Medicine 2004; 4:19) especially in eastern countries, and, increasingly, in western countries. Some of the commonly used herbs are extracts of Withania somnifera, Boswellia serrata, Zingiber officinale, Curcuma longa in tablet form(Soeken et al; Rheumatology 2003; 42: 652-659).Compositions composed of natural ingredients used for the treatment of pain and inflammation are disclosed, in U. S. Patent Nos 5,494,668; 5,683,698; 5,916,565; 5,888,514; 5,854291; 5,908,628; 5,788,971, 5,910,307, 7531194 and PCT/SG2007/000284. Prior arts disclose various formulations in oral/topical form using herbal ingredients but still fail to solve the problem of spreading this kind of diseases which are reported to be growing at rate of 13.67%. Arthritis limits the activity of over 7 million people in US alone and is second only to heart disease as a cause of work disability. Recent estimates place the direct medical cost of arthritis at $15.2 billion per year, with total costs of medical care and lost wages exceeding $64 billion.

This is because there was technical barrier to develop herbal formulations in new drug delivery system as disclosed in the current embodiment that can provide an additional benefits in terms of technological advancements.

Prevalent treatment of Rheumatoid diseases includes first line drugs for control of pain and inflammation classified as non-steroidal, anti-inflammatory drugs (NSAIDS). Secondary treatment include corticosteroids, slow acting anti-rheumatic drugs (SAARDS) or disease modifying (DM) drugs include penicillin amine like drugs such as cyclophosphamide, methotrexate, gold salts, azothioprine, levamisole. All these drugs have severe side effects and most of them are cytotoxic.

Some of the micro-emulsion based formulations have been disclosed in US. Pat. No. 6,638,537, 6638522 ,4,647,586 using phenyl butazone, sulindac, penicillamine, salsalate, piroxicam, azathioprine, indomethacin, meclofenamate sodium, gold sodium thiomalate, ketoprofen, diclofenac, auranofin, aurothioglucose, tolmetin sodium, colchicine, allopurinol, cyclosporin and other NSAIDs. These formulations are for oral administration only and thus cause huge side effects and have complications related to multi drug administration, thus fail to provide safe and effective therapy for better patient compliance. Frequently, anti-inflammatory medicaments cause abnormalities in the bowel tract, e.g.bleeding.

The drugs used till date have limited advantages and their effects mainly of short term duration and there are many disadvantages in the use of these drugs over extended periods of time. Further the drugs used at present are costly and have low-benefit risk ratio. The ideal formulation to modify the progress of the disease have not been found heretofore.

Summary of the Invention

In one aspect, there is provided a formulation to treat rheumatic disease associated with pain, inflammation of soft tissue and muscles, wherein said formulation is a micro-emulsion comprising at least one active ingredients; wherein said active ingredient comprises at least one of an essential oil mixed with an aqueous phase along with at least one of a surfactant and at least one of a co-surfactant; wherein said co-surfactant is medicated with 5% ± 3% extract of at least one of a herb; and wherein said herb is selected from a group consisting of Apium graveolens, Withania somnifera, Allium sativum, Myristica fragrans, Piper nigrum, Zingiber officinale, Piper longum, Cinnamomum zeylanicum, Cinnamomum tamala, Vitex negundo, Boswellia serrata, Cissus quadrangularis, Terminalia arjuna, Pluchea lanceolata, Commiphora mukul, Sida acuta, Cedrus deodara, Tinospora cordifolia, Cyperus rotundus, Trachyspermum ammi, Embelia ribes, Piper longum.

