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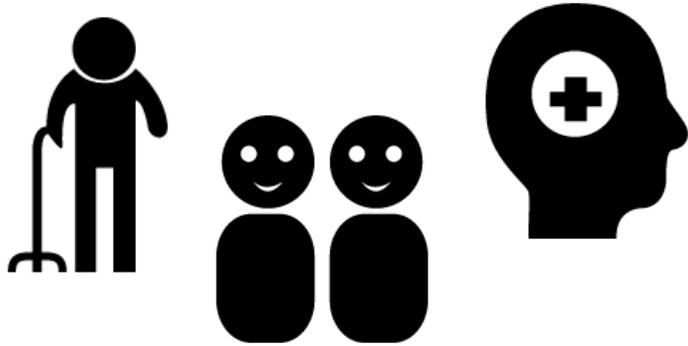
Evaluation of the usefulness of computer microtomography for the analysis of subdivided prolonged release tablets containing carbamazepine

Meisner Michał¹, Sarecka-Hujar Beata¹, Duda Piotr², Wilczyński Sławomir¹

¹ Medical University of Silesia, Faculty of Pharmaceutical Sciences in Sosnowiec, Department of Basic Biomedical Science, , Katowice, Poland

² University of Silesia, Faculty of Computer Science and Materials Science, Department of Biomedical Computer Systems, Institute of Computer Science, Poland

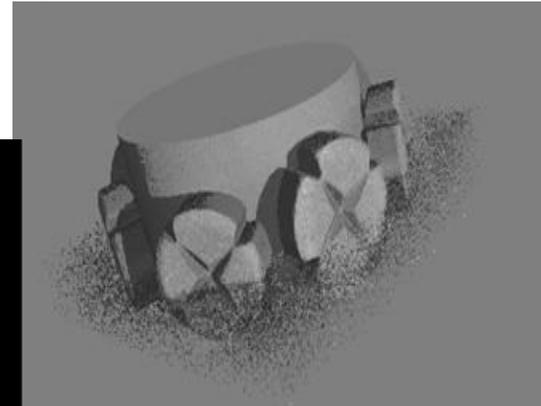
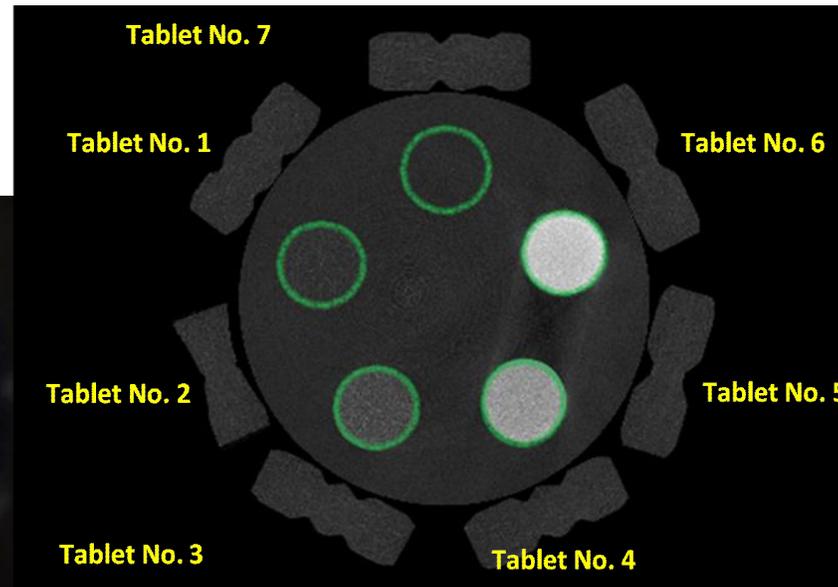
Can the tablet splitting be useful?



- The study was conducted on Finlepisn 200 retard, tablets containing carbamazepine.
- All tablets were carefully measured and weighted.
- A kitchen knife was used for the division.
- In the analysis, the correlation between brightness of scans of the tablets obtained with the Phoenix vltomelx Microtomograph (GE, Germany) and density was used.

