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PRE-CLINICAL & CLINICAL DEVELOPMENT OF BIOSIMILAR INSULINS/INSULIN ANALOGUES: THE CLINICAL IMPLICATIONS OF CRITERIA FOR SIMILARITY

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Biography

Agam Shah has rich professional experience of nearly 15 years in clinical development, medical affairs and academics. He has been an avid Clinical Research Physician with numerous scientific publication and presentations to his name. He has comprehensive experience of clinical development of biosimilars, complex generics and vaccine products.

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Introduction: Akin to generic product development through pharmaceutical equivalence followed by bioequivalence compared to reference medicinal product to ascertain similar safety and efficacy, biosimilar insulin/analogue product (BIP) development includes physio-chemical-biological characterization followed by human PK-PD study and safety-efficacy-immunogenicity study compared to reference insulin product (RIP) to ascertain the same. Although, development of multiple biosimilar insulin products has been undertaken throughout the world, clarity about the clinical implications of the results of these studies is not much discussed.

Objective: To assess the clinical implications of pre-clinical and clinical studies undertaken on BIP to establish its similarity to their RIP in terms of their results.

Methods: Results of studies conducted by Wockhardt Ltd. for development of their BIP of insulin glargine as per in comparison to RIP were evaluated to assess their criteria for similarity in the context of clinical implications.

Results: Results of the *in vitro* receptor binding assays, *in vitro* receptor auto-phosphorylation, *in vitro* metabolic assays and *in vivo* PD studies indicate that BIP is comparable to the RIP in the potential for glucose lowering effects. Whereas, results of the *in vitro* mutagenicity assays, sub-chronic toxicity study indicate that BIP is comparable to the RIP in potential for toxicities, pharmacokinetics and immunogenicity. Results of human PK-PD studies conducted in healthy volunteer and type 1 diabetics under euglycemic clamp settings proved that BIP is bioequivalent to the RIP in glucose lowering effect and insulin glargine exposure. Whereas, results of comparative safety-efficacy-immunogenicity studies in type 1 and type 2 diabetics confirmed that BIP is non-inferior to RIP in glycaemic control as well as comparable to it in hypoglycaemic events, other adverse events and immunogenicity.

Conclusion: Pre-clinical and clinical development data on BIP offers comprehensive information of clinical PK-PD, safety, efficacy and immunogenicity in comparison to RIP to understand clinical implications of BIP's use in practice.

Note: