

**CENTER FOR DRUG EVALUATION AND  
RESEARCH  
65-005**

*APPLICATION NUMBER:*

**CHEMISTRY REVIEW(S)**

1. CHEMIST'S REVIEW NO. #3

2. ANDA # 65-005

3. NAME AND ADDRESS OF APPLICANT

Global Pharmaceutical Corporation  
Attention: Marc M. Feinberg  
Castor & Kensington Avenues  
Philadelphia, PA 19124

Phone: 215-289-2220

Fax: 215-289-2223

4. LEGAL BASIS FOR SUBMISSION

Firm certifies that in its opinion and to the best of its knowledge, there is no marketing exclusivity in effect for the listed drug.

Reference listed drug: Minocin® Minocycline HCl Pellet-Filled Capsules, 50 mg and 100 mg by Lederle.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Minocycline Hydrochloride Capsules, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original ANDA 1/16/98

New Correspondence 2/20/98

Acknowledgment letter 2/26/98

Amend 5/29/98 to N/A letter 5/20/98

Amend 9/4/98 (labeling)

Amend 12/30/98 to MINOR Amendment 12/16/98



- Q3. Please explain the low yield of Exhibit Lot PF117: capsules were obtained from an expected theoretical yield of capsules. What is your acceptable yield range?
- A3. Firm explains that the calculation for accountability of this lot is a result of all the phases of manufacturing and packaging. Lot PF117 was produced on manufacturing equipment which inherently reduces the total number of capsules produced. The accountability is well within their limits of 98% to 102% at each of the stages. By adding the amount produced to the samples and rejects they are able to account for the usage of the product and can then assure the integrity of the batch. The low yield (the amount actually produced divided by the theoretical amount; through the end of manufacturing Lot PF117 it is reported as is primarily due to their Incapsulator. On larger production batches the equipment affect will be minor. Detailed information provided in text is acceptable.
- Q4. We note your in-process blend limits: of label claim. We recommend the acceptance criteria as to (mean of individual test results) with a relative standard deviation (RSD) of 5.0%.
- A4. Firm agrees to our recommendation: blend uniformity limits- from the individual test results, with a relative standard deviation (RSD) of 5.0%. The Master Manufacturing documents have been revised.

18. CONCLUSIONS AND RECOMMENDATIONS

Approval recommended (pending EER)

**(Specifications Comparison attached)**

19. REVIEWER: DATE COMPLETED:  
 Maria C. Shih 2/16/99

Page(s)

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

chem Rev 3

2/16/99