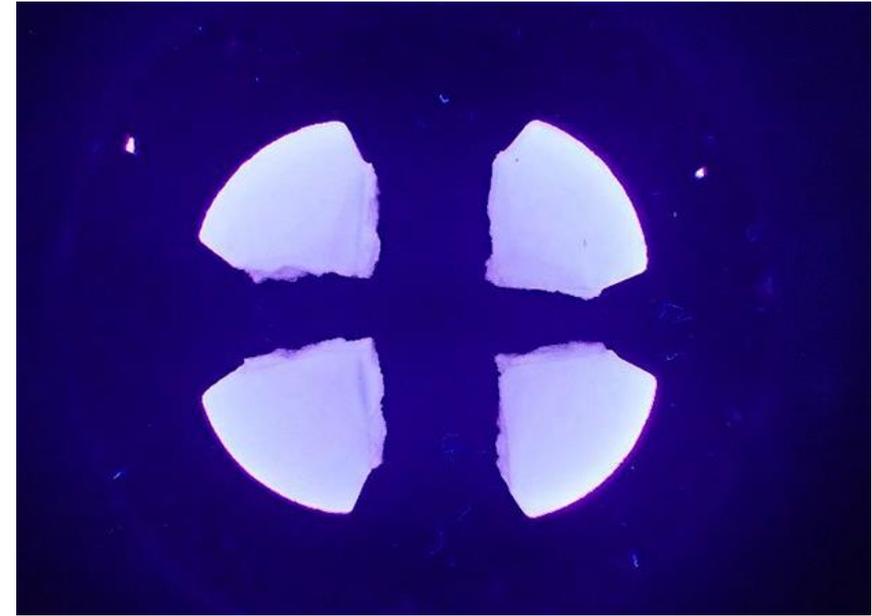
AIM:

To assess the usefulness of the x-ray computer microtomography in the analysis of ingredients' distribution in prolonged release tablets containing 200 mg of carbamazepine.



Results

- All tested tablets met the requirements set by the Polish Pharmacopoeia.
- After splitting into two parts, the weight loss for 2 of the tablets exceeded 3%. However, when divided into 4 parts, 4 of the tested tablets did not meet the requirements.
- The analysis of the homogeneity of the weights demonstrated that both, whole tablets and tablets divided into 2 parts, met the requirements set for them.*
- The weights of the individual tablet parts were also compared with the corresponding theoretical weights obtained as a result of the ideal division. There was a statistically significant difference between the weights of the left halves and only one of the quarters.

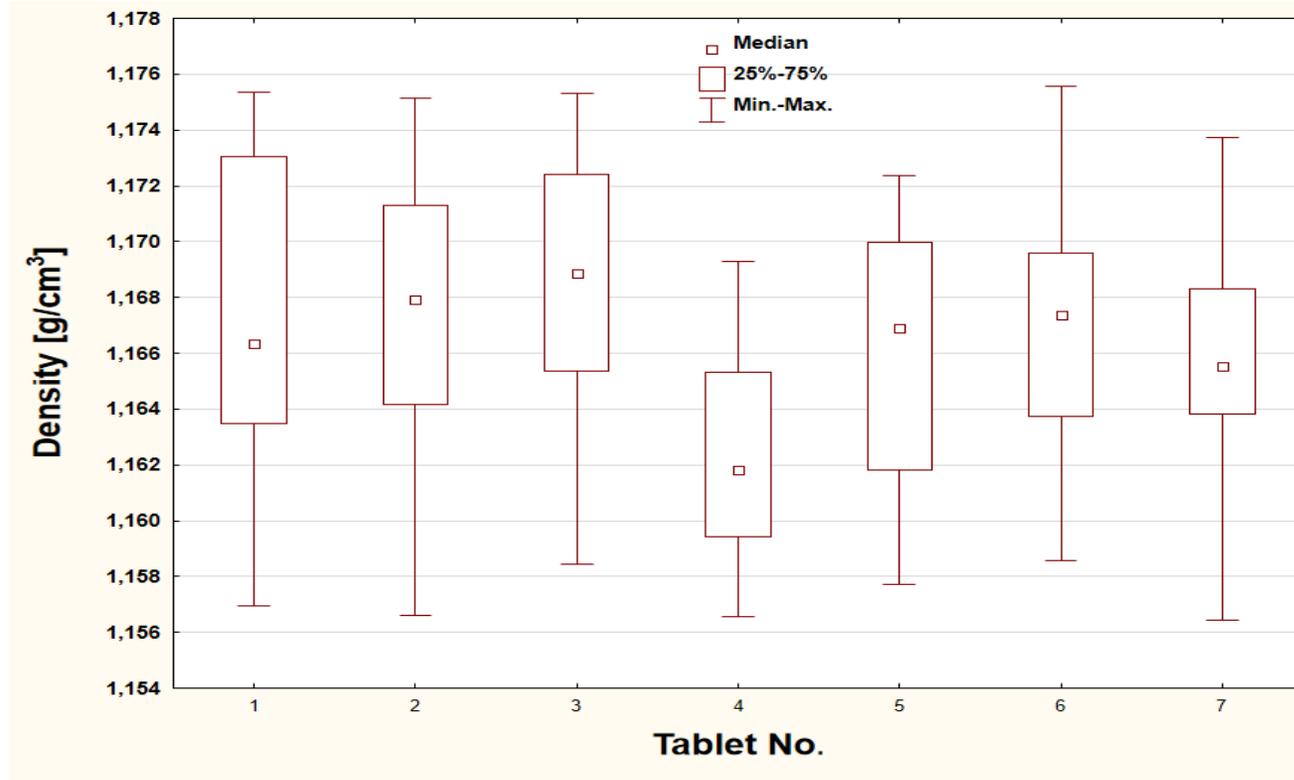


* For whole tablets, the range of 95% -105% of the average weight of the tablets was adopted, while for those divided into 2 parts, two criteria were determined: the first one was that no more than one part of the tablet may exceed the range of 85-115% of the average weight of a half tablet, and second, that no part of the tablet can exceed the range of 75% -125% of the average weight of the tablet half.

