

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 89-081

CHEMISTRY REVIEW(S)

89-081

Muro Pharmaceuticals

ANDA Number

Applicant Name

Prednisolone
Established Name of Drug

Oral Solution
Dosage Form

15mg/5ml
Strength

240ml bottles
Container size(s)

Date Found Satisfactory

Comment

Labeling

Chemistry, Manufacturing, and Controls

GMP's

Manufacturer - Finished Dosage Form

Outside Facilities

Manufacturer(s) - Active Ingredient(s)

Chemist Reviewer

Date

Branch Chief

Date

Petition Required

No Yes

petition approved see 12-17-84 LTR

Listed Drug Information 505(j)(2)(A)

Acceptable see 1-16-86 submission

Patent Certification 505(j)(2)(B)

Patent certification acceptable see 11-23-84 submission

Date Patent/Exclusivity Expires (if applicable)

N/A

Bioequivalence Section

Dissolution Required?

No Yes : DR DGD

In vivo study(s) required?

No Yes

Acceptable IN-VIVO study
see LTR 12-13-85
This is the only product (prednisolone oral solution) on the market it will be a single source item.

Study(s) Found Acceptable

Waiver Request Granted

N/A

Total Bioequivalence Requirement Met

See above

Administrative Reviewer

Date

1-23-86

Approved

Disapproved

Comments:

Director, Division of Generic Drugs

Date

2/4/86

CHEMIST'S REVIEW NDA 89-081

3. NAME AND ADDRESS OF APPLICANT
Muro Pharmaceuticals
Tewksbury, MA 18976
4. AF NUMBER
N/A
5. SUPPLEMENT(s)
N/A
6. NAME OF DRUG
Prednisone
7. NONPROPRIETARY NAME
Prelone
8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:
Original application November 20, 1985
10. PHARMACOLOGICAL CATEGORY
Adrenocortical Steroid
11. HOW DISPENSED
Rx
12. RELATED IND/NDA/DMF(s)
N/A
13. DOSAGE FORM(s)
Oral Solution
14. POTENCY
15 mg/5 mL
17. COMMENTS
1. Sample sent to validation February 21, 1985 - OK by Boston Lab
Comment sent to firm May 23, 1985. Firm's answer (June 4, 1985)
Sent back to lab.
 2. Bio satisfactory per bio letter December 13, 1985
18. CONCLUSIONS AND RECOMMENDATIONS
Approval
19. REVIEWER: Maria Shih . . . DATE COMPLETED:
20. COMPONENTS AND COMPOSITION
See attached
21. FACILITIES AND PERSONNEL
N/A
22. SYNTHESIS
Manufacturer of Active Ingredient:

1Pg. redacted
chemistry review.

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION	2. NDA NUMBER
3. NAME AND ADDRESS OF APPLICANT (City and State) Muro Pharmaceuticals Tewksbury, MA 018960		4. AF NUMBER	
		5. SUPPLEMENT(S)	
		NUMBER(S)	DATE(S)
6. NAME OF DRUG Prednisone	7. PROPRIETARY NAME Prelone		
8. SUPPLEMENT(S) PROVIDES FOR: Bio		9. AMENDMENTS AND OTHER (Reports, etc.) DATES June 4, 1985 June 21, 1985	
10. PHARMACOLOGICAL CATEGORY Adreneocortical Steroid	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM(S) Oral Solution	14. POTENCY (see) 15 mg/5 ml		
15. CHEMICAL NAME AND STRUCTURE		16. RECORDS AND REPORTS	
		CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS 1. Sample sent to validation February 21, 1985 - OK by Boston Lab Comment sent to firm May 23, 1985. Firm's answer (June 4, 1985) Sent back to Lab. 2. Bio under review			
18. CONCLUSIONS AND RECOMMENDATIONS Not Approvable			
19. NAME M Shih		REVIEWER <i>[Signature]</i>	
DISTRIBUTION		DATE COMPLETED	
<input type="checkbox"/> ORIGINAL JACKET	<input type="checkbox"/> REVIEWER	<input type="checkbox"/> DIVISION FILE	

Enter evaluation or comments for each item. If necessary, continue on 8" x 10" paper.
Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

20. COMPONENTS AND COMPOSITION (6, 7)

See Attached

21. FACILITIES AND PERSONNEL (8a,b)

N/A

22. SYNTHESIS (8c)

Manufacturer of Active Ingredient

23. RAW MATERIAL CONTROLS (8d,e)
a. NEW DRUG SUBSTANCE

USP

b. OTHER INGREDIENTS

USP

24. OTHER FIRM(s) (8f)

None

25. MANUFACTURING AND PROCESSING (8g,h,i,k)

All manufacturing, processing, packaging, labeling, in-process and finished product testing is performed by Muro.

