

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022305Orig1s000

STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Science
Office of Biostatistics

Statistical Review and Evaluation
45 days fileability review

NDA/Serial Number: 22-305
Drug Name: 97% purified water
Indication(s): Flush eyes of foreign objects
Applicant: Niagara Pharmaceuticals
Date(s): Stamp date: February 26, 2008
PDUFA date: December 26, 2008

Review Priority: Standard
Biometrics Division: IV
Statistical Reviewers: Mushfiqur Rashid, Ph.D.
Concurring Reviewers: Thamban Valappil, Ph.D.
Medical Division: Division of Anti-infective and Ophthalmology Products
Medical Reviewer(s) Jennifer Harris, M.D.

Medical Team Leader William Boyd, M.D.
Project Manager: Geri Smith
Keywords: NDA review, clinical studies, Flushing of eyes, Foreign objects, Purified water

Fileability Comments:

The applicant did not submit any clinical studies for statistical review.

Mushfiqur Rashid, Ph. D.
Mathematical Statistician

Concur:

Thamban Valappil
Statistical Team Leader

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/s/

Thamban Valappil
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BIOMETRICS

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