CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40191

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

ANDA: 40-191

DRUG PRODUCT: Meperidine Hydrochloride Tablets USP, 50 mg and 100 mg.

FIRM:Vintage Pharmaceuticals, Inc. DOSAGE FORM: Tablet

STRENGTH: 50 mg and 100 mg

CGMP STATEMENT/EIR UPDATE STATUS:
CGMP certification is satisfactory (See Vol. 1.1 Page 138).
EIR update : Requested on 7-18-96. Acceptable on 10-15-96. Update requested. ~~Pending~~. Satisfactory, 10/1/97.

BIO STUDY: Satisfactory.
The firm has requested for waiver of in vivo study for Meperidine HCl Tablets USP, 50 mg and 100 mg. Biostudy was reviewed by Z. Wahba and found acceptable on 1-2-97 by Division of Bioequivalence.

Bio. dissolution specification same as manufacturing:
NLT % (Q) in 45 minutes.

VALIDATION -(DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):
Not required.This is USP drug product.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?:
Containers used in the stability testing are the same as described in the container section.

Container 60 cc amber glass bottle.
Container: 60 cc, glass bottle(manufacturer
DMF# Bottle 100's
Container supplier:

Cap: 33 mm White metal cap, (manufacturer supplier
.Bottle 100's.
Primary Liner: .manufacturer:
DMF#
Secondary Liner: DMF#

Filler: Absorbent cotton, 16 g (manufacturer/supplier:
DMF#
For 50 mg tablets lot # 062105, Batch size: kg;
For 100 mg tablets lot # 063105, batch size kg;

Package size	Container size	Closure
100s	60 cc glass	33 mm metal cap

Filler: Cotton

LABELING:
Satisfactory per A.Vezza on 11-21-97.

STERILIZATION VALIDATION (IF APPLICABLE):
NA

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

Meperidine HCl tablets USP, 100 mg batch # 063105 is compared to the listed drug Demerol. A waiver of in vivo bioavailability testing for the 50 mg tablets was requested and granted.

The size of the bio batch was tablets(lot #062105).
Firm's source of NDS OK : Yes DMF#

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):
For 50 mg tablets: tablets, lot # 062105.
For 100 mg tablets: tablets, lot # 063105.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?:
For 50 mg tablets: tablets.
For 10 mg tablets: tablets.

Manufacturing process is the same as bio.stability.

CHEMIST: S. Basaran DATE:12-18-1997 /S/

Team Leader: U. Venkataram DATE: 12-18-1997
/S/ 12/22/97

1. CHEMIST'S REVIEW NO. 3

2. ANDA #40-191

3. NAME AND ADDRESS OF APPLICANT
Vintage Pharmaceuticals, Inc.
Attention: Rebecca Thurman
3241 Woodpark Blvd.
Charlotte, NC 28206

4. AF NUMBER OR LEGAL BASIS FOR ANDA SUBMISSION
Demerol - Sterling Winthrop

Patent Certification:
In accordance with Section 505(J)(2)(A)(vii) of the Federal Food, Drug and Cosmetic Act as amended, They certify that to the best of their knowledge, any patent claiming Meperidine Tablets, USP either has not been filed or has expired prior to the filing of this application.

Expiration of Exclusivity- No marketing exclusivity date.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
Meperidine HCl Tablets, USP

7. NONPROPRIETARY NAME
N/A

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

9. AMENDMENTS AND OTHER DATES:
Firm:
June 4, 1996: Original Submission
July 8, 1996: Amendment
August 22, 1996: Amendment
March 20, 1997: Amendment
November 14, 1997: Facsimile amendment
December 10, 1997: Telephone amendment

FDA:
July 1, 1996: Refuse to file letter.
August 6, 1996: Refuse to file letter.
September 13, 1996: Acknowledgment letter.
March 7, 1997: Deficiency letter
October 15, 1997: Facsimile deficiency
December 8, 1997: Telephone call

10. PHARMACOLOGICAL CATEGORY
Narcotic analgesic

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
NDA# N05010 001/N05010 004
DMF#
DMF#
DMF#
DMF#

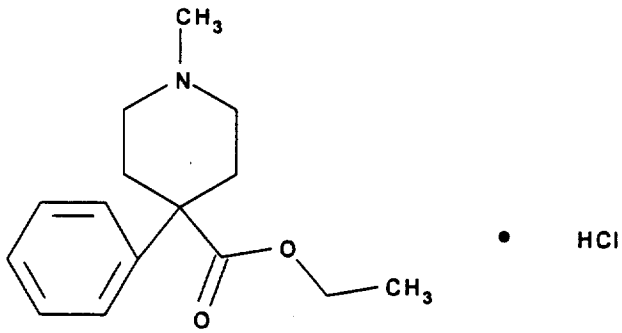
13. DOSAGE FORM
Tablets

14. POTENCY
50 mg and 100 mg

15. CHEMICAL NAME AND STRUCTURE

Meperidine Hydrochloride USP

$C_{15}H_{21}NO_2.HCl$; M.W. = 283.80



Ethyl 1-methyl-4-phenylisonipecotate hydrochloride.
CAS [50-13-5]

16. RECORDS AND REPORTS
N/A

17. COMMENTS
The following deficiencies are noted in the review:
N/A

18. CONCLUSIONS AND RECOMMENDATIONS
The application can be approved.

19. REVIEWER:
Sema Basaran Ph.D.

DATE COMPLETED:
11/18/97
12/15/97 (revised)