DEVELOPMENT OF IDENTIFICATION TESTS FOR COMPOUNDED PREPARATIONS CONTAINING FUROSEMIDE
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The development of rapid test systems for in-pharmacy control of compounded preparations and introduction to practice is of significant importance. Active pharmaceutical ingredients registered in Ukraine as pharmaceutical substances and finished medicinal products (tablets, capsules, ointments etc) may be used for extemporaneous preparation of drugs in the pharmacy. The use of finished medicinal products for compounding may complicate chemical control of the compounded drug due to the presence of excipients.

Aim: The aim of our study was to verify the possibility of using test strips treated with salts of heavy metals for identification of furosemide in single component compounded suspensions containing furosemide substance or furosemide tablets in simple syrup USP and to determine if excipients will significantly affect the desired result.

Materials and methods: 2mg/ml and 5mg/ml suspensions consisting of syrup USP and furosemide were compounded separately for both substance and crushed commercial tablets (brand “Arterium”, excipients: lactose monohydrate, magnesium stearate, potato starch). 0.1 M sodium hydroxide solution R was used as a solvent. Test strips impregnated with metal salts of copper (II) sulfate R, iron (III) chloride R2 and cobalt (II) nitrate R were used as reagents. To determine the reliability of the analytical effect, the suspensions were dissolved in the solvent at syrup-solvent ratios ranging from 1:0.1 to 1:1.6 (ml), shaken and allowed to stand for several minutes. A drop each of syrup, furosemide in syrup, 0.1 M sodium hydroxide solution R and mixture of furosemide suspension with sodium hydroxide were deposited on the test strips.

Results: Simple syrup and furosemide suspension in simple syrup had no changes on any of the treated strips. A drop of the solvent on the strip treated with copper (II) sulfate showed a blue spot. On the strips treated with iron (III) chloride an orange spot representing ferric hydroxide was seen. Sodium hydroxide solution produced a green spot corresponding to cobalt (II) hydroxide on the strips treated with cobalt (II) nitrate. When a drop of the mixture of furosemide suspension with 0.1 M sodium hydroxide was added to the copper (II) sulfate and iron (III) chloride treated strips, green and red spots respectively were seen. On cobalt (II) nitrate treated strips, very faint pink and relatively insignificant change was observed. These changes were the same for both samples of furosemide substance and powdered tablets suspensions in 0.1 M sodium hydroxide. No positive changes were observed with samples from 2 mg/ml furosemide suspension. The minimum concentration of furosemide in syrup USP for which identification on test strips treated with Copper sulphate R and Ferric Chloride R2 yielded positive results was 5 mg/ml. In the 5 mg/ml sample, the minimum syrup-0.1 M sodium hydroxide ratio for which the identification test were positive was 1 ml:0.1 ml, while the maximum volume was 1 ml:0.3 ml for test strips treated with Ferric Chloride R2. The minimum syrup-0.1 M sodium hydroxide ratio for which the identification test were positive was 1 ml:0.1 ml, while at volume ratio of 1 ml:1.6 ml a positive result was still observed for test strips treated with Copper sulphate R.

Conclusion: The study has proven the possibility of using test strips treated with copper (II) sulfate and iron (III) chloride for identification of furosemide in single component compounded suspensions of furosemide in syrup USP at a minimum concentration of 5 mg/ml in pharmacies. The excipients from the tablets did not interfere with the results of the test. Optimum suspension-0.1 M sodium hydroxide volume ratio required for positive reaction of test strips was 1 ml:0.2 ml. This identification test may be introduced to practice after validation.