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Strategies for Developing Bioanalytical Method for Certain Oral Antidiabetics

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The International Diabetes Federation estimates that 285 million people around the world have diabetes. This total is expected to rise to 438 million within 20 years. Each year a further 7 million people develop diabetes. Around 90 % of the diabetes patients are found to suffer from type 2 diabetes mellitus. Many patients suffering from type 2 diabetes require treatment with more than one antihyperglycemic drug to achieve optimal glycemic control. The combination of metformin hydrochloride – Biguanides with any one of the Sulphonylureas - glipizde, gliclazide, glibenclamide, glimperide or with Alpha glucosidase inhibitors - voglibose can present daunting challenges to analytical scientist during HPLC analysis. This talk will drill into the details of method development and discuss the common problems encountered as in case of metformin & sulphonyl urea – vast differences in their polarity, pk_a, makes extraction from the biological fluids very difficult which may lead to low recovery and low sensitivity. Differences based on their protein binding characteristics - sulphonyl urea strongly bound to proteins lead to low recovery. Strategies to optimize the mobile phase, extraction procedures in biological fluids, to increase the recovery by disrupting drug- protein binding will be highlighted. Challenges to improve the detection of low UV absorbing component as in the case of voglibose will be dealt. These methods are inevitable to monitor a population of diabetic patients who take several diabetic medications without changing HPLC colums.