CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40230

CHEMISTRY REVIEW(S)

DIVISION REVIEW SUMMARY

ANDA: 40-230

DRUG PRODUCT: Dicyclomine Hydrochloride Tablets USP

FIRM: Lannett Company Inc.

DOSAGE FORM: Oral

STRENGTH:20 mg

CGMP STATEMENT/EIR UPDATE STATUS: Satisfactory dated 2/3/99.

BIO INFORMATION:
Acceptable on June 23, 1997 by A.P. Patel. Bio sign off dated 1/26/98.

VALIDATION-(DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S)
The test methods are included on pages 1458-1529. The firm utilizes the chromatographic test (Reverse Phase with detector at nm). Methods utilized included USP 23 testing. However the firm revised many of their methods in the 4/13/98 amendment. See below.

Revised Analytical Methods for Dicyclomine HCl Tablets USP 20 mg:

The applicant submitted revised methods in their 4/18/98 amendment based upon the FDA deficiency letter of 3/10/98. The firm revised

STABILITY-ARE CONTAINERS USED IN THE STUDY IDENTICAL TO THOSE USED IN THE CONTAINER SETION?
The firm includes a post-approval stability commitment on page 1533. Room temperature testing will be performed at 25 ± 2°C at ambient RH. Accelerated testing is done at 40°C ±2°C at 75% RH ± 5% RH. The following tests will be performed in the post-approval stability protocol:

Test	Specification
Physical Appearance	Visual

Assay	%
*Degradation Products/Impurities	NMT % Total, NMT % Individual
Dissolution	NLT % (Q) in 45 minutes
*Hardness	1.5 kp - 5.5 kp
*Friability	NMT %
*Moisture	NMT %

*Added/revised upon request.

The firm included accelerated stability data (0,1,2, and 3 mos) and room temperature (0, 3 and 6 month) stability data for lot #61282001A (30 fill) and lot #61282001 (1000 fill). The 100 fill is bracketed. The firm proposes a 24 month expiration dating period.

LABELING
The labeling review was found satisfactory on 3/16/98 by J. Johnson.

STERLIZATION VALIDATION
NA

SIZE OF DEMONSTRATION BATCH

The manufacturing instructions are included on pages 1276-1277. The blank records are included on pages 1280-1330. A description of the equipment is included on pages 1299-1300. The proposed batch size is tablets.

PROPOSED PRODUCTION BATCH-MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?
The manufacturing process will be the same for the production batch as the stability batch. The proposed production size is tablets.

RECOMMENDATION: Approve

SIGNATURE: /S/ 2/10/99 DATE: January 6, 1999

cc: ANDA 40-230

F/T by pah/2/11/99
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1. CHEMIST'S REVIEW NO. 5

2. ANDA # 40-230

3. NAME AND ADDRESS OF APPLICANT
Lannett Company Inc.
Attention: Vlad Mikijanic
9000 State Road
Philadelphia, PA 19136

4. LEGAL BASIS FOR SUBMISSION
Pages 3-8 include a basis for submission. Patent information with exclusivity statement information also included.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
Bentyl

7. NONPROPRIETARY NAME
Dicyclomine Hydrochloride Tablets USP

7. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission	December 19, 1996
Acknowledgment Letter	February 3, 1997
Chemistry Deficiency Letter	April 24, 1997
Amendment Response	January 9, 1998
FDA Deficiency Letter	March 10, 1998
Amendment Response	April 16, 1998
Fax Deficiency Letter	September 15, 1998
Amendment Response	October 15, 1998
Fax Deficiency Letter	November 30, 1998
Amendment Response	December 22, 1998
T-Con	January 13, 1999
New Correspondence	January 19, 1999

10. PHARMACOLOGICAL CATEGORY
Antispasmodic and Anticholinergic

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
DMF
DMF
DMF
DMF
DMF

13. DOSAGE FORM
Tablet

14. POTENCY
20 mg

15. CHEMICAL NAME AND STRUCTURE
(Bicyclohexyl)-1-carboxylic acid, 2-(diethylamino)ethyl ester, hydrochloride

16. RECORDS AND REPORTS
N/A

17. COMMENTS
All deficiencies have been addressed satisfactorily.

18. CONCLUSIONS AND RECOMMENDATIONS
This application is now approvable.

19. REVIEWER: Karen A. Bernard, Ph.D.

DATE COMPLETED: 1/6/89