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RESEARCH**

APPLICATION NUMBER:
40277

MICROBIOLOGY REVIEW

REVIEW FOR HFD-617

**OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #1 of ANDA 40-277
March 6, 1998**

- A. 1. APPLICATION NUMBER:** ANDA 40-277
- APPLICANT:** Taylor Pharmaceuticals
1222 West Grand Avenue
Decatur, IL 62525
- 2. PRODUCT NAME:** AKTAINÉ®
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile proparacaine HCl ophthalmic solution, USP (0.5%) supplied in 15 mL plastic squeeze bottles with a dropper tip.
- 4. METHODS OF STERILIZATION:**
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Local anesthetic suitable for ophthalmic (topical) use.
- B. 1. DATE OF INITIAL SUBMISSION:** Sept. 11, 1997
- 2. RELATED DOCUMENTS:** AADA 64-096
AADA 64-096/S-001
- 3. DATE OF CONSULT:** February 12, 1998
- 4. ASSIGNED FOR REVIEW:** February 17, 1998
- C. REMARKS:** The submission references AADA 64-096 (approved 1/31/96) and AADA 64-096/S-001 (approved 3/19/97) in support of process validation of ophthalmics at Taylor Pharmaceuticals.

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microbiologist's review #1

REVIEW FOR HFD-617

**OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #2 of ANDA 40-277**

July 9, 1999

- A. 1. APPLICATION NUMBER:** ANDA 40-277
- APPLICANT:** Taylor Pharmaceuticals
1222 West Grand Avenue
Decatur, IL 62525
- 2. PRODUCT NAME:** Proparacaine Ophthalmic Solution, USP
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile proparacaine HCl ophthalmic solution, USP (0.5%) supplied in 15 mL plastic squeeze bottles with a dropper tip.
- 4. METHODS OF STERILIZATION:**
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Local anesthetic suitable for ophthalmic (topical) use.
- B. 1. DATE OF INITIAL SUBMISSION:** 9/11/97
- 2. DATE OF AMENDMENT:** 5/13/98
- 3. DATE OF CONSULT:** 5/10/99
- 4. ASSIGNED FOR REVIEW:** 5/13/99
- 5. RELATED DOCUMENTS:** AADA 64-096
AADA 64-096/S-001
- C. REMARKS:** Microbiologist's Review #1, dated 3/6/98 yielded two deficiencies which were conveyed to the applicant on 3/13/98. The applicant's 5/13/98 responses are the subject of this review (Microbiologist's Review #2).

D. CONCLUSIONS:

The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided

JS / 7/9/99

Neal Sweeney, Ph.D.
TK 7/13/99

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Microbiologist's Review # 2

REVIEW FOR HFD-617

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #3 of ANDA 40-277

September 27, 1999

- A. 1. **APPLICATION NUMBER:** ANDA 40-277
- APPLICANT:** Taylor Pharmaceuticals
1222 West Grand Avenue
Decatur, IL 62525
- 2. **PRODUCT NAME:** Proparacaine Ophthalmic Solution, USP
- 3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile proparacaine HCl ophthalmic solution, USP (0.5%) supplied in 15 mL plastic squeeze bottles with a dropper tip.
- 4. **METHODS OF STERILIZATION:**
- 5. **PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Local anesthetic suitable for ophthalmic (topical) use.
- B. 1. **DATE OF INITIAL SUBMISSION:** 9/11/97
- 2. **DATE OF AMENDMENT:** 9/7/99
- 3. **DATE OF CONSULT:** 9/13/99
- 4. **ASSIGNED FOR REVIEW:** 9/21/99
- 5. **RELATED DOCUMENTS:** AADA 64-096
AADA 64-096/S-001
ANDA 40-277 5/13/98 Amendment
- C. **REMARKS:** Microbiologist's Review #1 (dated 3/6/98) yielded two deficiencies which were conveyed to the applicant on 3/13/98. Microbiologist's Review #2, (dated 7/9/99) of the applicant's 5/13/99 amendment yielded one deficiency. The applicant's 9/7/99 response is the subject of this review.

D. CONCLUSIONS:

The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided

JSI *9/27/99*

Neal Sweeney, Ph.D.

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Microbiologist's Review #3

REVIEW FOR HFD-617

**OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #4 of ANDA 40-277**

December 8, 1999

- A. 1. APPLICATION NUMBER:** ANDA 40-277
- APPLICANT:** Taylor Pharmaceuticals
1222 West Grand Avenue
Decatur, IL 62525
- 2. PRODUCT NAME:** Proparacaine Ophthalmic Solution, USP
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile proparacaine HCl ophthalmic solution, USP (0.5%) supplied in 15 mL plastic squeeze bottles with a dropper tip.
- 4. METHODS OF STERILIZATION:**
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Local anesthetic suitable for ophthalmic (topical) use.
- B. 1. DATE OF INITIAL SUBMISSION:** 9/11/97
- 2. DATE OF AMENDMENT:** 11/19/99
- 3. DATE OF CONSULT:** 11/24/99
- 4. ASSIGNED FOR REVIEW:** 11/24/99
- 5. RELATED DOCUMENTS:** AADA 64-096
AADA 64-096/S-001
ANDA 40-277 5/13/98 and 9/7/99 Amendments
ANDA 75-086
- C. REMARKS:** Microbiologist's Review #3 resulted in one deficiency which was faxed to the applicant on 10/8/99. The applicant's 11/19/99 amendment is the subject of this review

D. CONCLUSIONS:

The submission is recommended for approval for issues concerning sterility assurance. Specific comments are provided

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Neal Sweeney, Ph.D.
JAC 12/20/99

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Microbiologist's Review #4