

SIMPLEST CONCEPT FOR DEVELOPMENT AND OPTIMIZATION OF HPLC METHOD FOR QUANTIFICATION OF THREE FLUOROQUINOLONES IN PHARMACEUTICAL DOSAGE FORMS: CIPROFLOXACIN, NORFLOXACIN AND MOXIFLOXACIN

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The existing chromatographic methods for quantification of these fluoroquinolones, contain certain disadvantages, such as generating peak tailings, which can vary in the range of 1.3-3. The characteristic structure of fluoroquinolones is the main reason for this peak asymmetry. Even official pharmacopoeial methods (1,2) for these fluoroquinolones allow peak tailing up to value of 2. This problem is usually overcome by addition of characteristic mobile phase additives, as triethylamine, for suppression of secondary analyte-column interactions in reversed phase chromatography, by blocking residual silanol groups from the stationary phase to interact with positive amino-group in the analyte molecule. During our research, we concluded that this problem with high peak asymmetry of these three fluoroquinolones: ciprofloxacin, norfloxacin and moxifloxacin, can be simply avoided by careful selection of the mobile phase constituents: type and percentage of organic solvents and use of organic acid, formic acid. The second important feature is a proper choice of column which yields best peak symmetry, by use of the proposed mobile phase. The best results were obtained with Zorbax C-8 columns, generating peaks with tailing factors ranging from 1.2-1.55. These research results enable creation, development, optimisation and validation of simple, rapid, selective, accurate and precise HPLC methods for quantification of each of these three quinolones in pharmaceutical dosage forms.

References

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**NAJEDNOSTAVNIJI KONCEPT ZA RAZVOJ I OPTIMIZACIJU HPLC METODA ZA
KVANTIFIKACIJU TRI FLUOROHINOLONA U FARMACEUTSKIM DOZIRANIM
OBLICIMA: CIPROFLOKSAIN, NORFLOKSACIN I MOKSIFLOKSACIN**

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Postojeće hromatografske metode za kvantifikaciju pomenutih fluorohinolona, sadrže određene nedostatke kao što je generisanje razvučenih pikova, koje variraju u rangu vrednosti 1.3-3. Sama karakteristična struktura fluorohinolona je osnovni razlog za pojavu asimetrije pikova. Čak je i u oficinalnim farmakopejskim monografskim metodama (1,2) dozvoljen *tailing* pikova na hromatoramu do vrednosti 2. Ovaj se problem obično rešava dodavanjem određene količine aditiva mobilne faze, kao što je trietilamin, za supresiju sekundarnih analit-kolona interakcija u reverzno-faznoj tečnoj hromatografiji, blokiranjem rezidualnih slobodnih silanolnih grupa iz stacionarne faze, koje intereaguju sa pozitivno-naelektrisanim amino grupama u samoj molekuli analita. Prilikom naših ispitivanja, mogli smo da zaključimo da se ovakav problem pojave visoke asimetrije pika ova tri fluorohinolona: ciprofloksacina, norfloksacina i moksifloksacina, može jednostavno eliminisati pomoću pažljive selekcije komponenata mobilne faze: tipa i procentne zastupljenosti organskih rastvarača, kao i acidifikatora eluenta, mravlje kiseline. Druga bitna stvar je izbor adekvatne kolone, koja daje najbolju simetriju pika, korišćenjem predložene mobilne faze. Prilikom naših ispitivanja, najbolje smo rezultate dobili korišćenjem kolona Zorbax C-8, kojima smo dobili pikove sa vrednostima *tailing* faktora u opsegu 1.2-1.55. Ovakvi eksperimentalni rezultati omogućavaju kreiranje, razvoj, optimizaciju i validaciju jednostavnih, brzih selektivnih, tačnih i preciznih HPLC metoda za kvantifikaciju svakog od ova tri fluorohinolona u svojim doziranim oblicima.

Literatura

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