26. CONTAINER (8j)

p. 127 Amber glass bottles/HDPE polypropylene cap. liner/ cap seal.

27. PACKAGING AND LABELING (8l,m)

See #25

28. LABORATORY CONTROLS (In-Process and Finished Dosage Form) (8n)

N/A

29. STABILITY (8p)

1. 4 lots up to 12 month at 35°C, 6 month at 40°C (p. 142-146)
2. 3 cycle stability data between 5°C and 45°C submitted March 11, 1985
18 month expiry date

30. CONTROL NUMBERS (8q)

N/A

31. SAMPLES AND RESULTS (8r)

a. VALIDATION

OK by Boston Lab

b. MARKET PACKAGE

32. LABELING (8s)

Satisfactory per T. Poux April 18, 1985

33. ESTABLISHMENT INSPECTION

Acceptable per T. Bozzo January 30, 1985

34. RECALLS

N/A

CHEMIST'S REVIEW NDA 89-081

3. NAME AND ADDRESS OF APPLICANT

Muro Pharmaceuticals, Inc.
Tewksbury, MA 01876

6. NAME OF DRUG

Prednisolone

7. NONPROPRIETARY NAME

Pre lone

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

Bio study

9. AMENDMENTS AND OTHER DATES:

May 28, 1985

10. PHARMACOLOGICAL CATEGORY

Adrenocortical Steroid

11. HOW DISPENSED

Rx

13. DOSAGE FORM(S)

Oral solution

14. POTENCY

15 mg/5 ml

17. COMMENTS

1. Bio study not acceptable per Bio letter of March 19, 1985.
2. Sample sent to validation February 21, 1985 - OK by Boston Lab.
Comment sent to firm May 23, 1985.

18. CONCLUSIONS AND RECOMMENDATIONS

Not Approvable

19. REVIEWER:

Maria Shih

DATE COMPLETED:

MJS - 6/10/85

20. COMPONENTS AND COMPOSITION

See attached

21. FACILITIES AND PERSONNEL

N/A

22. SYNTHESIS

Manufacturer of Active Ingredient:

CHEMIST REVIEW PAGE 2-

23. RAW MATERIAL CONTROLS

A. NEW DRUG SUBSTANCE: USP

B. OTHER INGREDIENTS: USP

24. OTHER FIRM(s)

None

25. MANUFACTURING AND PROCESSING

All manufacturing, processing, packaging, labeling, in-process and finished product testing is performed by Muro.

26. CONTAINER

p. 127 Amber glass bottles/HDPE Polypropylene cap/ liner/cap seal.

27. PACKAGING AND LABELING

See #25

28. LABORATORY CONTROLS (IN-PROCESS AND FINISHED DOSAGE FORM)

N/A

29. STABILITY

1. 4 Lots up to 12 month at 35°C, 6 month at 40°C (p. 142-146).

2. 3 cycle stability data between 5°C and 45°C submitted March 11, 1985 18 month expiry date.

30. CONTROL NUMBERS

N/A

31. SAMPLES AND RESULTS

OK by Boston Lab

32. LABELING

Satisfactory per T. Poux April 18, 1985

33. ESTABLISHMENT INSPECTION

Acceptable per T. Bozzo January 30, 1985

34. RECALLS

N/A

3 pg. redacted.

analyst comments.

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION	2. NDA NUMBER 89-081
3. NAME AND ADDRESS OF APPLICANT (City and State) Muro Pharmaceuticals Tewksbury, MA 01876		4. AF NUMBER	
		5. SUPPLEMENT (S)	
		NUMBER(S)	DATE(S)
6. NAME OF DRUG Prednisolone	7. NONPROPRIETARY NAME Prelone		
8. SUPPLEMENT(S) PROVIDES FOR: Labeling, Stability		9. AMENDMENTS AND OTHER (Reports, etc) DATES March 11, 1985	
10. PHARMACOLOGICAL CATEGORY Adrenocortical Steroid	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM (S) Oral Solution	14. POTENCY (see) 15 mg/5 ml		
15. CHEMICAL NAME AND STRUCTURE		16. RECORDS AND REPORTS	
		CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO	
		REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS 1. Bio study not acceptable per Bio letter of March 19, 1985 2. Sample sent to validation February 21, 1985			
18. CONCLUSIONS AND RECOMMENDATIONS Not Approvable			
19. NAME M. Shih		REVIEWER SIGNATURE	
		DATE COMPLETED	
DISTRIBUTION	<input type="checkbox"/> ORIGINAL JACKET	<input checked="" type="checkbox"/> REVIEWER	<input type="checkbox"/> DIVISION FILE

