CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

60-666

CHEMISTRY REVIEW(S)

MANUFACTURING AND CONTROLS REVIEW - FORM 6

Applicant: Beecham Pharmaceuticals Form 6 # 60-666
(submitted May 20, 1969, and supplemented on July 2, 1969, November 3, 1969, November 24, 1969, December 23, 1969, February 19, 1970, April 21, 1970, and April 30, 1970)

1. Drug Name: TOTACILLIN (ampicillin trihydrate) for ORAL SOLUTION.

(a) Therapeutic Use: Antibiotic for use in humans
(b) Route of Administration: Oral

2. Components and Composition:

(a) Antibiotic - Ampicillin Trihydrate - produced by applicant.
(b) Other Active Ingredients - NONE
(c) Inactive Ingredients - (see November 3 submission)

[redacted]

(d) Formula of drug per 5 ml. after Reconstitution -

Ingredients	125 mg./5 ml.	250 mg./5 ml.
Ampicillin trihydrate	125 mg.	250 mg.
[redacted]		

To be packaged in 16 and 30 dose packages
Maximum batch size: [redacted]

3. Raw Material Controls:

(a) Official compendium tests conducted on each lot of [redacted] Each lot of antibiotic chect tested by FDA prior to use in product.

(b) Applicant has established "Raw Material Specs" for

All raw materials are adequately tested.

4. Manufacturing, Processing, and Packaging Procedures: ADEQUATE

5. Laboratory facilities for Control Tests:

Tested in Beecham's laboratories - ADEQUATE

6. Stability Data:

Limited data contained in application for the drug product, and for the product after reconstitution. Studies are continuing and additional data will be submitted §146a.118 requires product to be labeled with 12 month outdate which application proposes to do. Data submitted are adequate to support use of 12 months outdate. Exhibit samples examined by NCAIA showed that reconstituted product remains at acceptable potency after storage in refrigerator for 14 days.

7. Numbering System: ADEQUATE

8. Labeling:

1. Labels for 80 cc and 150 cc size bottles of the 125 mg. strength submitted on April 21, 1970, are considered acceptable by Dr. McQueen.

2. Labels for 80 cc and 150 cc size bottles of the 250 mg. strength also considered as acceptable by Dr. McQueen.

3. Cartons for 80 cc and 150 cc size packages of both strengths are acceptable.

4. Final printed package insert submitted April 30, 1970, is acceptable.

Labeling is complete and suitable for approval.

9. Inspection Reports:

Last inspection of manufacturing facilities was during January 1970. Applicant's facilities are new and adequate to manufacture product.

10. Other Comments:

[redacted]

11. Recommendation:

Application appears complete in all respects. Recommend approval of the application and inform applicant that batches of his formulation described on November 3, 1969, can be considered for certification.

John D. Harrison

John D. Harrison, BD-240
May 5, 1970

APPEARS THIS WAY
ON ORIGINAL

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Page(s) of trade secret and /or confidential commercial information