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Evaluation of the applicability of computer microtomography to study the internal structure of tablets containing trazodone hydrochloride. Safety of tablet subdivision

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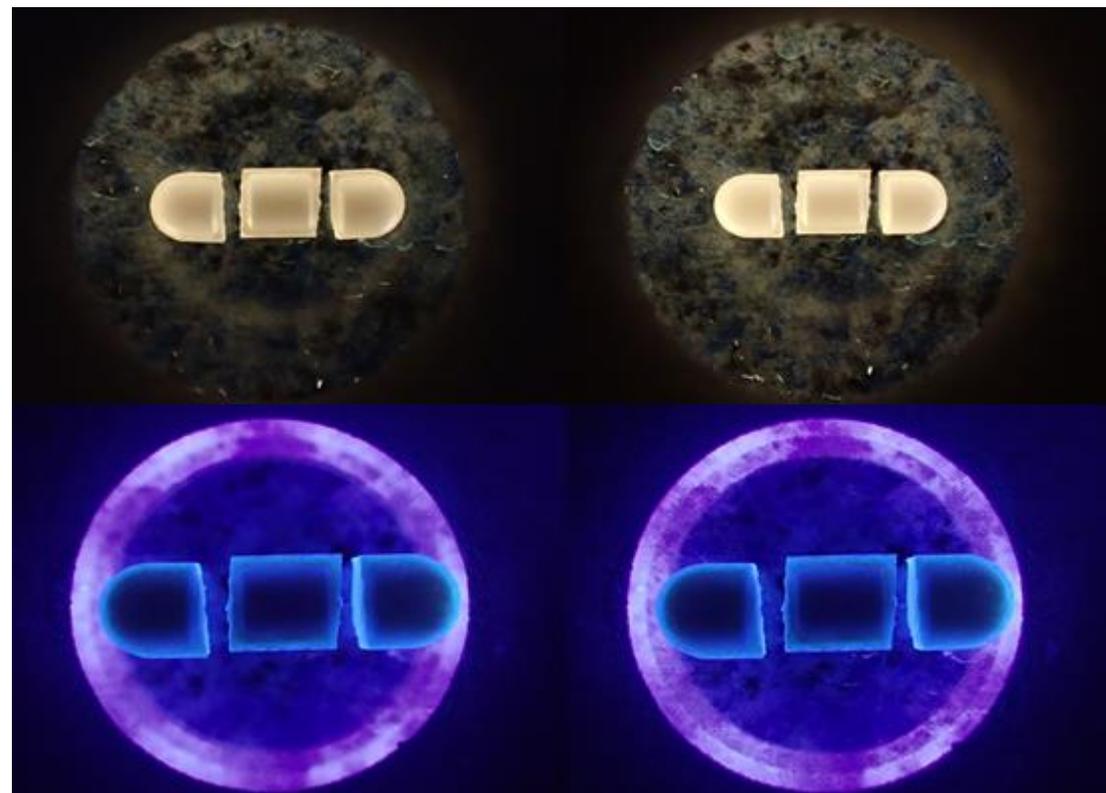
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Summary

- **Background:** In order to assess the safety of tablet dividing practice and its influence on the uniformity of the dose of the drug substance in the resulting parts of the tablets, and at the same time on the effectiveness of the therapy, many modern research methods are used, including computer microtomography.
- **Aim:** The objectives of the study were, as follows: a) to investigate the applicability of computer microtomography techniques to assess the homogeneity of the distribution of ingredients in tablets; b) to discuss already gathered data concerning the problems with tablet subdivision, such as precision and safety for the patient.
- **Methods:** Prolonged release tablets containing 75 mg of trazodone hydrochloride were measured with a calliper and then weighed to check mass uniformity. After dividing into three parts using a kitchen knife, the mass of the resulting parts was weighed and checked for uniformity. Using a microtomograph, scans of the tablets were taken before and after subdividing the tablets. The calibration curve was determined based on the scans of the microtomograph calibration phantom containing areas of known density.

