

DEVELOPMENT AND OPTIMIZATION OF FAST, EFFICIENT, ECONOMICAL AND GREEN HPLC METHOD FOR IBUPROFEN IMPURITIES TESTING BY USE OF CORE-SHELL COLUMN

Marjan Piponski^{1*}, Tanja Bakovska Stoimenova¹, Liliya Logoyda², Marina Topkoska¹, Elena Lazarevska Todevska¹, Elena Petrovska¹, Stefan Angelevski¹

¹Replek Farm Ltd., Skopje, N. Macedonia

²I. Horbachevsky Ternopil National Medical University, Department of Pharmaceutical Chemistry, Ternopil, Ukraine

*piponski99@gmail.com

Ibuprofen is still very often used nonsteroidal anti-inflammatory drug, beside the fact that its origin dates a half century ago. This is one of the reasons for continuous improvement of its quality control analytical methods. Current pharmacopoeial monographs (1,2) for ibuprofen prescribe HPLC method for impurities testing by use of C18 column (150 mm × 4.6 mm, 5 μm), gradient elution at flow rate of 2 mL/min and run time of about 80 minutes. In a bunch of core-shell particle columns from different vendors, with different physico-chemical characteristics, inducing different intensity of interactions between analyte and stationary phase, a proper separation and system suitability parameters, could be achieved only with some selected ones. This indicates that beside incomparable separation characteristics between 5 μm fully porous and 2.7 μm core-shell particles, it did not warrant successful separation and simple replacement of monograph recommended standard column with any of modern powerful core-shell particles columns. Thus, we followed to investigate and calculate the benefits of replacement. By use of samples and standards prepared in accordance to monographs, we tested few more powerful new core-shell columns, with different length, diameter, particle size and different vendors. The best results were achieved with Shimadzu C18 Next Leaf SH-SPP and Poroshell C18, both with 2.7 μm particles, which reduced the run time by 7-8 times, when compared to the pharmacopoeial method (1,2). Beside shortening run time, this method offers many advantages from economic and ecological aspects, and increases sensitivity and resolution to significantly improved values.

References

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RAZVOJ I OPTIMIZACIJA BRZE, EFIKASNE, EKONOMIČNE I ZELENE HPLC METODE ZA ISPITIVANJE NEČISTOĆA IBUPROFENA KORIŠĆENJEM “CORE-SHELL” KOLONE

**Marjan Piponski^{1*}, Tanja Bakovska Stoimenova¹, Liliya Logoyda²,
Marina Topkoska¹, Elena Lazarevska Todevska¹, Elena Petrovska¹,
Stefan Angelevski¹**

¹Replek Farm d.o.o, Skoplje, S. Makedonija

²Ternopoljski Nacionalni Medicinski Univerzitet I. Horbačevski, Katedra za farmaceutsku hemiju, Ternopolj, Ukrajina

*piponski99@gmail.com

Ibuprofen je i dalje veoma često korišćen nesteroidni antiinflamatorni lek, pored toga što je nastao pre pola veka. Ovo je jedan od razloga za stalno unapređenje analitičkih metoda kontrole kvaliteta. Aktuelne farmakopejske monografije (1,2) za ibuprofen propisuju HPLC metodu za ispitivanje nečistoća korišćenjem C18 kolone (150 mm × 4,6 mm, 5 µm), gradijentnog eluiranja, brzine protoka 2 mL/min uz vreme analize od oko 80 minuta. U gomili kolona sa “core-shell” čestica, različitih proizvođača, sa različitim fizičko-hemijskim karakteristikama, koje uzrokuju različit intenzitet interakcija između analita i stacionarne faze, odgovarajuća separacija i parametri podobnosti sistema, mogu se postići samo sa nekim odabranim. Ovo ukazuje da i pored neuporedivih karakteristika razdvajanja između 5 µm potpuno poroznih i 2,7 µm “core-shell” čestica, ovo nije garantovalo uspešno razdvajanje i jednostavnu zamenu standardne kolone preporučene u monografiji sa bilo kojom od modernih moćnih “core-shell” kolona. Stoga smo produžili da istražimo i izračunamo prednosti zamene. Koristeći uzorke i standarde pripremljene u skladu sa monografijama, testirali smo nekoliko snažnijih novih “core-shell” kolona, različite dužine, prečnika, veličine čestica i različitih proizvođača. Najbolji rezultati su postignuti sa Shimadzu C18 Next Leaf SH-SPP i Poroshell C18, obe sa česticama od 2,7 µm, što je smanjilo vreme analiza za 7-8 puta u poređenju sa farmakopejskom metodom (1,2). Pored skraćivanja vremena rada, ovaj metod nudi mnoge prednosti sa ekonomskog i ekološkog aspekta, i povećava osetljivost i rezoluciju do značajno poboljšanih vrednosti.

Literatura

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