In another aspect, there is provided the use of the formulation as defined above in the manufacture of a medicament for treating rheumatic disease associated with pain, inflammation of soft tissue and muscle comprising:
Lupus, Sjögren's syndrome, scleroderma (systemic sclerosis), dermatomyositis, polychondritis, polymyositis, polymyalgia rheumatica, osteoarthritis, septic arthritis, fibromyalgia, sarcoidosis, gout, pseudogout, spondyloarthropathies, ankylosing spondylitis, reactive arthritis, psoriatic arthropathy, enteropathic spondylitis, reactive arthropathy, vasculitis, polyarteritis nodosa, Henoch-Schönlein purpura, serum sickness, Wegener's granulomatosis, giant cell arteriti, temporal arteritis, Takayasu's arteritis, Behçet's syndrom, Kawasaki's disease (mucocutaneous lymph node syndrome), Buerger's disease (thromboangiitis obliterans) , Juvenile Idiopathic Arthritis including joint disorders affecting Children, Rheumatic arthritis; Soft Tissue Rheumatism affecting the joints and structures around the joints including tendons, ligaments capsules, bursae, Stress Fractures, muscles, nerve entrapment, vascular lesions, ganglion and Osteoporosis,
osteomalasia, renal osteodystrophy, Fluorosis, Rickets, Congenital and familial Disorders affecting Joints; Hyperextensible joints; Ehlers-Danlos Syndrome, Achondroplasisa, Marfan's Syndrome, Osteomyelitis and Bone TB.

In another aspect, there is provided a process for preparing the formulation as defined above to treat rheumatic disease associated with pain, inflammation of soft tissue and muscle, wherein said formulation is a micro-emulsion comprising at least one active ingredients; wherein said active ingredient comprises at least one of an essential oil mixed with an aqueous phase along with at least one of a surfactant and at least one of a co-surfactant; and wherein said co-surfactant is medicated by an extract of at least one of a herb, said process comprising the steps of: initially mixing at least one of said essential oil with (0.01 ± 10)% of menthol to obtain a mixture; wherein said mixture is filtered with a 0.2 micron filter to obtain a filtrate; (30 ± 7)% of said filtrate is mixed with (7 ± 5)% of a water as said aqueous phase to obtain a mixture "A"; at least one of said surfactant is mixed in the weight ratios of 90:20 to 20: 90 to obtain a mixture "B"; said "A" is emulsified with the (20 ± 10)% of said mixture "B" to obtain an emulsified mixture; wherein said emulsified mixture is stirred for 15 minutes under a inert atmospheric condition to obtain a micro-emulsion; wherein said micro-emulsion is mixed with (8 ± 5)% of said surfactant to the obtained a transparent micro-emulsion "C"; (95± 5)% of an alcohol is taken as said co-surfactant and is mixed with said extract of one or more of said herbs in equal proportions; wherein said herbs are dissolved in 12 to 16 times volume of 95% of said alcohol to obtain a solution "D"; (35 ± 10)% of said "D" is mixed into "C" to obtain a mixture "E"; a colloidal mill is used and said "E" is filtered to obtain a resultant micro-emulsion.

In view of the forgoing, a formulation to treat rheumatic disorders and related infections is provided. The formulation is a micro-emulsion including at one or more of an active

We Claim:

1. A formulation to treat rheumatic disease associated with pain, inflammation of soft tissue and muscles, wherein said formulation is a micro-emulsion comprising at least one active ingredients; wherein said active ingredient comprises at least one of an essential oil mixed with an aqueous phase along with at least one of a surfactant and at least one of a co-surfactant; wherein said co-surfactant is medicated with 5% ± 3% extract of at least one of a herb; and wherein said herb is selected from a group consisting of Apium graveolens, Withania somnifera, Allium sativum, Myristica fragrans, Piper nigrum, Zingiber officinale, Piper longum, Cinnamomum zeylanicum, Cinnamomum tamala, Vitex negundo, Boswellia serrata, Cissus quadrangularis, Terminalia arjuna, Pluchea lanceolata, Commiphora mukul, Sida acuta, Cedrus deodara, Tinospora cordifolia, Cyperus rotundus, Trachyspermum ammi, Embelia ribes, Piper longum.

