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EXPERIMENTAL PHARMACOLOGICAL RESEARCH OF NEW COMBINED MEDICINAL PRODUCT FOR TREATMENT OF SENSORINEURAL HEARING LOSS

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Background: **Sensorineural hearing loss (SHL)** affects the perception of sounds from the inner ear, auditory nerve, subcortical, and cortical auditory centers. The drug treatment of SHL is usually symptomatic and includes vasodilators, steroids, nootropics, and antioxidants [1].

Material and Method: The research algorithm consists of establishing the method for inducing SHL and peripheral vestibulopathy (gentamicine); experimental audiometric methods (otoacoustic emissions, Preyer reflex) for monitoring SHL; preclinical testing of static and dynamic locomotor coordination in *Wistar rats* (open field test, horizontal walking, and forced motor activity test to maintain balance).

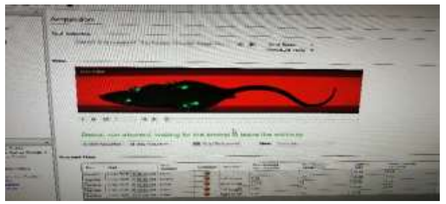
Results

1. This study aimed to develop and evaluate a novel oral fixed- dose combination capsule containing nicergoline, piracetam, and hawthorn extract (test product) for SHL management (1). All procedures describing experiments involving laboratory animals were conducted in accordance with Directive 2010/63/EU and national Law no. 211/2017.
The test product demonstrated low acute toxicity across administration routes (ATC 5). In gentamicin-induced SHL models, animals treated with the test product showed a clear otoprotective effect, as evidenced by improved otoacoustic emission results (Transitory OAE, Distortion Product OAE > 0 dB SPL; signal-to-noise ratio > 3 dB Sound Presure Level in the 1000–4000 Hz range), Preyer reflex at 80 dB SL in contrast to the untreated ototoxicity group ($p < 0.05$).

2. Preclinical research in the fields of audiology and experimental vestibulometry demonstrated the beneficial effect of the studied product in the complex treatment of SHL and peripheral vestibular disorders (using OEA, Cat Walk, Rota Rod Tests).







3. The fixed-dosed medicinal product therapy yielded the most significant benefits, with no notable side effects observed. The novelty of the project involves measuring the effectiveness audiometric and vestibulometric preclinical researches of SHL and peripheral vestibulopaty. Has been developed a practical basis for an interdisciplinary and systemic conceptual approach of preclinical studies on the development,pharmacological treatment of sensorineural ear pathology.

References

1. Rus L.M., Uncu A., Parii S. et al. Development and Preclinical Evaluation of Fixed-Dose Capsules Containing Nicergoline, Piracetam, and Hawthorn Extract for Sensorineural Hearing Loss. Pharmaceutics. 2025; 17(8):1-25. https://doi.org/10.3390/pharmaceutics17081017

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Conclusion

This study pharmacologic characterized a novel combined drug in capsules containing nicergoline, piracetam, and hawthorn extract, for potential use in SHL therapy. The data of experimental audiological and vestibular tests in rats encouraging further preclinical and clinical research.

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