CHEMIST'S REVIEW, Page 2

Enter evaluation or comments for each item. If necessary, continue on 8" x 10 1/2" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

NDA NUMBER

20. COMPONENTS AND COMPOSITION (6, 7)

See attached

21. FACILITIES AND PERSONNEL (8a,b)

N/A

22. SYNTHESIS (8c)

Manufacturer of Active Ingredient:

23. RAW MATERIAL CONTROLS (8d,e)

a. NEW DRUG SUBSTANCE

USP

b. OTHER INGREDIENTS

USP

24. OTHER FIRM(s) (8f)

None

25. MANUFACTURING AND PROCESSING (8g,h,i,j,k)

All manufacturing, processing, packaging, labeling, in-process and finished product testing is performed by Muro.

26. CONTAINER (8i)

p. 127 Amber glass bottles/HDPE Polypropylene cap/ liner/cap seal.

27. PACKAGING AND LABELING (8l,m)

See #25

28. LABORATORY CONTROLS (In-Process and Finished Dosage Form) (8n)

N/A

29. STABILITY (8p)

1. 4 lots up to 12 month at 35°C, 6 month at 40°C (p. 142-146).
2. 3 cycle stability data between 5°C and 45°C submitted March 11, 1985
18 month expiry date

30. CONTROL NUMBERS (8q)

N/A

31. SAMPLES AND RESULTS (8r)

a. VALIDATION to be validated **b. MARKET PACKAGE**

32. LABELING (8s)

Satisfactory per T. Poux April 18, 1985

33. ESTABLISHMENT INSPECTION

Acceptable per T. Bozzo January 30, 1985

34. RECALLS

N/A

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION	2. NDA NUMBER 89-081
3. NAME AND ADDRESS OF APPLICANT (City and State) Muro Pharmaceutical, Inc. Tewksbury, MA 01876		4. AF NUMBER	
		5. SUPPLEMENT (S)	
		NUMBER(S)	DATE(S)
6. NAME OF DRUG Prednisolone	7. NONPROPRIETARY NAME Prelone		
8. SUPPLEMENT(S) PROVIDES FOR:		9. AMENDMENTS AND OTHER (Reports, etc.) DATES	
10. PHARMACOLOGICAL CATEGORY Adrenocortical Steroid	11. HOW DISPENSED XXX <input type="checkbox"/> RX <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM (S) Oral Solution	14. POTENCY (see) 15 mg/5 ml		
15. CHEMICAL NAME AND STRUCTURE		16. RECORDS AND REPORTS	
		CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS Bio needed?			
18. CONCLUSIONS AND RECOMMENDATIONS Not Approvable			
19. NAME M Shih		REVIEWER SIGNATURE	
		DATE COMPLETED 7/12/85	
<input type="checkbox"/> DISTRIBUTION	<input type="checkbox"/> ORIGINAL JACKET	<input type="checkbox"/> REVIEWER	<input type="checkbox"/> DIVISION FILE

