CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-734

CHEMISTRY REVIEW(S)

NDA 21-734

Children's ElixSure™ - 24hr Antihistamine (Loratadine Oral Suspension), 5 mg/5 mL

Taro Pharmaceuticals U.S.A. Inc.

Chong Ho Kim, Ph.D.
Division of Pulmonary and Allergy Drug Products

Table of Contents

Chemistry Review Data Sheet

1. NDA #: 21-734

2. REVIEW #: 3

3. REVIEW DATE: 30-AUG-2005

4. REVIEWER: Chong Ho Kim, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	19-JAN-2004
Amendment [BZ]	06-MAY-2004
Amendment[BZ]	04-AUG-2004
Amendment[BC]	26-AUG-2004
Amendment[BC]	02-SEP-2004
Amendment[BC]	16-SEP-2004
Amendment [AZ]	01-APR-2005
Amendment[BC]	12-JUL-2005

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Amendment [BC]	22-AUG-2005
Amendment[C]	26-AUG-2005
Amendment[BF]	02-SEP-2005

7. NAME & ADDRESS OF APPLICANT:

Name:	Taro Pharmaceuticals U.S.A. Inc.
Address:	5 Skyline Drive, Hawthorne, N.Y. 10532
Representative:	Ms. Kalpana Rao Vice President, Regulatory Affairs
Telephone:	Tel:914-345-9001, Fax:914-593-0078

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Children's ElixSure™

b) Nonproprietary Name (USAN): Loratadine Oral Suspension, 5 mg/5 mL

Chemistry Review Data Sheet

c) Code Name/#:
d) Chem. Type/Submission Priority:
- Chem. Type: 3
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b)(2) Application

10. PHARMACOL. CATEGORY: Antihistamine

11. DOSAGE FORM: Suspension

12. STRENGTH/POTENCY: 5 mg/5 mL

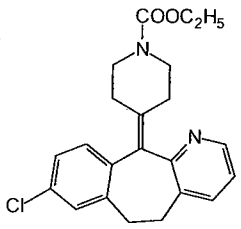
13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: ___Rx _X_ OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):
_____SPOTS product – Form Completed

___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:



Loratadine

Ethyl 4-(8-chloro-5,6-dihydro-11H-benzo[5,6]-cyclohepta [1,2-b]pyridin-11-ylidene)-1-piperidinecarboxylate

Chemical Name: 11-[N-(ethoxycarbonyl)-4-piperidylidene]-8-chloro-6,11-dihydro-5H-benzo[5,6] cyclohepta[1,2-b]-pyridine
1-Piperidinecarboxylic acid, 4-(8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)-ethyl ester

CAS Number: [79794-75-5]

Chemistry Review Data Sheet

Molecular Formula: $C_{22}H_{23}ClN_2O_2$

Molecular Weight: 382.89

17. RELATED/SUPPORTING DOCUMENTS:

A. Supporting DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS[3]
	II			3	Adequate	**10/17/02**	Dr. Dhanesar***
	IV			1	Adequate	9/24/04	
	III			1	Adequate	6/29/05	
	III			1	Adequate	7/19/05	
	III			3	Adequate	8/12/99	Dr. Vidra
	III			3	Adequate	2/12/03	Dr. Rodriguez**
	III			3	Adequate	1/7/04	Dr. Cooper*
	III			3	Adequate		
	III			2	Adequate		
	III			3	Adequate	9/16/04	CMC information was updated on May 3, 2001.
	III			1	Adequate	9/23/04	
	III			1	Adequate	7/25/05	

Chemistry Review Data Sheet

[redacted]	III	3	Adequate	5/18/04	Dr. Pun found it [redacted]
	III	6	Adequate[4]	9/28/04	

[1] Action codes for DMF Table:
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Other codes indicate why the DMF was not reviewed, as follows:
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5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

[3] Include reference to location in most recent CMC review

* Dr. Cooper [redacted]