Research results

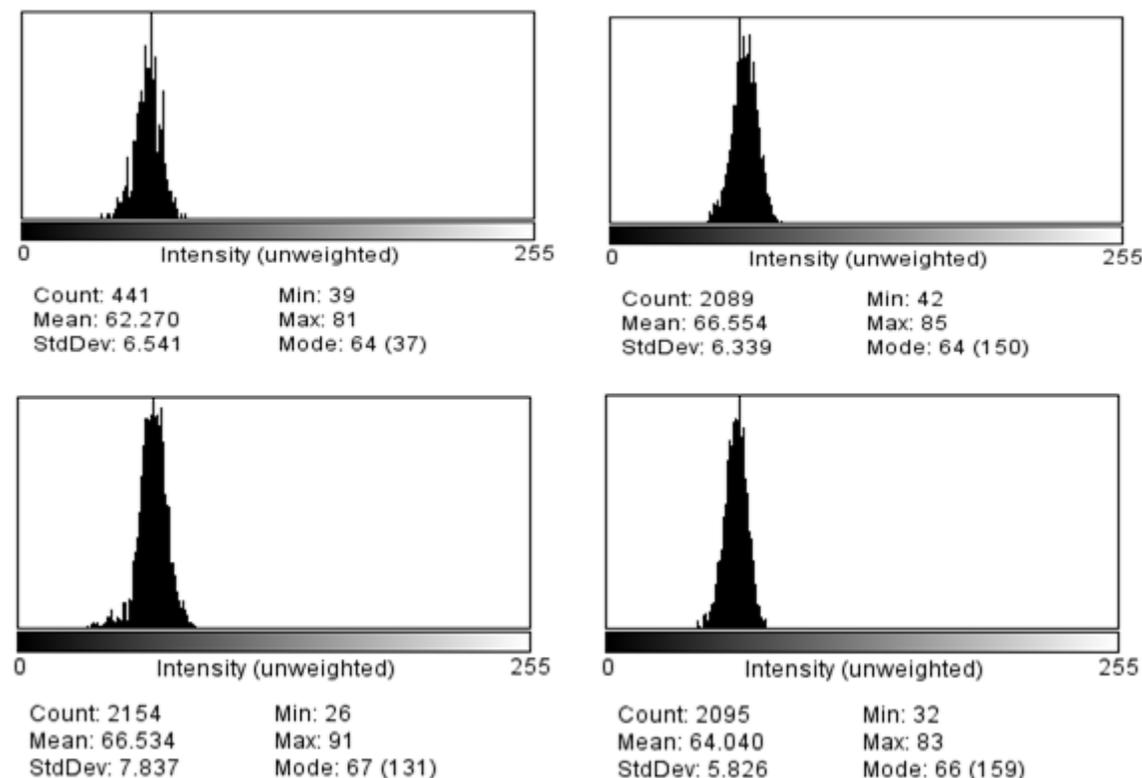
Tablets before and after splitting met the pharmacopoeia weight uniformity requirements. The loss of weight after dividing the tablets was found to be lower than 3% which is in compliance with FDA requirements. The weight significantly differentiated the parts of the tablet obtained after subdividing. The analysis of the pixel brightness along with the density correlated with it showed that both the tablets and their parts differed significantly from each other.



Pictures of subdivided tablets in visible light (top) and UV light (bottom)

Conclusion

Computed microtomography supported by techniques of image analysis and processing can be successfully used to analyze the internal structure of tablets. Dividing the prolonged release tablets containing 75 mg of trazodone with a kitchen knife does not guarantee obtaining tablet fragments that have the same amount of the active substance. In addition, the weights of the obtained parts differ significantly from each other. This, in turn, creates a risk of large fluctuations in the dose of medication taken by the patient.



Exemplary histograms showing the density of tablet fragments