HPLC method for stability evaluation of pharmaceutical preparations containing sodium picosulfate

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Introduction

Nowadays, HPLC is the most widely spread and powerful analytical tool in drug control. It is the first choice method for the solution of all problems connected with the evaluation of related substances and the assay of the active substance as well as the preservative. This separation method was thus used to develop an analytical method which enables evaluation of oral liquid drug preparations containing sodium picosulfate as the favoured laxative drug.

Results and discussion

The developed method was based on a valid pharmacopoeial one[1)], it was optimized for and then it was validated[2)] as sufficiently selective, precise, accurate, linear and sensitive. Robustness was tested by means of the Plackett-Burman design[3)] and it was found that the ratio of acetonitrile in the mobile phase exerts the greatest influence on separation from all proved parameters. On the other hand, flow, buffer concentration and the ratio of propan-2-ol in the mobile phase little affect the separation.

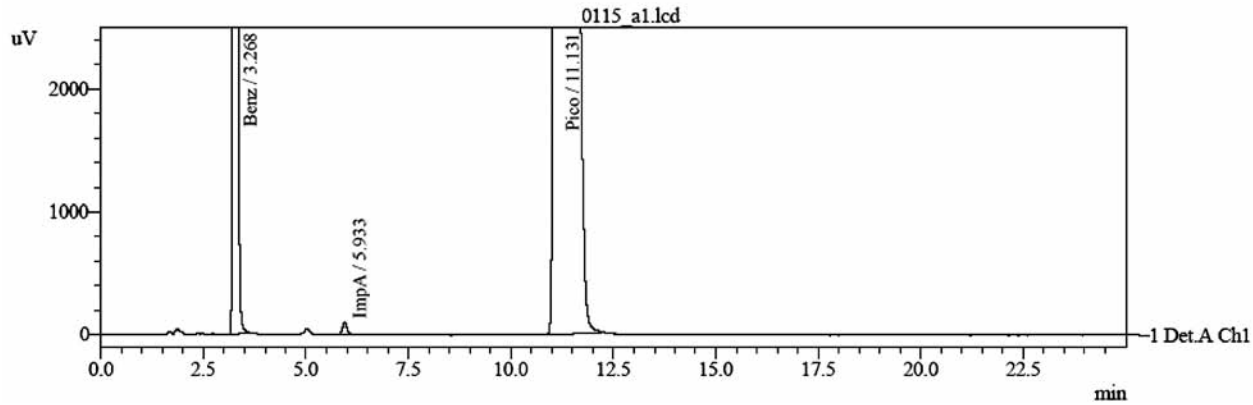

Fig. 1. A typical chromatogram of a pharmaceutical preparation containing sodium picosulfate as the active ingredient, sodium benzoate as the preservative and impurity A, which is the main hydrolytical degradation product of the active substance

Experimental method

HPLC separation of components was achieved with LiChroCART®, 250 × 4.0, Purospher® STAR, RP – 18 C, 5 µm column using a UV detector at 263 nm. The mobile phase consisted of a buffer, acetonitrile and isopropylalcohol in the ratio of 55 : 43 : 2 (v/v/v). The buffer contained disodium hydrogen phosphate, water R and cetyltrimethylammonium bromide. The pH value was adjusted by phosphoric acid to 7.0. The temperature of the column was 40 °C, injection volume 4 µl, the flow rate was adjusted to 1.0 ml/min.

Conclusions

The developed method enables simultaneous evaluation of the content of the active ingredient, its related substances and the preservative. It was sufficiently validated from the standpoint of selectivity, linearity, precision, accuracy, sensitivity and robustness, and can be used for release control of the pharmaceutical preparation and for its stability studies, too.

This work was supported by a research project SVV 260062.

Conflicts of interest: none.

References

1. European Pharmacopoeia. 8th ed. Strasbourg: Council Of Europe, 2013.
2. ICH [online] 2013 [cit. 2013-12-11]. Available from: http://www.ich.org/products/guidelines/quality/qualitysingle/article/validation-of-analytical-procedures-text-and-methodology.html
3. **Holík M.** Optimalizace analytických postupů pomocí Plackettova-Burmanova plánu. Chemické listy. Praha: Česká společnost chemická 2004; 98.

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