

Mission: Cost-effective cure for kala azar

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Funded by the Department of Biotechnology and supported by the Department of Scientific and Industrial Research, the creation of liposomal amphotericin B by Lifecare Innovations, is a true example of a public-private partnership, where each of the partners have played their role successfully

Biospecialppkalaazar known amphotericin B, an antibiotic obtained from *Streptomyces* sp, is known to be one of the most potent anti-fungal agents, but is applied topically because of its toxicity. The alternative for this drug was successfully developed by Gurgaon-based Lifecare Innovations. Liposomal amphotericin B uses liposome as a carrier and delivery system and can carry the drug at the specific site. It is also required in much lower concentration.

The initial research to make an affordable substitute of AmBisome (a US product) at the Department of Bio-chemistry, Delhi University, was supported by the Department of Biotechnology (DBT). After the formulation development was completed proving the efficacy and substantiated pre-clinical work, the results were transferred to Seth GS Medical College and KEM Hospital, Mumbai, for clinical evaluation following which the clinical trials for kala azar were successfully completed and the technology was formally handed over to National Research Development Corporation (NRDC) by DBT for licensing and commercialization.

Although the commercialization of technology failed to take off with first licensee Ace Diagnostics and Biotech Limited, the same became a huge success when it was licensed to Lifecare Innovations in 1999. With the license fee of 25 lakh and royalty of three percent for 10 years to commercialize the product, the company was also asked to further improve the formulation to overcome the doses related toxicities of amphotericin B as compared to the imported lipid formulations such as AmBisome, Ampholip (Abelcet) and Amphocil (Amphotek). Further R&D at Lifecare Innovations led to the commercialization, which was supported by the Department of Scientific and Industrial Research through program aimed at Technological Self Reliance (PASTER scheme). Also a pre-proof-of- concept on the development of affordable, toxicity-free amphotericin B

loaded liposomal preparation for treatment of Kala Azar was supported by DBT through its Small Business Innovation & Research Initiative (SBIRI) scheme. "We took the laboratory-scale technology of DBT and we complemented it with nanosomization to make nanosomes of liposomal amphotericin B," said Dr JN Verma, MD, Lifecare Innovations.

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The way forward

The product, liposomal amphotericin B, which is marketed by Lifecare Innovations as "FUNGISOME i.v.", contains cholesterol essential for minimizing toxicity of Amphotericin B to a safe level. It converts into several small unicellular liposomes, thereby substantially increasing the therapeutic index. "FUNGISOME i.v." requires sonication for application which enhances the therapeutic index of the drug and the administration can be done in one hour. According to the company, the product is the least toxic drug available in the country in its category. Unlike the imported drug, it comes in various doses thereby reducing wastage and cost, also being less than one-tenth the cost of the imported equivalent.

Furthermore, the company also developed a liposomal dithranol for the treatment of psoriasis. The company has developed an anti-TB formulation in collaboration with the Post Graduate Institute (PGI), Chandigarh.

Rahul Koul in New Delhi