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DoE for identification of incompatibilities in formulation development

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Design of experiments (DoE) has been used to investigate stability issue of hydrochloride salt of an active compound (API) converting into weak base in tablets. Compatibility studies of an API with excipients (cellulose microcrystalline, talc, stearic acid and magnesium stearate) at different ratios were designed and magnesium stearate was identified as responsible factor. Using ^{13}C ssNMR it was proven that base formation depends on concentration of magnesium stearate. Level of the API base similar to observed in the reference product (20-30% in stress conditions, 64h, 80°C) was measured only at 0.25% concentration of magnesium stearate and was significantly higher at higher concentrations of magnesium stearate. For technological reasons, the lubricant was replaced with its acidic counterpart at a concentration of 4% which resulted in formation of less than 10% base in stress conditions. Long-term stability of the product has been already confirmed in registration batches. Reasonable DoE application allowed for fast and effective identification of instability factor and resulted in development of a stable product over entire shelf-life.

Biography

Pawel Stasiak has completed his Ph.D. in Pharmaceutical Technology from Medical University of Gdansk (Poland) in 2009 and Euro-Ph.D. in Advanced Drug Delivery in 2010. Currently he is a Formulation Leader at Zentiva k.s, Prague (Czech Republic).

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