2.The formulation of claim 1, wherein said essential oil is present as an oil phase and water as said aqueous phase; wherein said oil phase and said aqueous phase is present in a ratio of 1:4 to 4:1; wherein said surfactant and said co-surfactant is present in a ratio of 0.5: 1 to 1: 1.5; wherein said surfactant is at least one of a non-ionic long chain polymer; wherein said non-ionic long chain polymer is selected form the group consisting of polyoxyethylenesorbitan monooleate, polyoxyethylenesorbitan monolaurate, sorbitan monooleate, sorbitan monolaurate, 4-Nonylphenyl-polyethylene glycol, polyethylene glycol monohexadecyl ether, Cetostearyl alcohol, Cetyl alcohol, diethanolamine, monoethanolamine, Decyl glucoside, Glyceryl laurate, Lauryl glucoside, Nonylphenol Ethoxylate, Narrow range ethoxylate, Nonylphenyl Polyethylene Glycol Ether,Nonoxynols, Octaethylene, glycol monododecyl ether, Oleyl alcohol, Pentaethylene glycol monododecyl ether, Poloxamer, Polyglycerol, polyricinoleate, Polyoxyethylene, Sorbitan monostearate, Sorbitan tristearate, Stearyl alcohol & Octylphenolethylene oxide condensate; wherein a particle size of said formulation is 0.005 to 0.5 microns; wherein Poly Dispersity Index (PDI) of said formulation is 0.100 to 0.300; and wherein a Zeta potential of said formulation is -0.100 to -0.500.

3.The formulation of claim 1, wherein said essential oil is selected from a group consisting of a wintergreen oil or gaultheria procumbens oil, cinnamomum camphora oil, eucalyptus oil, cedrus oil, terpentine oil, clove oil, garlic oil, cyperus oil, basil oil, lavender oil, rosemary oil, mint oil, Geranium oil.

4. The formulation of claim 1, 2 and 3, wherein said essential oil further comprises any or both of a Capsicum Annuum and menthol.

5.The formulation of claim 1 or 2 or 3, wherein said co-surfactant is at least an alcohol.

6. The formulation of claim 2, wherein said surfactants are at least one of polyoxyethylenesorbitan monooleate or polyoxyethylenesorbitan monolaurate or a combination thereof, wherein weight ratio of said polyoxyethylenesorbitan monooleate : said polyoxyethylenesorbitan monolaurate is 90:20 to 20:90.

7. The formulation of claim 3, wherein a winter green oil or Gaultheria procumbens oil is present in an amount (20± 3)% as volume/volume, wherein camphor oil is present in an amount (5 ± 3)% as volume/ volume, wherein eucalyptus oil is present in an amount (6± 3)% as volume/volume along with weight/volume range of menthol in an amount (5± 3)%; wherein said menthol is dissolved in said essential oils as said oil phase; wherein said water is present in range of (7±5)% as aqueous phase; wherein said co-surfactant is comprising an extract which is medicated by Vitex negundo, Boswellia serrata and Apium graveolens; wherein said Vitex negundo, Boswellia serrata and Apium graveolens are present in the proportion of 1:1:1 respectively; and wherein said formulation has a particle size in the range of ≤ 0.005 micron , a zeta

potential is ≤ - 0.268 and poly dispersity index is ≤ 0.136.

8.The formulation of claim 1 to 7, wherein said formulation is a water in oil micro-emulsion.

9.The formulation of claim 2, wherein said essential oil is present as: Winter green oil/ Gaultheria precumbens oil in an amount (13± 3)% as volume/volume, Cedrus deodara oil is present in an amount (1 ± 3)% volume/volume, Cyperus rotundus oil is present in an amount (1 ± 3)% volume/volume, Cinnamomum camphora oil is present in an amount (4 ± 3)% volume/volume, eucalyptus oil is present in an amount (7± 3)% volume/volume along with weight/volume range of Capsicum Anuum in (0.05 ± 3)% and menthol in (4± 3)% dissolved in said essential oils as oil phase; wherein said surfactant comprises said polyoxyethylenesorbitan monooleate and said polyoxyethylenesorbitan monolaurate in volume / volume ratio of 90:20 to 50:50; wherein said co-surfactant is medicated and comprising an extract of Apium graveolens and a ratio of said surfactant to said co-surfactant is 0.56:1 with a HLB value of 16.7; and wherein said formulation has a particle size in the range of ≤ 0.5 micron , zeta potential is ≤ - 0.350 and poly dispersity index is ≤ 0.150.

