

### **Relative stability of anti-diabetic drug metformin with pharmaceutical excipients**

The primary objective of this investigation was to develop a formula for an anti-diabetic namely Metformin which used in the treatment for non-Insulin-dependent diabetics. Initially we studied the physical and chemical properties of pharmaceutical excipients, which were used in manufacturing pharmaceutical dosage forms. Four formulations with Metformin Hydrochloride (I) and appropriate combination of selected excipients were mixed and compressed into tablets. Tablets were analysed as per British Pharmacopoeia (BP) for chemical and physical properties. Three selected formulae were exposed to high temperatures, light and humidity for several days and formulae were exposed to high temperatures, light and humidity for several days and analysed as per BP. Analytical data, before and after exposing to harsh conditions, were not stable.

Under the related test cyanoguanidine (II) as a byproduct was observed in all three formulations. In order to find out the type of conditions which favors the formation of cyanoguanidine, Metformin Hydrochloride was treated with various conditions including having catalysts, acids and bases in aqueous TLC and found that the formation of cyanoguanidine was favored under basic media. Cyanoguanidine was isolated in 22% yield. From this study we concluded Metformin Hydrochloride forms Cyanoguanidine mainly under basic condition. Thus, by keeping the formula under acidic pH level, a stable formula for Metformin tablet 500 mg (BP) was developed, which complies with all the tests in BP.