Isocratic Reversed-Phase HPLC Method with PDA Detector for the Assay and Purity Evaluation of Olanzapine & Paliperidone in Bulk Drug

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Abstract: The rapid, selective and stability indicating HPLC method was developed and validated for the simultaneous estimation of Olanzapine and Paliperidone. The numbers of column such as waters symmetry C18 (250 x 4.6mm, 5.0µm), YMC packpro C18 (250 x 4.6mm, 5.0µm) Inertsil ODS 3V (250 x 4.6mm, 5.0µm) were used during method development. The separation was achieved using Isocratic program of solution A (i.e. Solution A used Contains 0.1% Ammonium Acetate in water): and Solution B is Acetonitrile in the ratio of 95:5 v/v. The flow rate was set at 0.8 ml/min and column was maintained at 450C. The injection volume was set 3µl and detector was set at a wavelength of 254 nm. The method was applied for determination of olanzapine and Paliperidone tablets with satisfactory results.

Key words: forced degredation, olanzapine, paliperidone, stability indicating method.

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1. INTRODUCTION:

Olanzapine: Five atypical antipsychotic drugs (APDs) such as Clozapine and its four related drugs (Olanzapine, Quetiapine, Risperidone And Ziprasidone) are the most frequently used.[6]

Paliperidone : Paliperidone is approved for constant rate over twenty four hour period. Study of paliperidone is necessary to explore the tolerability, safety and treatment response of flexible doses [5].

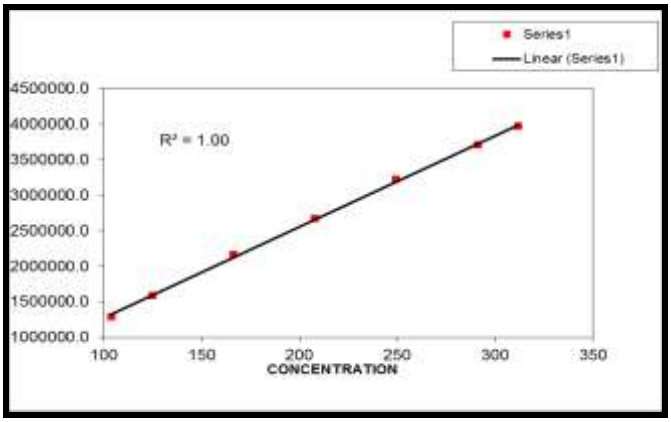
2. METHOD:

Simple Isocratic Chromatographic method having good peak shape and good S/N was developed and validated. Several HPLC methods [8-9] have been published for determination of Olanzapine in human serum using UV or fluorescence detection [2]. While the sensitivity of analysis is significantly reduced due to dilution of the samples after de-proteinization, injection of the acid supernatant after precipitation of proteins by perchloric acid leads to numerous late eluting peaks and significant reduction of the lifetime of analytical column. The numbers of column such as waters symmetry C18 (250 x 4.6mm, 5.0µm), YMC packpro C18 (250 x 4.6mm, 5.0µm) Inertsil ODS 3V (250 x 4.6mm, 5.0µm) were used during method development. The separation was achieved using Isocratic program of solution A (i.e. Solution A used Contains 0.1% Ammonium Acetate in water): and Solution B is Acetonitrile in the ratio of 95:5 v/v. the flow rate was set at 0.8 ml/min and column was maintained at 450C. The injection volume was set 3µl and detector was set at a wavelength of 254 nm.

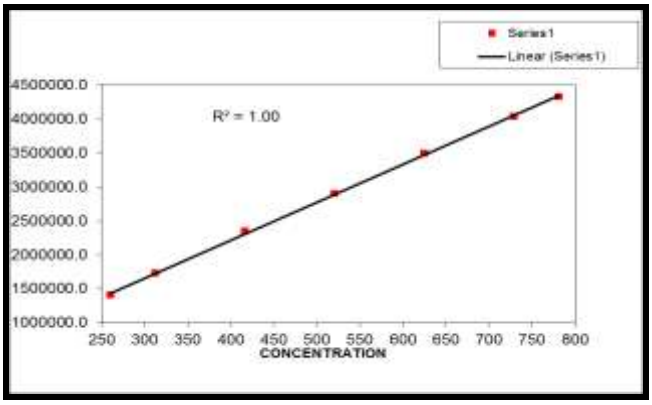
3. RESULTS:

The diluent was selected for dissolving Olanzapine and Pliperidone was mixture of water and Olanzapine (in ration of 50:50 v/v). Standard solution of Olanzapine and Pliperidone were prepared in diluent having concentration of 0.2 mg/ml and 0.5 mg/ml respectively. Olanzapine and Pliperidone sample solution were prepared in the concentration of 0.2 mg/ml and 0.5 mg/ml respectively and injected.

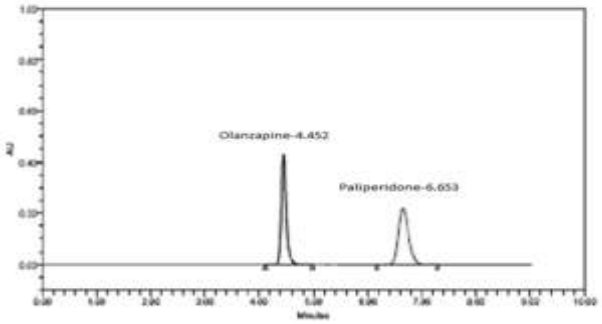
Force Degradation Conditions: Elevated Temperature, Acidic & Basic Condition, Oxidation & Reduction, Hydrolysis. **Calibration curves: Linearity for Olanzapine:**



Linearity for Paliperidone:



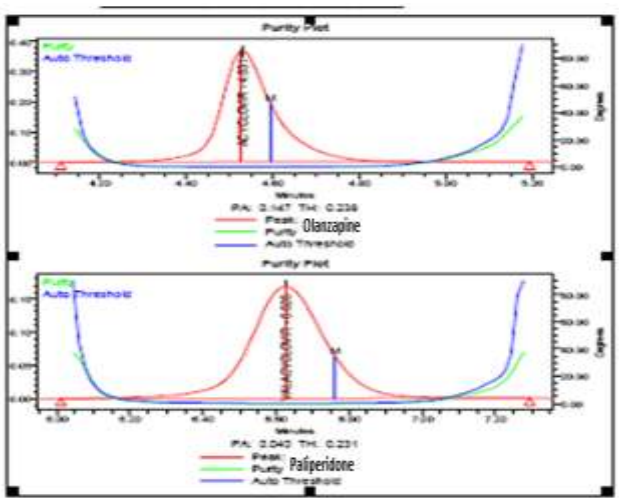
Standard chromatograms:



Force degradation study:

Chromatograms:

Condition	Sample Area of Olanzapine	% Recovery of Olanzapine	Sample Area of Paliperidone	% Recovery of Paliperidone
Control	3189071	99.16	2403651	94.99
EV	3247062	100.97	2445863	96.66
Lux	3237368	100.6	2442162	96.51
Watt	3281661	102.04	2476492	97.87
Acidic 1Hr	2919073	90.77	2640459	104.35
Basic 1Hr 0.1M	2901547	90.22	2681637	105.98
Oxidation 2Hr	3247062	100.97	2445683	96.65
Reduction 1Hr	3112548	96.78	2752460	108.77
Hydrolysis 2Hr	3179852	98.88	2684972	106.11



4. CONCLUSION:

The proposed LC method is selective for the quantification of Olanzapine and Paliperidone. Hence this method is useful for the detection Olanzapine and Paliperidone in routine analysis.

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