1 pg- redacted
chemist Review

CHEMIST REVIEW 89-081

NAME AND ADDRESS OF APPLICANT

Muro Pharmaceuticals, Inc.
890 East Street
Twexbury, MA 01876

PURPOSE OF AMENDMENT/SUPPLEMENT

S-002 Labeling revision
S-003 Package addition - physician sample

PHARMACOLOGICAL CATEGORY

Glucocorticoid

NAME OF DRUG

Prednisolone

DOSAGE FORM

Syrup

POTENCY

15 mg/ml

HOW DISPENSED

Rx

DATE OF SUBMISSION

February 14, 1986

SUPPLEMENT

S-002, S-003

LABELING

FPL for carton labels needed per T. Poux March 17, 1986

BIOLOGIC AVAILABILITY

N/A

ESTABLISHMENT INSPECTION

Not on current alert list

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

N/A

PACKAGING

Need Information

STABILITY

Protocol: N/A

Exp. Date: N/A

REMARKS AND CONCLUSIONS

Review Waiting Firm

REVIEWER

Maria Shih

DATE

CHEMIST REVIEW 89-081

NAMD AND ADDRESS OF APPLICANT

Muro Pharmaceuticals, Inc.
890 East Street
Tweksbury, MA 01876

PURPOSE OF AMENDMENT/SUPPLEMENT

S-002 labeling revision
S-003 packaging addition - Physician Sample

PHARMACOLOGICAL CATEGORY

Glucocorticoid

NAME OF DRUG

Prednisone

DATE OF SUBMISSION

February 14, 1986
April 7, 1986

SUPPLEMENT

S-002, S-003

DOSAGE FORM

Syrup

POTENCY

15 mg/5 ml

LABELING

FPL for Physician sample carton Satisfactory per T. Poux April 21, 1986

BIOLOGIC AVAILABILITY

N/A

ESTABLISHMENT INSPECTION

Not on alert list

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

N/A

PACKAGING

Information submitted, satisfactory

STABILITY

Protocol: N/A
Exp. Date: N/A

REMARKS AND CONCLUSIONS

supplemental approval

REVIEWER

Maria Shih

DATE

11/0

5/12/84

✓
U

CHEMIST'S REVIEW FOR ANDA OR SUPPLEMENT - ANDA 89-081/S-006, S-007

NAME AND ADDRESS OF APPLICANT:

Muro Pharmaceutical, Inc.
890 East Street
Tewksbury, MA 01876

PURPOSE OF AMENDMENT/SUPPLEMENT

S-006 Additional package size
S-007 Labeling revision

DATE(S) OF SUBMISSION(S)

September 3, 1987

PHARMACOLOGICAL CATEGORY

Glucocorticoid

NAME OF DRUG

Prednisone

HOW DISPENSED

RX

DOSAGE FORM

Syrup

POTENCY

15 mg/5 mL

LABELING

Satisfactory per T. Poux 10-7-87

ESTABLISHMENT INSPECTION

Not on current alert list

PACKAGING

New size of 20 mL (physician sample)

STABILITY

Protocol: Not submitted

Exp. Date: Not submitted

REMARKS AND CONCLUSION

Review Waiting Firm

REVIEWER

Maria Shih

DATE COMPLETED

October 14, 1987

→ 10/14/87

CHEMIST REVIEW 89-081

NAME AND ADDRESS OF APPLICANT

Muro Pharmaceuticals, Inc.
890 East Street
Twexbury, MA 01876

PURPOSE OF AMENDMENT/SUPPLEMENT

S-004 packaging change
S-005 exp. date

PHARMACOLOGICAL CATEGORY

Glucocorticoid

NAME OF DRUG

Prelone

DATE OF SUBMISSION

February 20, 1987

SUPPLEMENT

S-004, S-005

DOSAGE FORM

Syrup

POTENCY

15 mg/5 mL

LABELING

N/A

BIOLOGIC AVAILABILITY

N/A

ESTABLISHMENT INSPECTION

Not on current alert list

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

N/A

PACKAGING

Plastic bottles with pulp-vinyl cap liner

STABILITY

Protocol: Satisfactory

Exp. Date: 2 years

REMARKS AND CONCLUSIONS

Supplemental approval

REVIEWER

Maria Shih

DATE

3/23/87

CHEMIST'S REVIEW FOR ANDA OR SUPPLEMENT - ANDA 89-081/S-006, S-007, S-008

NAME AND ADDRESS OF APPLICANT:

Muro Pharmaceutical, Inc.
890 East Street
Tewksbury, MA 01876

PURPOSE OF AMENDMENT/SUPPLEMENT

S-006 Additional package size
S-007 Labeling revision
S-008 Expiration dating

DATE(S) OF SUBMISSION(S)

September 3, 1987
November 30, 1987

PHARMACOLOGICAL CATEGORY

Glucocorticoid

NAME OF DRUG

Prednisone

HOW DISPENSED

RX

DOSAGE FORM

Syrup

POTENCY

15 mg/5 mL

10

LABELING

Satisfactory per GJohnston 1-5-88

ESTABLISHMENT INSPECTION

Not on current alert list

PACKAGING

New size of 20 mL (physician sample)

STABILITY

Protocol: 3 month accelerated
Exp. Date: Recommended 18 month

REMARKS AND CONCLUSION

Approval - Only 2 copies of FPL received. Called 1-25-88, will submit 6 more copies.

