

## COCHLEAR FLUIDS SIMULATOR

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**Background:** Local drug therapy of the inner ear became popular in the 1990s to treat a number of ear disorders. Local therapy allows the drug to bypass entry barriers, reducing systemic toxicities. For novel drugs to be delivered to the inner ear, pharmacokinetic (PK) values such as half-life and maximum concentration of drug (Cmax) are crucial to assess and compare dosing protocols. In addition, the Food and Drug Administration (FDA) have recently started to require PK studies and simulations for novel drugs for inner human ear delivery prior to the approval for market. Yet, at present, there is still only a limited understanding of the pharmacokinetics of drugs in the ear and no simple method of accomplishing PK for novel drugs to be applied to the inner ear.



**Technology Description:** Researchers at Washington University have developed a simulation program for drug dispersion in the inner ear. Calculations utilize anatomical data (guinea pig, mouse, and human) derived for the ear to interpret PK studies of drug delivery. The software also includes information regarding all the fluid and tissue compartments of the cochlea (including spiral ligament, spiral ganglion, auditory nerve, etc.) and the fluid compartments of the vestibule. The software is fully functional and can be used for the study of any developing drugs used for hearing loss, vertigo, tinnitus, etc.

### Key Advantages:

- Ability to test PK preliminarily before investments of time, effort and finance in developing and validating the drug
- Informational and accurate PK values are based upon the anatomical data currently known for the inner ear and similar drugs seen in past literature
- Very simple and comprehensive technique in terms of assessing PK