** Dr. Rodriguez had reviewed the DMF and found it adequate [redacted]

*** Dr. Dhanesar (HFD-623) reviewed annual update with regard [redacted] found it adequate. I concur with Dr. Dhanesar.

% No DMF

B. Other Supporting Documents: None

C. Related Documents:

DOCUMENT	APPLICATION NUMBER	OWNER	DESCRIPTION/COMMENT
Claritin Syrup	N20-704/S-008	Schering Co.	The supplement was provided for the over-the-counter use of Claritin Syrup. Approved on 11/27/02

Chemistry Review Data Sheet

18. CONSULTS/CMC-RELATED REVIEWS:

CONSULTS	SUBJECT	DATE FORWARDED	STATUS/ REVIEWER	COMMENTS
Biometrics	N/A			See stability data analysis on page 41 of this review.
EES	ds and dp sites		ACCEPTABLE	2/23/2005
Pharm/Tox	N/A			
Biopharm	**dissolution**			
LNC	N/A			
Methods Validation				*
OPDRA	acceptability of the trade name		pending	
EA	exclusion requested		acceptable	
Microbiology	N/A			

* After reviewing the methods validation package, it was determined that test methods are routine and do not meet the criteria for initiating FDA laboratory evaluation.

Chemistry Assessment Section

The Chemistry Review for NDA 21-734

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

May be approved from a CMC standpoint.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

1). [redacted] manufactures the loradtadine drug substance. The DMF is current and adequate to support this NDA.

2). The applicant claims that the Loratadine Oral Suspension [redacted]. The formulation contains [redacted] glycerin, [redacted] propylene glycol, [redacted] sodium hydroxide, [redacted] Carbomer 934P, [redacted] Poloxamer 188, [redacted] butylparaben, [redacted] Loratadine, [redacted] sucralose liquid concentrate [redacted] masking agent, [redacted] peach flavor and [redacted] of purified water.

3). Up to 24 months long term stability data and 6 months accelerated stability data are provided. Two key attributes, loratadine assay and degradation products show no trend over time. Based on the adequacy of the stability data provided, a biometrics consult on the proposed **24 months expiration dating period** is not necessary.

4). An evaluation of the test methods by the FDA laboratory is not necessary; it was determined that test methods are routine and do not meet the criteria for initiating FDA laboratory evaluation.

5). The EER for all sites is acceptable.

B. Description of How the Drug Product is Intended to be Used

The drug product is Loratadine Oral Suspension, 5 mg/5 mL. It will be used for [redacted] in children. The drug product will be marketed in a [redacted] 8 fl oz (240 mL) [redacted] bottles. [redacted]

C. Basis for Approvability or Not-Approval Recommendation

The application may be approved from CMC standpoint.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block

Chemist:	Chong Ho Kim/ 31-AUG-2005
Chemistry Team Leader:	Richard Lostritto/
ProjectManager:	Anthony Zeccola/

C. CC Block

Orig. NDA #21-734
HFD-570/Division File
HFD-570/CHKim
HFD-570/RLostritto
HFD-570/AZeccola
R/D Init. by:

Doc: N21-734r3.831

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Chong-Ho Kim
9/7/2005 02:20:10 PM
CHEMIST

Richard Lostritto
9/9/2005 05:17:48 PM
CHEMIST

NDA 21-734

Children's ElixSure™ - 24hr Antihistamine (Loratadine Oral Suspension), 5 mg/5 mL

Taro Pharmaceuticals U.S.A. Inc.

Chong Ho Kim, Ph.D.
Division of Pulmonary and Allergy Drug Products

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4. REVIEWER: Chong Ho Kim, Ph.D.

