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Development of bio-similar to exendin-4, a major drug for type 2 diabetes

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The hallmark of diabetes mellitus is hyperglycemia resulting from impaired carbohydrate metabolism. Type 2 diabetes has a complex patho-physiology characterized by deficient insulin activity arising from decreased insulin secretion secondary to beta-cell failure, compromised insulin action in peripheral target tissues (insulin resistance), or a combination of the two abnormalities. Type 2 diabetes accounts for approximately 85% to 95% of diabetes cases in developed regions like the European Union. Age and weight are established risk factors for type 2 diabetes. The majority of patients with type 2 diabetes are overweight or obese. Byetta (Exenatide, Exendin-4) contains exenatide which is an incretin mimetic. Endogenous incretins, such as glucagon like peptide 1 (GLP-1), facilitate insulin secretion following their release from the gut into the circulation in response to food intake. Exenatide is licensed for the treatment of type 2 diabetes mellitus in combination with metformin and/or a sulfonylurea, or pioglitazone in patients who have not achieved adequate glycemic control with these drugs alone or in combination. The increasing expenditures and cost of treatment of Byetta® highlight the absence of lower-cost generic substitutes for this drug usually referred to as biosimilars or follow-on-biologics. Biosimilars or follow-on biologics are protein-based therapeutic products that are near-identical (similar), comparable and equivalent to the branded therapeutic product. As, there is no single bio-similar developed or approved for Byetta®, we have developed the bio-similar of it using microbial route thus lowering the COGS significantly. The cell line development, process and analytical similarity data will be presented.

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High level intracellular expression of recombinant streptokinase as an inclusion body in *E. coli*

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Streptokinase, a 414 amino acid polypeptide with molecular weight of 47 kDa, is a potent activator of the fibrinolytic system in humans. High level expression of recombinant protein in *E. coli* frequently results in accumulation of protein as insoluble aggregates known as inclusion bodies and they do offer several advantages. Expression as inclusion bodies is useful to obtain large amount of the protein, provided refolding is not difficult and recovery of the active protein is high. This is particularly true with the proteins not having disulfide bonds. Since streptokinase does not have disulfide bonds, the focus is to obtain higher quantity of stable protein as inclusion bodies. In the present study, an attempt was made to investigate the effect of temperature and post induction time on stable (non-degradable) expression of recombinant streptokinase of higher content as inclusion body in *Escherichia coli.*

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