

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40183

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

ANDA: 40-183 DRUG PRODUCT: Methylprednisolone Tablets, USP

FIRM: Vintage Pharmaceuticals

DOSAGE FORM: oral, tablets STRENGTH: 4 mg

CGMP STATEMENT/EIR UPDATE STATUS: *Accepted 12/1/98* ~~acceptable, 06-04-97~~

BIO STUDY: approval letter dated 07-05-96

VALIDATION: DS and DP are compendial

STABILITY: The specified market containers are used in stability.

Expiration: 24 months; based on 4.5 months accelerated data and
24 months room temperature data

Tests and Specifications for the Final Product:

LABELING: approval, per email dated 09-26-97

STERILIZATION VALIDATION: n/a

SIZE OF BIOBATCH: DMF - ADEQUATE, per review dated 10-22-97

SIZE OF STABILITY BATCHES: tablets

PROPOSED PRODUCTION BATCH: tablets. The manufacturing process is
the same as that used for the stability batch.

CHEMIST: *Melissa Maust 12-31-97*

TEAM LEADER:

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ANDA APPROVAL SUMMARY

ANDA: 40-183 DRUG PRODUCT: **Methylprednisolone Tablets, USP**

FIRM: **Vintage Pharmaceuticals**

DOSAGE FORM: oral, tablets STRENGTH: 4 mg

CGMP STATEMENT/EIR UPDATE STATUS: **acceptable**, 12-10-98

BIO STUDY: approval letter dated 07-05-96

VALIDATION: DS and DP are compendial

STABILITY: The specified market containers are used in stability.

Expiration: 24 months; based on 4.5 months accelerated
data and 24 months room temperature data

Tests and Specifications for the Final Product:

LABELING: approval, per email dated 09-26-97

STERILIZATION VALIDATION: n/a

SIZE OF BIOBATCH: " DMF - ADEQUATE, per review dated 12-21-98

SIZE OF STABILITY BATCHES: tablets

PROPOSED PRODUCTION BATCH: tablets. The manufacturing
process is the same as that used for the stability batch.

CHEMIST: *JS/* 12-21-98

TEAM LEADER:

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1. CHEMISTRY REVIEW NO. 5 2. ANDA # 40-183
3. NAME AND ADDRESS OF APPLICANT
Vintage Pharmaceuticals, Inc
 Attention: Ms. Rebecca Childers
 3241 Woodpark Blvd, Charlotte, NC 28206
4. LEGAL BASIS FOR SUBMISSION Medrol from Upjohn Co.
 patent #N11153 001, expired, no exclusivity
6. PROPRIETARY NAME n/a
7. NONPROPRIETARY NAME **Methylprednisolone Tablets, USP**

9. AMENDMENTS AND OTHER DATES:

02-29-96	Original Submission	09-19-97	Labeling Amendment
03-18-96	Refusal to File Letter	09-24-97	T-con Amendment
03-22-96	Amendment to Refusal Letter	10-02-97	T-Con with Firm
04-10-96	Filing Letter	10-03-97	T-Con Amendment
06-11-96	Labeling Review-Deficient	11-12-97	Minor Amend
06-01-96	Bio Amendment	12-05-97	T-Con w/firm
01-07-97	Major Amendment	12-23-97	T-Con Amend
08-28-97	Facsimile Amendment	02-05-98	FDA letter to firm
09-19-97	T-con with Firm	12-09-98	Minor Amendment-this review

10. PHARMACOLOGICAL CATEGORY glucocorticoid 11. Rx

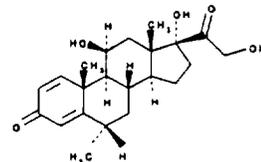
12. RELATED IND/NDA/DMF(s) See #37 for DMF information

13. DOSAGE FORM tablets, oral

14. POTENCY 4 mg - white, flat faced, oval shaped, with beveled edge; uppers are quadrasected and embossed with "42/16/V" with the "42/16" above the lengthwise bisect and the "V" in the lower right hand corner; lowers are embossed with "4"

15. CHEMICAL NAME AND STRUCTURE Methylprednisolone USP

CHEMICAL NAME: 11 β ,17,21-Trihydroxy-6 α -methylpregna-1,4-diene-3,20-dione, CAS NUMBER: [83-43-2], MOLECULAR WEIGHT: 374.48,
 CHEMICAL FORMULA: C₂₂H₃₀O₅



17. COMMENTS none

18. CONCLUSIONS AND RECOMMENDATIONS **APPROVE**

19. REVIEWER Melissa Maust DATE COMPLETED December 21, 1998

cc: ANDA 40-183

DUP Jacket

Division File

Endorsements:

HFD-623/M. Maust/

HFD-623/V. Sayeed, Ph.D./

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F/T by

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