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Control strategy applied to a LC-DAD quality control method as part of the analytical quality by design approach: one year of routine use

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The analytical quality by design approach has been previously applied to the method development. The analytical target profile (ATP) was defined as the baseline separation of the two analytes of interest, cannabidiol and Δ^9-tetrahydrocannabinol. The critical method attributes (CMAs) were set as the critical resolution between a peak pair (Rs) and the analysis time (t). Critical method parameters were studied, and the response surface methodology was used to optimise the method. The method operable design region (MODR) was obtained by Monte-Carlo simulations and risk of failure maps setting the probability of meeting the specifications ($Rs \geq 0.85$ and $t \leq 6$ min) at 95%. A working point within the MODR was chosen, validated, and implemented in routine analyses. The information collected during the optimisation studies was conveyed to the planning of the control strategy consisting in system suitability test and control charts. The CMAs used for method optimisation were chosen as system suitability criteria to monitor the behaviour of the method performance. The evaluation was conducted over a period of one year of routine use. Both the CMAs showed values within the specifications in each analysis performed. On the basis of these results, a new and more complete risk evaluation was achieved.

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