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# B12-Functionalized PEGylated Liposomes for the Oral Delivery of Insulin: In Vitro and in Vivo Studies

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**Abstract :** Orally administered Insulin has to survive the harsh gastrointestinal tract condition, penetrate the enteric epithelial barrier, and bypass the first pass effect before reaching the bloodstream. To address this problem, PEGylated liposomal insulin was prepared and modified with B12 to improve the stability and absorption of insulin in the gastrointestinal environment. Liposomes were prepared by film method plus extrusion, linked to B12, and characterized for their particle size, zeta potential, and encapsulation efficiency (EE%). The release profile in simulated gastric fluid (SGF) and simulated intestinal fluid (SIF) were evaluated. The results indicated that B12-targeted PEGylated liposomes were more stable than non-functionalized Lip-PEG in SGF and SIF. In vitro, results showed significantly enhanced cellular uptake of B12-targeted PEGylated liposomes in Caco-2 cells compared to non-targeted liposomes. In the meantime, they had no toxicity on Caco-2 cells. In BALB/c mice, B12-targeted PEGylated liposomes showed higher insulin accumulation in the intestine and liver. In diabetic rats B12 targeted PEGylated liposomes provided higher insulin bioavailability compared with other formulations. These findings suggest that B12-targeted liposomes could be an effective formulation for oral delivery of insulin and merits further investigations.

**Keywords :** insulin, liposomes, vitamin B12, oral delivery
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