



Title: Antileishmanial activity of Amphotericin B entrapped in cationic liposomal formulation (Patent:049NF2006/IN)

INTRODUCTION- Major hurdle of successful anti-leishmanial therapy using amphotericin B stems from multiple doses of drug administration, toxicity and inability of overcoming infection induced life-long immune suppression of host. Therefore single –shot application of suboptimal dose of AmB within cationic liposome can bring the combinatorial benefit of overcoming issues mentioned above. Additionally cationic liposomal formulation induces Th1-biased immune response of host which can further subside the relapse and treatment failure cases of VL.

CHALLENGE

- Anti-leishmanial efficacy of free Amphotericin B is compromised by the toxicity of the drug and chronic immune suppression of host induced by parasites.
- Available liposomal formulation like Ambisome is unable to maintain the inherent immunostimulatory effect of free AmB.

APPLICATION DOMAIN

- Single shot application of liposomes
- Synergistic effect of immune activating cationic liposome
- Remarkable low dose of AmB can be obtained that can induce Th1 response in host.

OPPORTUNITY

- Single shot application of cationic liposome entrapped AmB can induce successful clearance of infection with induction of immune activation of host.
- This formulation has very good antileishmanial activity, so there is a good possibility for its commercialization.
- Our formulation can prevent PKDL development.

STAGE OF TECHNOLOGY DEVELOPMENT

- The project has already started to produce GLP level liposomal formulations for commercialization standards. The co-development project with industry will be completed in July 2021.
- After this co-development R&D activity CSIR-IICB will be the stake holder for commercialization agreement with the industry.

REFERENCES-

Banerjee A, De M, Ali N. Complete cure of experimental visceral leishmaniasis with amphotericin B in stearylamine-bearing cationic liposomes involves down-regulation of IL-10 and favorable T cell responses. *J Immunol.* 2008 Jul 15;181(2):1386-98

PATENTS- The US patent for this formulation has been approved (**US 264798**, dated 22.01.2015).

PROJECT INVESTIGATORS- Dr. Nahid Ali