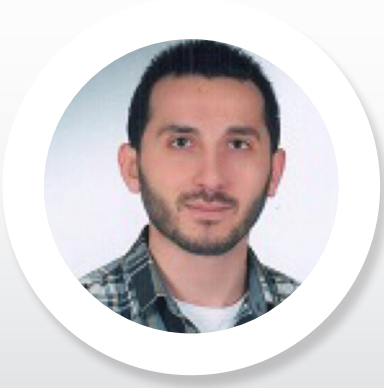
Joint Event
4th Pharmaceutical Chemistry Conference | 12th World congress on Future Pharma
June 27-28, 2019 | Amsterdam, Netherlands



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Novel stability indicating LC methods for determination of tasimelteon

Tasimelteon (TAS) is a melatonin receptor agonist compound, which is currently in use for the treatment of non-24-hour sleep–wake disorder in totally blind people. In this study, novel stability-indicating LC methods have been developed for the determination of TAS besides its degradation products. Three different LC set-ups were used within this study. Initially, an LC-PDA instrument was developed for quantification of TAS; the separation of TAS from its degradation products was achieved on an Ascentis® Express F5-bonded fused-core silica particle column using the mobile phase of acetonitrile: acetate buffer (0.025 M, pH 4.5): water (40:10:50, v/v/v); the elution was performed in isocratic mode at 0.8 mL min^{-1} flow rate, detecting the analytes at 281 nm. In addition, an alternative method was developed by using an LC-DAD-MS/MS instrument; the responses of DAD and MS/MS detectors were used as separate analytical signals for TAS and other compounds. A second-generation C18-bonded monolithic silica column was used as stationary phase in this method, while the mobile phase was a mixture of 0.1% (v/v) formic acid in water and 0.1% (v/v) formic acid in acetonitrile (60: 40 (v/v), pH=2.5). The instrumental and analytical performances of all three set-ups were compared in terms of validation parameters mentioned in ICHQ2(R1) guideline. On the other hand, a new degradation product was identified using an LC/MS-IT-TOF instrument. In conclusion, determination of TAS besides its degradation products and identification of a novel degradation product was successfully performed using the protocols reported in this study.

Biography

Serkan Levent is a Lecturer in Anadolu University and also a PhD student at the Department of Analytical Chemistry of the same university. He has published more than 30 papers in highly reputed journal, which are mostly indexed in Science Citation Index of Thomson-Reuters.

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