10.Use of the formulation of any one of the preceding claims in the manufacture of a medicament for treating rheumatic disease associated with pain,inflammation of soft tissue and muscle comprising: Lupus, Sjögren's syndrome, scleroderma (systemic sclerosis), dermatomyositis, polychondritis ,polymyositis, polymyalgia rheumatica, osteoarthritis, septic arthritis, fibromyalgia, sarcoidosis, gout, pseudogout, spondyloarthropathies, ankylosing spondylitis, reactive arthritis , psoriatic arthropathy, enteropathic spondylitis, reactive arthropathy, vasculitis, polyarteritis nodosa , Henoch-Schönlein purpura, serum sickness, Wegener's granulomatosis, giant cell arteriti, temporal arteritis, Takayasu's arteritis, Behçet's syndrom, Kawasaki's disease (mucocutaneous lymph node syndrome), Buerger's disease (thromboangiitis obliterans) , Juvenile Idiopathic Arthritis including joint disorders affecting Children, Rheumatic arthritis; Soft Tissue Rheumatism affecting the joints and structures around the joints including tendons, ligaments capsules, bursae, Stress Fractures, muscles, nerve entrapment, vascular lesions, ganglion and Osteoporosis,

osteomalasia, renal osteodystrophy, Fluorosis, Rickets , Congenital and familial Disorders affecting Joints; Hyperextensible joints; Ehlers-Danlos Syndrome, Achondroplasisa, Marfan's Syndrome, Osteomyelitis and Bone TB.

11. A process for preparing the formulation of claim 1 to 9 to treat rheumatic disease associated with pain,inflammation of soft tissue and muscle , wherein said formulation is a micro-emulsion comprising at least one active ingredients; wherein said active ingredient comprises at least one of an essential oil mixed with an aqueous phase along with at least one of a surfactant and at least one of a co-surfactant; and wherein said co-surfactant is medicated by an extract of at least one of a herb, said process comprising the steps of: initially mixing at least one of said essential oil with (0.01 ± 10)% of menthol to obtain a mixture; wherein said mixture is filtered with a 0.2 micron filter to obtain a filtrate; (30 ± 7)% of said filtrate is mixed with (7 ± 5)% of a water as said aqueous phase to obtain a mixture "A"; at least one of said surfactant is mixed in the weight ratios of 90:20 to 20: 90 to obtain a mixture "B"; said "A" is emulsified with the (20 ± 10)% of said mixture "B" to obtain an emulsified mixture; wherein said emulsified mixture is stirred for 15 minutes under a inert atmospheric condition to obtain a micro-emulsion; wherein said micro-emulsion is mixed with (8 ± 5)% of said surfactant to the obtained a transparent micro-emulsion "C"; (95± 5)% of an alcohol is taken as said co-surfactant and is mixed with said extract of one or more of said herbs in equal proportions; wherein said herbs are dissolved in 12 to 16 times volume of 95% of said alcohol to obtain a solution "D"; (35 ± 10)% of said "D" is mixed into "C" to obtain a mixture "E"; a colloidal mill is used and said "E" is filtered to obtain a resultant micro-emulsion.

12. The process of claim 11, wherein (0.05 ± 03)% of Capsicum Anuum is added to said initial mixing of said essential oil.

13. The process of claim 11, wherein (7± 5)% of an alcohol is added into "E".

14. The process of claim 11, wherein said oil phase comprises of at least one of said essential oil of a winter green oil or Gaultheria precumbens oil, a camphor oil, an eucalyptus oil, wherein said essential oil is mixed with said aqueous phase comprising of a water along with said surfactantpolyoxyethylenesorbitan monooleate,polyoxyethylenesorbitan monolaurate; wherein said co-surfactant is ethanol; and wherein said co-surfactant is medicated by an extract of Vitex nigundo, Boswellia serrata and Apium graveolens.

15. The process of claim 11, wherein said herb is selected from a group consisting of Apium graveolens, Withania somnifera, Allium sativum, Myristica fragrans, Piper nigrum, Zingiber officinale, Piper longum, Cinnamomum zeylanicum, Cinnamomum tamala, Vitex negundo, Boswellia serrata, Cissus, Terminalia arjuna, Pluchea lanceolata, Commiphora mukul, Sida acuta, Cedrus deodara, Tinospora cordifolia, Cyperus rotundus, Trachyspermum ammi, Embelia ribes, Piper longum.