ABSTRACT

The stability indicating HPLC method is an analytical method which can detect Impurities and Drug Equivocally in their respective bulk drug as well as pharmaceutical formulation. The intrinsic solubility of bulk drug and its formulation product is mandatory for IND, NDA as well as ANDA submission. The Stress study can be carried out at 10°C increment from 40°C/75%RH and 5 % in relative humidity. This makes the method more reliable for the estimation of amount of degradation in the given sample. Generally, stability of bulk drug and its formulation product is carried out on the various combination with permutations between temperature and Humidity. The most commonly stability conditions are Long term (25°C/60%RH), Intermediate condition (30°C/65%RH) and Accelerated condition (40°C/75%RH).

The stability indicating HPLC method for Metformin HCl, Vildagliptin, Rosiglitazone, Sitagliptin Phosphate and Pioglitazone HCl was developed by using Stationary phase as Octadecyl Silane. The mobile phase buffer contains Ion pair i.e. Sodium hexane sulphonate. The major effect of ion pair can be seen on the ionic compound i.e. Metformin HCl. The remaining compounds were eluted using gradient.

The stability indicating characteristics of an analytical method was established using FD study/ Stress study. The forced degradation study proves the developed method is a stability indicating method and can be used to access the % Assay of the routine as well as stability for the various pharmaceutical dosage forms.