

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**40372**

**CHEMISTRY REVIEW(S)**

## ANDA APPROVAL SUMMARY

<b>ANDA:</b> 40-372	<b>CHEMIST:</b> Kathy P. Woodland	<b>DATE:</b> 5/16/00
<b>DRUG PRODUCT:</b> Promethazine Hydrochloride Injection USP		
<b>FIRM:</b> Abbott Laboratories		
<b>DOSAGE FORM:</b> Injection	<b>STRENGTH:</b> 25 mg/mL 50 mg/mL	
<b>cGMP:</b> Pending		
<b>BIO:</b> Waiver granted, C. Kim 7/99		
<b>VALIDATION - (Description of dosage form same as firm's):</b> USP drug substance and product		
<b>STABILITY:</b> The containers in the stability studies are identical to those in the container section.		
<b>LABELING:</b> Approved by Jim Barlow, 2/3/00.		
<b>STERILIZATION VALIDATION (if applicable):</b> Micro approvable April 18, 2000, P.DeLeo		
<b>SIZE OF BIO BATCH (Firm's source of NDS ok?):</b> Waiver granted.		
<b>SIZE OF STABILITY BATCHES (if different from bio batch, were they Manufactured via the same process?):</b> : 25 mg/mL : 50 mg/mL		
<b>PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:</b> Production batch sizes are L: 25 mg/mL and L: 50 mg/mL. Manufacturing process is the same.		
<b>Signature of chemist:</b>  Kathy Woodland	<b>Signature of supervisor:</b>  Paul Schwartz 5/24/00 <i>/S/</i>	

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 40-372

3. NAME AND ADDRESS OF APPLICANT  
Abbott Laboratories/McPherson, KS2  
1776 N. Centennial Drive  
McPherson, KS 67460

4. LEGAL BASIS FOR SUBMISSION  
Innovator Product: Phenergan Injection  
Innovator Company: Wyeth-Ayerst Company  
Patent Expiration Date: The patent for Phenergan<sup>®</sup> Injection, held by Wyeth Laboratories Inc., a Wyeth-Ayerst Company, has expired. Phenergan<sup>®</sup> Injection is not entitled to a period of marketing exclusivity.

5. SUPPLEMENT (s)  
N/A

6. PROPRIETARY NAME  
Promethazine Hydrochloride Injection

7. NONPROPRIETARY NAME  
Promethazine Hydrochloride Injection, USP

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

9. AMENDMENTS AND OTHER DATES:

Submission date	Submission type
05/31/99	original
01/18/00	amendment (chem&micro)
04/14/00	Amendment (micro)
05/22/00	Amendment (chem)

10. PHARMACOLOGICAL CATEGORY  
Anti-histaminic, sedative,  
antimotion-sickness, anti-emetic,  
and anti-cholinergic effects

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF (s)

DMF number	DMF type	DMF holder	LOA(s)
	Elastomeric compound		Vol 1.3, p 467
	Drug Substance		
	Rubber		Vol 1.3, p. 477
	Glass container		Vol 1.3, p 463

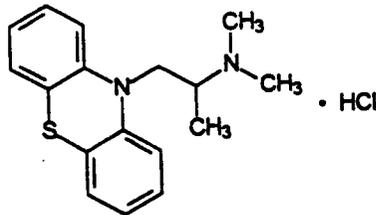
13. DOSAGE FORM  
injection

14. POTENCY

Strength	Strength units
25	mg/mL
50	mg/mL

15. CHEMICAL NAME AND STRUCTURE

10H-Phenothiazine-10-ethanamine, N,N,□-trimethyl-, monohydrochloride, (±) - .C<sub>17</sub>H<sub>20</sub>N<sub>2</sub>S·HCl.



16. RECORDS AND REPORTS  
None

17. COMMENTS

None.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:  
Kathy P. Woodland

DATE COMPLETED:  
May 24, 2000

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pages of trade

secret and/or

confidential

commercial

information

Chem Review #3

Kathy P. Woodland

Reviewer

/S/

Signature

5/24/00

Date

**APPEARS THIS WAY  
ON ORIGINAL**