests were selected for further study of globule size analysis, viscosity assessment, zeta potential and in vitro release studies. The optimized SNEDDS (D2) were characterized for refractive index, optical microscopy, percentage transmittance, droplet size analysis, viscosity, zeta potential, Transmission electron microscopy(TEM) and drug content. Release from optimized and selected (D2) SNEDDS formulation was found to be significantly higher ($p<0.001$) as compared with that of plain *Boswellia serrata* solution and marketed formulation The release was higher in pH 1.2 as compared to release in other buffers of different pH. Non-everted rat intestinal membrane studies were carried out for accessing the permeability of AKBA. Results indicated cumulative transport and Papp across ileum was found in following order: SNEDDS >Marketed formulation> Plain drug solution. Stability study of SNEDDS as per as ICH guidelines at 25 ± 2 ˚C, 60 ± 5 % RH and 8 ± 2 ˚C, 60 ± 5 % RH were also carried out. The refractive index and droplet size of optimized SNEDDS formulation were not significantly changed during 3 months of storage suggesting that prepared developed SNEDDs of Boswellia serrata was physically stable. From the accelerated stability studies shelf life of snedds was determined to be 2.63 years at room temperature. These results indicated that both physical as well as chemical stability of extract can be enhanced in developed SNEDDS formulation.

Pharmacodynamic studies were carried out on rat model. Diagnostic Reagent kit for in vitro detection of C-Reactive Protein (CRP) in Rat Serum by qualitative and semi-quantitative rapid Latex Slide Tests (*arthritis kit*) was used. Pharmacokinetic studies were carried out on rats. The column Phenomenex Dimension 250*4.6 mm, pore size 5 µ C18 was used. The mobile phase consisted of methanol-water-acetic acid (80:20:0.2 v/v/v). At flow rate 1ml/min, run time 20 minutes, injection volume 20 µl, RT at 13 minutes for AKBA was achieved. The Cmax (ng/ml), Tmax (hr) and AUC 0-t (ng.hr/ml) for boswellia serrata extract SNEDDS, Marketed preparation and plain extract suspension were found to be as follows:

| Groups | C max (ng/ml) | Tmax (hr) | AUC0-t (ng.hr/ml) |
|---|---|---|---|
| Boswellia serrata extract SNEEDS | 287.14 | 2.00 | 2035.51 |
| Marketed preparation | 121.48 | 0.50 | 599.86 |
| Plain extract suspension | 37.24 | 1.00 | 223.34 |

The Cmax of SNEDDS was found to be 287.14 ng/ml whereas its value for the marketed formulation and plain extract suspension was found to be 121.48 ng/mL and 37.24 ng/mL respectively. Plasma concentration profile of Boswellia extract suspension, Marketed preparation and *Boswellia serrata* extract SNEDDS obtained from pharmacokinetic study in rats (n=4). Statistically, the Cmax of Boswellia SNEDDS was found to be extremely significant ($p <0.001$) in comparison to the drug suspension and capsule formulations. Based on the above results, the *Boswellia serrata* SNEDDS product is found to be supra bioavailable as compared to the reference product, Marketed preparation and *Boswellia serrata* plain suspension.