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# Validation of Assay for Seneciphyline and Related Impurities in Platyphylline Hydrotartrate Substance and «Platyphylline-Zdorovie» Injectable Preparation by Using RP HPTLC Method

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*The article shows the results of determination of validation parameters of assay for seneciphyline and related impurities in platyphylline hydrotartrate substance and "Platyphylline-Zdorovie" injectable preparation by reversed-phase high-performance thin-layer chromatography method. The instrumental tools for drawing samples onto chromatographic plate and chromatodensimetry for quantitative processing of the results were used in the work. Range of assay linearity was 0.05–0.45 μg/spot, which is 25–225% relatively to the maximum permissible impurity content 0.2 μg/spot (1.0%); detection limit 0.02 μg/spot; quantitation limit 0.05 μg/spot; relative standard deviation obtained in the study of accuracy, precision and repeatability does not exceed 8%. Obtained results of the validation studies indicate compliance with the requirements of the State Pharmacopoeia of Ukraine. Thus, the assay can be recommended to pharmaceutical companies for quality control of platyphylline hydrotartrate substance and injectable preparation on its base.*

**Keywords:** platyphylline hydrotartrate, seneciphyline, reversed-phase high-performance thin layer chromatography, related impurities, assay, validation