

The invention is directed to a stable complex with controlled particle size, increased apparent solubility and increased dissolution rate comprising as active compound Sirolimus or derivatives thereof, which is useful in the prophylaxis of organ rejection in patients receiving renal transplants, in the treatment of psoriasis, facial angiofibromas associated with tuberous sclerosis, fibrofolliculomas found in Birt-Hogg-Dube Syndrome, chronic erosive oral lichen planus, Early Stage Cutaneous T-cell Lymphoma, Treatment of Autoimmune Active Anterior Uveitis, dry eye syndrome, age-related macular degeneration, diabetic macular edema, noninfectious uveitis, telangiectasia, inflammatory skin diseases (dermatitis, including psoriasis and lichen ruber planus), Pachyonychia Congenita and in the suppression of angiogenesis pathways. More specifically, the complex of the present invention possesses increased apparent solubility, permeability and enhanced biological performance including significantly improved exposure, earlier  $t_{max}$ , higher  $C_{max}$  and higher trough concentrations at 24 hours which will allow the reduction of the dose. Furthermore, the complex of the present invention possesses exceptional stability as a redispersed solution allowing the development of liquid based formulation for transdermal and other topical applications. The invention also relates to methods of formulating and manufacturing complex according to the invention, pharmaceutical compositions containing it, its uses and methods of treatment using the complex and its compositions.