

Conference Name: Melbourne International Conference on Research in Life-Science & Healthcare, 20-21 March 2026

Conference Dates: 20-Mar- 2026 to 21-Mar- 2026

Conference Venue: Rendezvous Hotel Melbourne, 328 Flinders Street, Melbourne VIC 3000

Appears in: LIFE: International Journal of Health and Life-Sciences (ISSN 2454-5872)

Publication year: 2026

Ribeiro & Pessoa, 2026

Volume 2026, pp. 22-23

DOI- <https://doi.org/10.20319/icrlsh.2026.2223>

This paper can be cited as: Ribeiro, A. & Pessoa, B. (2026). Factorial Design Developed Biopolymer Nanoparticles for Oral Delivery of Insulin. Melbourne International Conference on Research in Life-Science & Healthcare, 20-21 March 2026. Proceedings of Healthcare and Biological Sciences Research Association (HBSRA), 2026, 22-23

## **FACTORIAL DESIGN DEVELOPED BIOPOLYMER NANOPARTICLES FOR ORAL DELIVERY OF INSULIN**

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### **Abstract**

*The development of chitosan-coated alginate/dextran sulphate nanoparticles for insulin encapsulation is addressed. Nanoparticles are produced by ionotropic gelation followed by polyelectrolyte complexation. The objective of this study is to optimize chitosan-based biopolymer nanoparticles for the oral delivery of insulin using a quality-by-design (QbD) approach. Four input factors are considered: Concentrations of alginate /dextran sulfate, chitosan, poloxamer, and insulin, together with process parameters, flow rate (ml/min) and agitation speed rate during chitosan addition were the input factors considered. Critical quality attributes include particle size, polydispersity index, zeta potential, and encapsulation efficiency. The implemented built-quality method follows three successive QbD runs, each based on a specific design of experiments (DoE). First, a screening of the material attributes is performed using a fractional factorial design, followed by a second run using a Box-Behnken design to identify the design space and extract four*

*eligible control operating regions in which the probability of meeting the CQA specifications exceeds 95%. In the last run, one of these optimal operating conditions was qualified by testing eight endpoints across the region using a full factorial design.*

**Keywords:**

Biopolymer, Factorial Design, Insulin, Nanoparticle