

**PATENT NO. 328209**  
**SURFACE-MODIFIED BILE-SALT STABILIZED NON-IONIC SURFACTANT**  
**NANO-VESICLES FOR ORAL DELIVERY OF BIOACTIVES**

**APPLICATION NO.** 1564/DEL/2012

**APPLICANT**  
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**ABSTRACT**

The present invention relates to a pharmaceutical formulation comprising a bioactive pharmaceutical entrapped within the aqueous core of the novel surface-modified bile-salt-stabilized nano-vesicular delivery system. The novel surface-modified bile-salt-stabilized nano-vesicular delivery system comprises an aqueous core within a non-ionic surfactant bilayer stabilized with bile salt, wherein the outer membrane of the bilayer is coated with a mucoadhesive agent i.e. chitosan. The present invention also provides a vaccine formulation comprising of nano-vesicular delivery system. The vaccine can be used for the induction of systemic as well as mucosal antibody response against various infectious diseases including diphtheria.

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**CLAIM 1**

A pharmaceutical formulation comprising a bioactive pharmaceutical entrapped within an aqueous core of bilayered nano-vesicles; wherein the bilayer comprises non-ionic surfactant, cholesterol and negative charge inducer in a molar ratio range from 541 to 821, and said bilayer is coated with mucoadhesive agent; wherein the size of the nano-vesicles is in the range of 10 nm to 200 nm.