

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**40231**

**CHEMISTRY REVIEW(S)**

**ANDA APPROVAL SUMMARY**

**ANDA:** 40-231

**DRUG PRODUCT:** Chlorpromazine Hydrochloride Oral Concentrate

**FIRM:** Pharmaceutical Associates, Inc.

**DOSAGE FORM:** Oral Concentrate                   **STRENGTH:** 30 mg/mL

**CGMP:** Statement/EIR Update Status:

EER is pending on Lonza, Inc.

**BIO:** The waiver request was accepted by the Division of Bioequivalence. (reviewed by Z. Wahba, 5/15/97).

**VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):**

Method validation is acceptable for the Chlorpromazine Hydrochloride Oral Concentrate (2/25/97).

**STABILITY:** (Are containers used in study identical to those in container section?)

The containers used in the stability study are identical to those described in the container section.

**LABELING:**

Container, carton and insert labeling have been found satisfactory (Labeling approval summary 12/15/99, reviewed by T Watkins)

**STERILIZATION VALIDATION (IF APPLICABLE):**

Not applicable

**SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):**

The       gallons of the exhibit batch (bio batch) of the Chlorpromazine Hydrochloride Oral Concentrate USP 30 mg/mL (lot#13836) were manufactured.  
DMF       (Chlorpromazine Hydrochloride USP drug substance) was found adequate (12/10/98, reviewed by Liang-Lii Huang, Ph.D.)

**SIZE OF STABILITY BATCHES- (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):**

The exhibit batch (lot#13836) was the stability batch.

**PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:**

The proposed production batches are           gallons for the Chlorpromazine Hydrochloride Oral Concentrate USP, 30 mg/mL. The manufacturing process will be the same as was used for the exhibit batch.

**CHEMIST:** Liang-Lii Huang, Ph.D.

**DATE:** December 17, 1999

**SUPERVISOR:** Paul Schwartz, Ph.D.

**DATE:** December 20, 1999

/S/

OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION  
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMISTRY REVIEW NO. Three (3)

2. ANDA #40-231

3. NAME AND ADDRESS OF APPLICANT

Pharmaceutical Associates, Inc.  
Attention: Kaye B. McDonald  
P.O. Box 128  
Conestee, SC 29636

4. LEGAL BASIS FOR SUBMISSION

The listed reference product is Thorazine<sup>®</sup> Concentrate 30 mg/mL  
Manufactured by SmithKline Beecham Pharmaceuticals. Thorazine<sup>®</sup> is  
not covered by any patent or exclusivity provisions.

5. SUPPLEMENT(s)

None

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Chlorpromazine HCl Oral Concentrate

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

None

9. AMENDMENTS AND OTHER DATES:

Original submission: December 19, 1996  
Major amendment: March 5, 1998  
Minor amendment: September 21, 1999  
Fax amendment: November 18, 1999

10. PHARMACOLOGICAL CATEGORY

Antipsychotic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

<u>DMF# (type) Product</u>	<u>DMF holder</u>	<u>LOA</u>
		p130, 478
		p187
		p410
		p201, 346
		p204, 349
		p351, 411
		p361, 420
		p419, 444
		p369, 421, 446
		p359
		p364
		p372
		p456
		p463
ANDA 40224	100 mg/mL strength of the same drug	

13. DOSAGE FORM

Oral Concentrate

14. POTENCY

30 mg/mL

15. CHEMICAL NAME AND STRUCTURE

Name: Chlorpromazine Hydrochloride

Chemical name: 10H-Phenothiazine-10-propanamine, 2-chloro-N,N-dimethyl-, monohydrochloride

CAS number: 69-09-0

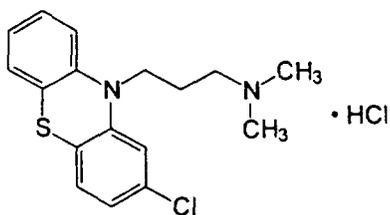
Molecular weight: 355.33

Chemical formula: C<sub>17</sub>H<sub>19</sub>ClN<sub>2</sub>S•HCl

Pharmacologic/therapeutic category: Anti-emetic, antipsychotic

Reference: USP 23, page 354

Structural formula:



16. RECORDS AND REPORTS

None

17. COMMENTS

This application is approvable.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

DATE COMPLETED:

Liang-Lii Huang, Ph.D.      December 16, 1999  
 Endorsed by Paul Schwartz, Ph.D. / December 16, 1999

cc:

ANDA 40-231  
 ANDA DUP 40-231  
 DIV FILE  
 Field Copy  
 HFD-600 /Reading File

Endorsements (Draft and Final with Dates):

HFD-627 / Liang-Lii Huang, Ph.D. / 12/16/99  
 HFD-627 / Paul Schwartz, Ph.D. / 12/16/99

CHEMISTRY REVIEW - APPROVABLE

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 Date: December 16, 1999