REVIEWER

Maria Shih

DATE COMPLETED

January 26, 1988

88

CHEMIST'S REVIEW FOR ANDA OR SUPPLEMENT - ANDA 89-081/S-006, S-007, S-008

NAME AND ADDRESS OF APPLICANT:

Muro Pharmaceutical, Inc.
890 East Street
Tewksbury, MA 01876

PURPOSE OF AMENDMENT/SUPPLEMENT

S-006 Additional package size
S-007 Labeling revision
S-008 Expiration dating

DATE(S) OF SUBMISSION(S)

September 3, 1987
October 19, 1987

PHARMACOLOGICAL CATEGORY

Glucocorticoid

NAME OF DRUG

Prednisone

HOW DISPENSED

RX

DOSAGE FORM

Syrup

POTENCY

15 mg/5 mL

LABELING

Satisfactory per TPoux 10-7-87

ESTABLISHMENT INSPECTION

Not on current alert list

PACKAGING

New size of 20 mL (physician sample)

STABILITY

Protocol: 3 month accelerated
Exp. Date: Recommended 18 month

REMARKS AND CONCLUSION

Review Waiting Firm

REVIEWER

Maria Shih *MS*

DATE COMPLETED

November 25, 1987

11/25/87

Chem Review No.2

ANDA89-081/S-009

NAME AND ADDRESS OF APPLICANT:

Muro
Tewksbury, MA

PURPOSE OF AMENDMENT/SUPPLEMENT

Child resistant cap

DATE(S) OF SUBMISSION(S)

Sept 18, 1989 amended November 27, 1990 in response to Nov 14, 1990 NA letter. Minor amendment.

PHARMACOLOGICAL CATEGORY

steroidal antiinflammatory

TRADE NAME

Prelone

NONPROPRIETARY NAME

Prednisolone

DOSAGE FORM

Syrup

POTENCY

15 mg/5mL

RX OR OTC

Rx

SAMPLES

N/A

RELATED IND/NDA/DMF

STERILIZATION

LABELING

N/A

BIOEQUIVALENCY STATUS

AB

ESTABLISHMENT INSPECTION

Not on April 15, 1991 Alert list

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

No change

REMARKS AND CONCLUSION

Approvable for 240 mL bottle. Firm should be informed that approval does not apply to the 20 mL bottle.

Reviewer

Paul Schwartz, Ph.D.

Date Completed

April 23, 1991

Paul Schwartz 4/30/91

4/30/91

91/B:\89081S09.RPS

R. K. K. 4-30-91

1. CHEMIST'S REVIEW
2. ANDA # 89-081/S-010, S-011, S-012
3. NAME AND ADDRESS OF APPLICANT
Muro Pharmaceutical, Inc.
Attention: Joseph A. Celona
890 East Street
Tewksbury, MA 01876
6. PROPRIETARY NAME
Prelone® Syrup
7. NONPROPRIETARY NAME
Prednisolone Syrup USP
8. SUPPLEMENT(S) PROVIDE(S) FOR:
S-010 Label revision.
S-011 Packaging addition of 480 mL PET bottle.
S-012 Expiration dating of 18 months.
9. AMENDMENTS AND OTHER DATES:
July 27, 1991 Original submission
May 28, 1992 NA letter
June 8, 1992 Amendment
June 24, 1992 Satisfactory label review
July 20, 1992 NA letter (minor)
July 29, 1992 Amendment
10. PHARMACOLOGICAL CATEGORY
synthetic glucocorticoid
(steroid)
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM
syrup
14. POTENCY
15 mg/5 mL
16. RECORDS AND REPORTS
June 1, 1992 Fax regarding deficiency #3 of May 28,
1992 NA letter.
18. CONCLUSIONS AND RECOMMENDATIONS APPROVAL
19. REVIEWER: Jon E. Clark DATE COMPLETED: August 19, 1992

Endorsements:

HFD-633/J. Clark/8-20-92
HFD-633/R. Kishore/8-20-92
B:\89081S12.BJC
F/T by dvw/8-21-92

