

7th Indo Global Diabetes Summit and Medicare Expo

November 23-25, 2015 Bengaluru, India

Examination of intricacies involved in designing of once a day tablet containing newer combination of anti-diabetic drugs for type 2 diabetes

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Type II diabetes is a lifelong (chronic) disease in which high levels of sugar (glucose) in the blood is observed. Currently, India leads the world with the largest number of diabetic patients and this is expected to further rise in the coming years. The combination therapy is used to provide an optimal level of glycemic control over non-insulin dependent diabetes mellitus (NIDDM) patient. One of the extended released formulation available in market, TRIEXER contains three oral anti-hyperglycaemic drugs namely Glimepiride, Pioglitazone hydrochloride and Metformin hydrochloride in the management of type II diabetes (NIDDM). The disadvantages of Pioglitazone hydrochloride are weight gain, slow onset of action, liver toxicity, etc. Clinical trial data shows that Sitagliptin 100 mg once daily, significantly improved glycaemic control and beta-cell function in patients with type II diabetes who had inadequate glycaemic control with glimepiride or glimepiride plus metformin therapy. In the light of above reserch, the objective of the present project work is to develop fixed dose triple combination of antidiabetic drugs wherein Sitagliptine and Glimepride are as immediate release form and Metformin is as extended release (ER) form. Primarily, formulational optimization of Metformin was done for extended release by factorial design. In the second set of experiments, design space for process parameters (inlet, outlet temp, atomizing pressure and flow rate) and its influence on coated tablet characteristics was developed. Result of above study was revealed that clinically relevant newer fix dose combination formulation successfully designed by implementing principal of Quality by Design.

Biography

Vaishali Thakkar has completed her PhD in Pharmaceutical Science from Sardar Patel University, Gujarat. She is Professor and Head of Pharmaceutics Department at Anand Pharmacy College. She has more than 15 years of teaching experience and research experience. She has published more than 40 papers in reputed journals and also recipient of two national level awards for Best Innovative Research Project by SRISTI and 3M and has been serving as an Editorial Board Member of repute.

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