Microtomographic analysis

- A statistically significant difference in density between the whole tested tablets was observed (Fig. 1)

Figure 1. Box plots for density comparison between whole tablets



- No statistically significant difference was found for brightness of pixels between the tablet halves (Fig. 2)

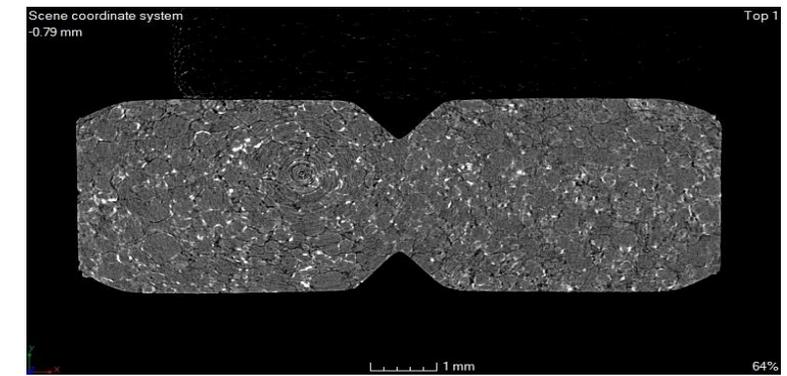
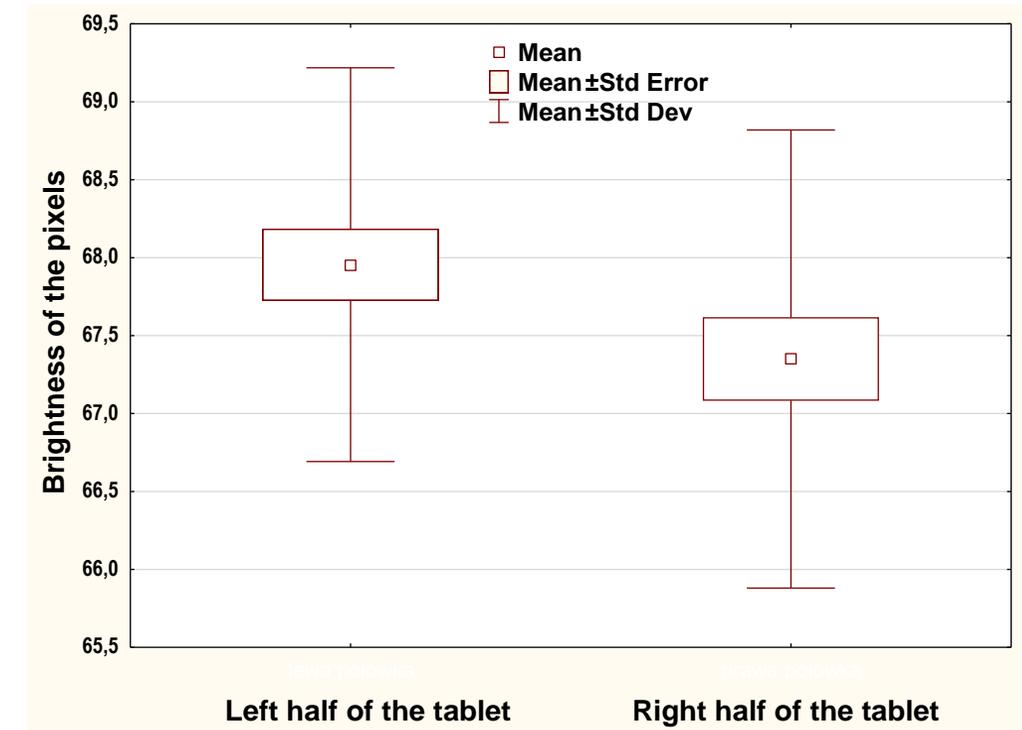


Figure 2. Box plots for brightness of pixels comparison between halves of tablets



Conclusions

- Microtomographic methods followed by picture analysis enable the assessment of the homogeneity of the ingredients' distribution in carbamazepine-containing tablets.
- Subdivision of the carbamazepine-containing tablets showed a homogeneous distribution of the ingredients in tablets halves.
- There were differences between the theoretical and actual weights of the divided tablet parts, which may result in incorrect dosing by the patient.