1 pg. redacted
chemistry

1. CHEMISTRY REVIEW NO. 1
2. ANDA 89-081/S-014; R-013
3. NAME AND ADDRESS OF APPLICANT
Muro Pharmaceutical. Inc.
Attention: Joseph A. Celona
890 East Street
Tewksbury, MA 01876
4. LEGAL BASIS FOR SUBMISSION
NA
5. SUPPLEMENT(s)
S-014
6. PROPRIETARY NAME
Prelone Syrup
7. NONPROPRIETARY NAME
Prednisolone Syrup USP, 15 mg/5 mL
8. SUPPLEMENT(s) PROVIDE(s) FOR:
The supplemental application provides for the physical expansion of the manufacturing facility. Equipment used to manufacture this product will be moved into this new area of the building.
9. AMENDMENTS AND OTHER DATES:
S-014: Initial submission May 20, 1993
10. PHARMACOLOGICAL CATEGORY
Synthetic glucocorticoid
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
NA
13. DOSAGE FORM
oral liquid
14. POTENCY
15 mg/5 mL
15. CHEMICAL NAME AND STRUCTURE
NA
16. RECORDS AND REPORTS
R-013: Dated March 16, 1993
19. REVIEWER: Jon E. Clark DATE COMPLETED: Sep. 24, 1993

ben 14, 1993

2 pgs redacted in what
chemistry.

1. CHEMISTRY REVIEW NO. 1
2. ANDA 89-081/S-016; R-014
3. NAME AND ADDRESS OF APPLICANT
Muro Pharmaceutical. Inc.
Attention: Joseph A. Celona
890 East Street
Tewksbury, MA 01876
4. LEGAL BASIS FOR SUBMISSION
21 CFR 314.70(b) expedited review
5. SUPPLEMENT(s)
S-016
6. PROPRIETARY NAME
Prelone Syrup
7. NONPROPRIETARY NAME
Prednisolone Syrup USP, 15 mg/5 mL
8. SUPPLEMENT(s) PROVIDE(s) FOR:
The supplemental application provides for a new closure because the previous supplier is on strike. Muro also takes the opportunity to report a change in the bottle resin.
9. AMENDMENTS AND OTHER DATES:
March 10, 1994 Initial submission: S-016
April 14, 1994 CMC NA letter
April 22, 1994 CMC amendment: **THIS REVIEW.**
10. PHARMACOLOGICAL CATEGORY
Synthetic glucocorticoid
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
NA
13. DOSAGE FORM
oral liquid
14. POTENCY
15 mg/5 mL
15. CHEMICAL NAME AND STRUCTURE NA
16. RECORDS AND REPORTS
89-081/R-014: Stability data is adequate. Some editorial changes to the batch sheet and specifications. No manufacturing changes are reported. **NAI**
17. COMMENTS
All the information for the closure change is in order. The information for the bottle resin change is adequate.
18. CONCLUSIONS AND RECOMMENDATIONS **APPROVAL**
19. REVIEWER: Jon E. Clark DATE COMPLETED: May 4, 1994

F/T by

1 pg redacted in whole.
chemistry

1. CHEMISTRY REVIEW NO. 1
2. ANDA 89-081/S-016; R-013
3. NAME AND ADDRESS OF APPLICANT
Muro Pharmaceutical. Inc.
Attention: Joseph A. Celona
890 East Street
Tewksbury, MA 01876
4. LEGAL BASIS FOR SUBMISSION
21 CFR 314.70(b) expedited review
5. SUPPLEMENT(s)
S-016
6. PROPRIETARY NAME
Prelone Syrup
7. NONPROPRIETARY NAME
Prednisolone Syrup USP, 15 mg/5 mL
8. SUPPLEMENT(s) PROVIDE(s) FOR:
The supplemental application provides for a new closure because the previous supplier is on strike. Muro also takes the opportunity to report a change in the bottle resin.
9. AMENDMENTS AND OTHER DATES:
S-016: Initial submission March 10, 1994
10. PHARMACOLOGICAL CATEGORY
Synthetic glucocorticoid
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
NA
13. DOSAGE FORM
oral liquid
14. POTENCY
15 mg/5 mL
15. CHEMICAL NAME AND STRUCTURE
NA
16. RECORDS AND REPORTS
NA
17. COMMENTS
All the information for the closure change is in order. The information for the bottle resin change is deficient.
18. CONCLUSIONS AND RECOMMENDATIONS Not Approvable minor
19. REVIEWER: Jon E. Clark DATE COMPLETED: April 1, 1994

