

5th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 16-18, 2015 Crowne Plaza, Dubai, UAE

Preformulation solubility and distribution coefficient studies of Olanzapine in various buffers using in-house developed UV-spectrophotometric method

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Preformulation studies such as solubility and log D of atypical-antipsychotic drug, Olanzapine (OLN) have been determined in a series of buffers of varying pH, using in-house developed UV-spectrophotometric method. Solubility studies of OLN were carried out using modified-shake flask method in buffered solutions, of pH ranging from 1 to 12, for 48 hr at $37 \pm 0.5^\circ\text{C}$. Analysis was performed using in-house developed UV-spectrophotometric method [(absorbance = $0.0697 \times \text{concentration in } \mu\text{gml}^{-1} + 0.008$; $r^2 = 0.9999$) in 100mM hydrochloric acid]. OLN showed pH-dependent solubility of $0.076 \pm 0.012 \text{mgml}^{-1}$ at neutral pH, with maximum solubility in pH 1 ($16.561 \pm 0.746 \text{mgml}^{-1}$) and minimum solubility in pH 12 ($0.028 \pm 0.008 \text{mgml}^{-1}$), owing to the fact that Olanzapine, a weak basic drug with pKa 4.6, exists more in ionized form in acidic media and unionized form in basic media. Another significant preformulation study, apparent distribution coefficient was determined using shake flask method with minor modifications. Octanol was selected as organic phase and different buffers with pH ranging from 1 to 12 were used as aqueous phase. It was found that apparent distribution coefficients of OLN also followed pH-dependency with a reverse trend (as compared to solubility studies) of higher log D in alkaline buffers (presence of more unionized species) and lower values in acidic buffers (presence of low unionized species) with a log D value of 1.8 ± 0.12 at neutral pH. These results obtained by preformulation solubility and distribution coefficient studies of OLN in various buffers using in-house developed UV-spectrophotometric method, would help in better formulation development for OLN with maximum efficacy.

Biography

Emil Joseph is a senior research fellow in Industrial Research Lab, Department of Pharmacy, BITS Pilani, India with UGC-Government of India fellowship for pursuing doctoral research. He has qualified national level competitive exam, GATE twice and received numerous awards including prestigious Department of Science and Technology-Government of India international travel award for young scientist. He has published numerous articles in reputed journals and presented as well as reviewed posters in international conferences. He also has diverse research experience in central labs such as Central Drug Research Institute of India and Formulation & Development division of reputed pharmaceutical industries.

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