Chapter- 8

Conclusions
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1) A simple, Precise cost effective and stability indicating Normal Phase HPLC method has been developed and validated for the determination of related substances of Clopidogre Bisulphate Drug Substance. The method was found to be Specific, Precise, Rugged, Accurate, Linear, Robust and Stability indicating and suitable for its intended use. Chromatographic separation was achieved on a Chiral Cel OD-H Column (250 × 4.6 mm, 5μ) using a mobile phase consisting of 920ml n-Hexane, 50ml Ethanol and 30ml of Isopropyl alcohol and 0.3ml of Diethylamine at a flow rate of 0.9 ml per minute. The detection was made at 240nm. The retention time of Clopidogre peak is 20.8 minutes. The proposed method was validated as per the ICH and USP guidelines.

2) A simple, Precise cost effective and stability indicating Reverse Phase HPLC method has been developed and validated for the determination of Assay of Pioglitazone Drug Substance. The separation was carried out using Prontosil C8 SH (250*4.6mm), 5μ or equivalent using a mobile phase consisting of 550ml Phosphate buffer with Triethyl amine at 4.0 pH, 300ml Acetonitrile and 150ml of Methanol at a flow rate of 1.5 ml per minute. The detection was made at 254nm. The Column oven temperature was 40°C, Injection volume 20μl and Run time was 10 minutes. The retention time of Clopidogre peak is 5.9 minutes. The proposed method was validated as per the ICH and USP guidelines.
3) A simple, Precise cost effective and stability indicating **Normal Phase HPLC method has been developed and validated for the determination of Chiral purity of Armodafinil Drug Substance**. All the validation parameters are performed and are satisfied. Chromatographic separation was achieved on a (R,R) Whelk O1 (250 x 4.6 mm),5μ using a mobile phase consisting of 150 mL of filtered Ethanol with 850 mL of filtered n-Hexane and 1 mL of Trifluoroacetic acid at a flow rate of 1.5 ml per minute. The detection was made at 220nm. The Column oven temperature, Injection volume and Run time were 40°C, 20μl and 30 minutes. The retention time of in-house impurity-9 and Armodafinil is 11.8 and 15.0 minutes. The proposed method was validated as per the ICH and USP guidelines.

4) A simple, Precise cost effective and stability indicating **Reverse Phase HPLC method has been developed and validated for the simultaneous determination of related substances of Tramadol Hydrochloride and Acetaminophen in Drug Product**. All the validation parameters are performed and are satisfied. Chromatographic separation was achieved on a Inertsil C8, 250mm×4.6mm, 5μm using a mobile phase-A consisting of pH 4.5 with Trifluoroacetic acid and Mobile phase-B consisting of methanol with gradient programme at a flow rate of 1.0 ml per minute. The detection was made at 271nm. The Column oven temperature, Injection volume and Run time were 25°C, 100μl and 50 minutes. The retention time of Acetaminophen and Tramadol hydrochloride is about 11.0 minutes and 26.0 minutes respectively. The proposed method was validated as per the ICH and USP guidelines.