Development and validation of UV-spectrophotometric methods of efavirenz quan-titative determination in urine

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Introducion

Efavirenz is a non-nucleoside reverse transcriptase inhibitor and attributed to the group of antiretroviral medicines, and used for treatment of HIV infection. At the same time it is possessed of quite a number of side effects showed by psychiatric symptoms, including in-somnia, nightmares, memory loss, depression, and anxiety. Use of efavirenz can produce a false positive result in urine tests for marijuana.

Aim

To develop UV-spectrophotometric procedures of efavirenz quantification in urine and to validate the developed procedures.

Material and methods

Efavirenz of pharmacopoeial purity was used in the experiment. favirenz isolation from urine was carried out using acetonitrile with subsequent sepa-ration of organic layer under the conditions of aqueous phase saturation by ammonium sul-phate. Isolation was carried out in the acid (pH = 2), weak-acid (pH = 5) and alkaline medium (pH = 11). The calibration and model and also blank-samples and blank-solutions were analysed for each developed procedure.

Results

The development and validation of procedures of efavirenz quantitative determination was carried out with application of the normalized coordinates; the application ranges was 25 – 175%; the number of concentration levels was g = 7. The efavirenz concentration in urine corresponding to the point of 100% was 12 μg/ml. Validation was carried out by such parameters as «specificity/selectivity», «recovery», «linearity», «accuracy» and «precision».The results of specificity study show that efavirenz isolation from urine using acetonitrile provides low contribution of biological matrix components into the absorbance of the sample to be analysed, and the lowest value corresponds to the experiment in the weak-acid medium. By the results of recovery study the method with acetonitrile application in the alkaline medium is characterized by the best extraction efficiency. The values of reproducibility for recovery and blank-samples absorbance satisfy the acceptability criteria for all variants of the methods. All examined methods are characterized by the acceptable parameters of linearity, accuracy and precision, and the obtained data are the evidence of application possibility of the developed methods for efavirenz spectrophotometric determination in urine.

Conclusion

We have developed the set of UV-spectrophotometric methods of efavirenz quantitative determination in urine using acetonitrile for analyte isolation from matrix under the conditions of aqueous phase saturation by ammonium sulphate. Acetonitrile application in the weak-acid medium is optimal by specificity and extraction efficiency.