International Journal of ChemTech Research
CODEN (USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.10 No.6, pp 1073-1082, 2017

# Cost Effective Stabilty Indicating Reverse Phase High Performance Liquid Chromatography Analytical Method Validation for Determination of Related Substance of Cyproterone Acetate

**Asheesh Singh[1]*, Parul Singh[2]**

[1]Alpa Laboratories Limited, Pharma zone, Pithampur (India)-454775
[2]Department of Pharmacy, Guru Ghasidas University, Bilaspur(India)-495009

**Abstract :** Cyproterone acetate (CPA) is a steroidal synthetic progestagen and anti-androgenic compound used as a treatment for metastatic prostate cancer. A simple, sensitive, stability-indicating reversed-phase high-performance liquid chromatographic method was developed for the determination of Cyproterone acetate and related impurities in Cyproterone acetate Active Pharmaceutical ingredient. The chromatographic separation was achieved on a Waters, Spherisorb ODS II, 125 mm x 4.6 mm, 3 µm column, using a mobile phase consisting of Water: Acetonitrile (60: 40) %, v/v, at a flow rate of 1.5 mL/min and temperature of 25°C. Quantification was achieved with photodiode array detection at 254 nm. The described method showed excellent linearity over a range of limits of quantification to 150% of specification limit. The drug product was subjected to the stress conditions of oxidative, acid, base, thermal and photolytic degradation. Cyproterone acetate degradation was observed in acid hydrolysis, base hydrolysis and peroxide stress conditions. Cyproterone acetate was stable in thermal and photolytic degradation conditions. The method is validated for the quantification of impurities and degradation of Cyproterone acetate in Cyproterone acetate Active Pharmaceutical ingredient. This method was validated for Specificity, accuracy, precision, linearity and Robustness as per ICH guidelines.

**Keywords :** Cyproterone acetate, progestagen, Analytical Method, Validation, High performance Liquid Chromatography.

**Asheesh Singh *et al*** /International Journal of ChemTech Research**,** 2017,10(6): 1073-1082.

*****