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ACCELERATED DEGRADATION OF PROPYLTIOHINOTIADIAZOL IN STABILITY RESEARCH

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INTRODUCTION

Stability research is a key step in assessing the quality and safety of a drug substance.

The purpose. Evaluation of the stability of propylthiohinothiadiazole by accelerated isothermal degradation and under stress.

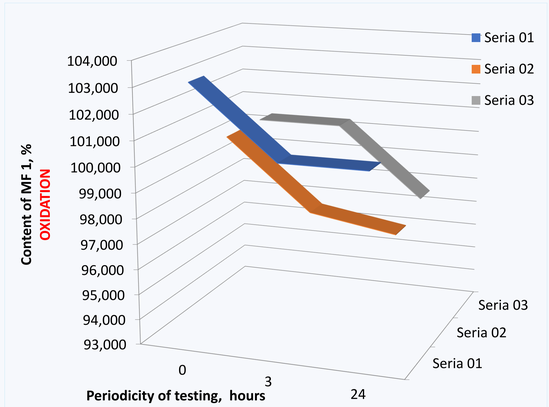
MATERIAL AND METHODS

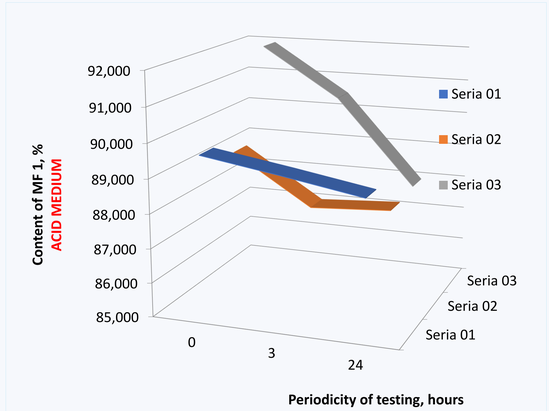
Stability testing methodology ICH Topic Q1A (R2); 3 series of propylthioquinothiadiazole in bulk; Shimadzu LC-20AD liquid chromatograph with UV-VIS detector; Perkin Elmer-40 spectrophotometer; thermogravimeter Q200 V24.4 Build 116; solvents, reagents in accordance with the European Pharmacopoeia.

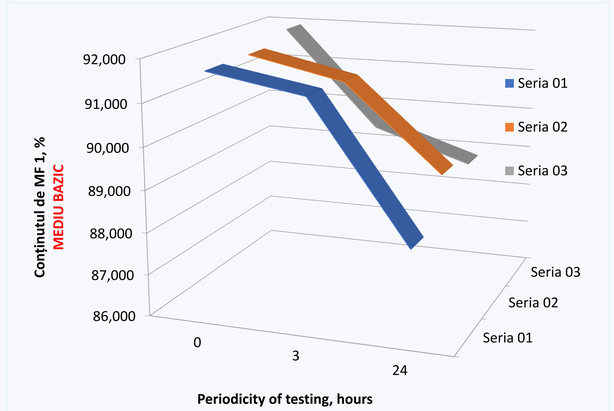
RESULTS

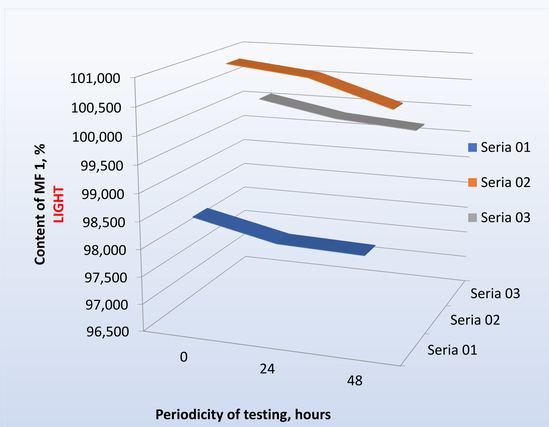
Under conditions of oxidative, hydrolytic, thermal, acid-base, photocatalytic stress, it was established by UV-VIS spectrophotometric method that the substance is stable at temperature, humidity and acidic environment. Propylthioquinothiadiazole degrades under the influence of the oxidant and in the basic medium (decreasing the concentration by 3% and 5%). DSC thermal analysis shows that the substance undergoes thermal changes after 110^{0}C. By experimental storage, using "Accelerated degradation" method at 40^{0}C and 60^{0}C, with the determination of the concentration by the HPLC method, was calculated the shelf life for the substance of 7 years.

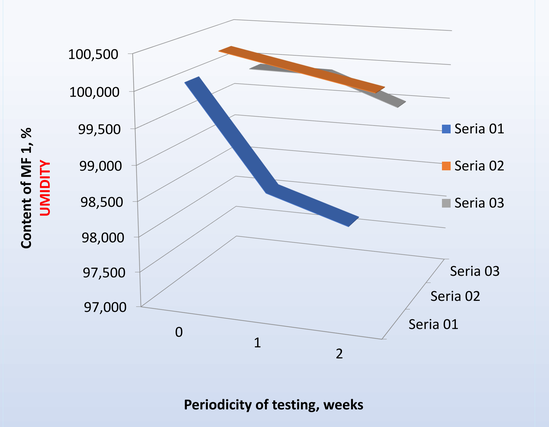
Fig. 1. Modification of the concentration of propylthiohinothiadiazole (MF1) following stress degradation

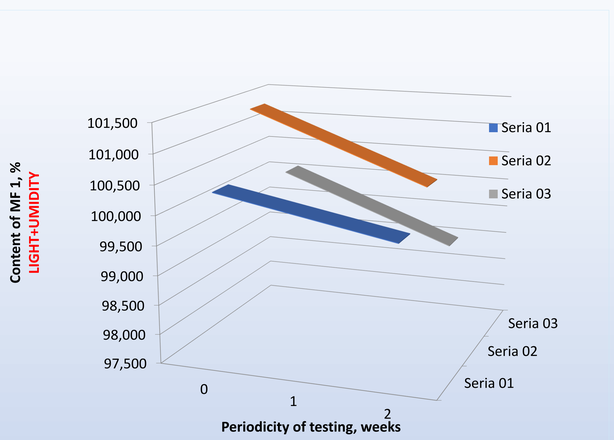












CONCLUSIONS

The results obtained will also be confirmed by real-time stability studies. Currently the substance is stored under normal conditions (25^{0}C; 65% RH) for 3 years and 10 months. By now, the drug substance meets all the quality criteria set out in the draft of quality specification..

Keywords: Stability, propylthiohinothiadiazole, shelf life.

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