4/13/94

1 Pg. redacted in whole.
chemistry

1. CHEMISTRY REVIEW NO. 2 2. ANDA 89-081/S-019
3. NAME AND ADDRESS OF APPLICANT Muro Pharmaceutical, Inc.
Attention: Mr. Joseph A. Celona
890 East Street, Tewksbury, MA 01876
4. LEGAL BASIS FOR SUBMISSION 314.70
5. SUPPLEMENTS S-019
6. PROPRIETARY NAME N/A
7. NONPROPRIETARY NAME Prelone Syrup 15 mg/mL
8. SUPPLEMENTS PROVIDE FOR additional drug substance supplier
9. AMENDMENTS AND OTHER DATES
06-mar-98 S-019 original submission
13-mar-98 fax to J. Wilson
17-mar-98 expedited review request granted
05-MAY-98 **minor amendment - this review**
01-JUN-98 **fascimile response to t-con - this review**
10. PHARMACOLOGICAL CATEGORY antiinflammatory allergic reactions
11. Rx
12. RELATED IND/NDA/DMF(s) See DMF checklist.
13. DOSAGE FORM oral, syrup
14. POTENCY 15 mg/5 mL
15. CHEMICAL NAME AND STRUCTURE as per USP
16. RECORDS AND REPORTS R-018 amendment, dated 05-06-98, period covering 2/97-2/98, NAI
17. COMMENTS none
18. CONCLUSIONS AND RECOMMENDATIONS **approve**
19. REVIEWER M. Maust DATE COMPLETED May 27, 1998

4 pg. redacted in whole.
Chemistry

1. CHEMISTRY REVIEW NO. 1 2. ANDA # 89-081
3. NAME AND ADDRESS OF APPLICANT
Muro Pharmaceutical, Inc. Attention: Joseph A. Celona
890 East Street, Tewsbury, MA 01876
4. LEGAL BASIS FOR SUBMISSION 314.70
5. SUPPLEMENTS 89-081/S-017
6. PROPRIETARY NAME Prednisolone Syrup USP, 15 mg/5 mL
7. NONPROPRIETARY NAME Prelone® Syrup
8. SUPPLEMENTS PROVIDE FOR: packaging addition for an amber PET
60 mL container
9. AMENDMENTS AND OTHER DATES:
02-10-97 Original Submission - this review
10. PHARMACOLOGICAL CATEGORY: anti-inflammatory steroid
11. Rx
12. RELATED IND/NDA/DMF(s) N/A
13. DOSAGE FORM syrup, oral
14. POTENCY 15 mg/5 mL
15. CHEMICAL NAME AND STRUCTURE as per USP
16. RECORDS AND REPORTS R-016, period covering 2/96-3/95, NAI
R-017, period covering, 2/96-2/97, NAI
17. COMMENTS none
18. CONCLUSIONS AND RECOMMENDATIONS **APPROVE**
19. REVIEWER: Melissa Maust DATE COMPLETED: July 22, 1997

nrp-023/v. Sayeed, Ph.D. / N/A

3 pgs redacted in whole.
chemistry

1. CHEMISTRY REVIEW NO. 1
2. ANDA 89-081/S-019
3. NAME AND ADDRESS OF APPLICANT Muro Pharmaceutical, Inc.
Attention: Mr. Joseph A. Celona
890 East Street, Tewksbury, MA 01876
4. LEGAL BASIS FOR SUBMISSION 314.70
5. SUPPLEMENTS S-019
6. PROPRIETARY NAME N/A
7. NONPROPRIETARY NAME Prelone Syrup 15 mg/mL
8. SUPPLEMENTS PROVIDE FOR additional drug substance supplier
9. AMENDMENTS AND OTHER DATES
06-mar-98 S-019 original submission - this review
13-mar-98 fax to J. Wilson - this review
17-mar-98 expedited review request granted
10. PHARMACOLOGICAL CATEGORY antiinflammatory allergic reactions
11. Rx
12. RELATED IND/NDA/DMF(s) See DMF checklist.
13. DOSAGE FORM oral, syrup
14. POTENCY 15 mg/5 mL
15. CHEMICAL NAME AND STRUCTURE as per USP
16. RECORDS AND REPORTS R-018, dated 04-03-98, period covering
2/97-2/98, IR letter sent to firm
18. CONCLUSIONS AND RECOMMENDATIONS na/minor
19. REVIEWER M. Maust DATE COMPLETED April 1, 1998
Updated: April 27, 1998

4 pages redacted in whole.
chemistry