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Telephone:	Tel:914-345-9001, Fax:914-593-0078

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a) Proprietary Name: Children's ElixSure™

b) Nonproprietary Name (USAN): Loratadine Oral Suspension, 5 mg/5 mL

c) Code Name/#:

d) Chem. Type/Submission Priority:

- Chem. Type: 3
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b)(2) Application

10. PHARMACOL. CATEGORY: Antihistamine

11. DOSAGE FORM: Suspension

12. STRENGTH/POTENCY: 5 mg/5 mL

13. ROUTE OF ADMINISTRATION: Oral

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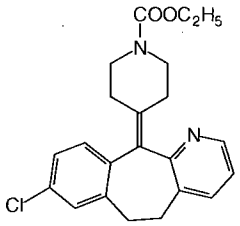

Loratadine

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Chemical Name: 11-[N-(ethoxycarbonyl)-4-piperidylidene]-8-chloro-6,11-dihydro-5H-benzo[5,6] cyclohepta[1,2-b]-pyridine
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* Dr. Cooper [redacted] an [redacted]

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% No DMF

B. Other Supporting Documents: None

C. Related Documents:

DOCUMENT	APPLICATION NUMBER	OWNER	DESCRIPTION/COMMENT
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Biopharm	**dissolution**			
LNC	N/A			
Methods Validation				*
OPDRA	acceptability of the trade name		pending	
EA	exclusion requested		acceptable	
Microbiology	N/A			

* Applicant should provide three copies of method validation package.

Appears This Way
On Original

Chemistry Assessment Section

The Chemistry Review for NDA 21-734

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Approvable from a CMC standpoint.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None

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4). Methods validation will be deferred until all pending approvability issues are completely resolved.

5). The EER for all sites are acceptable.

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Chemistry Assessment Section

C. Basis for Approvability or Not-Approval Recommendation

The application is approvable. The pending deficiencies listed at the end of the review should be addressed to gain approval.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block

Chemist: Chong Ho Kim/ 11-AUG-2005
Chemistry Team Leader: Richard Lostritto/
ProjectManager: Anthony Zeccola/

C. CC Block

Orig. NDA #21-734
HFD-570/Division File
HFD-570/CHKim
HFD-570/RLostritto
HFD-570/AZeccola
R/D Init. by:

Doc: N21-734r2.811

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Chong-Ho Kim
8/12/05 07:24:28 AM
CHEMIST

Richard Lostritto
8/12/05 03:53:08 PM
CHEMIST

NDA 21-734

Children's ElixSure™ - 24hr Antihistamine (Loratadine Oral Suspension), 5 mg/5 mL

Taro Pharmaceuticals U.S.A. Inc.

Chong Ho Kim, Ph.D.
Division of Pulmonary and Allergy Drug Products

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Chemistry Review Data Sheet

1. NDA #: 21-734

2. REVIEW #: 1

3. REVIEW DATE: 28-SEP-2004

4. REVIEWER: Chong Ho Kim, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	19-JAN-2004
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c) Code Name/#:

Chemistry Review Data Sheet

d) Chem. Type/Submission Priority:

- Chem. Type: 3
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b)(2) Application

10. PHARMACOL. CATEGORY: Antihistamine

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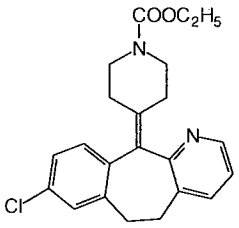

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[redacted]	III	[redacted]	1	Deficient	9/23/04	IR letter issued (10/1/04)
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% No DMF

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OPDRA	acceptability of the trade name		pending	
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Microbiology	N/A			

* Method validation will be deferred until pending method- related issues are fully resolved.

Chemistry Assessment Section

The Chemistry Review for NDA 21-734

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4). Method validation will be deferred until pending issues are completely resolved.

5). EER is pending; three sites are acceptable, however, remaining two sites are pending as of September 30, 2004.

B. Description of How the Drug Product is Intended to be Used

The drug product is Loratadine Oral Suspension, 5 mg/5 mL. It will be used for [redacted] for children. The drug product will be marketed in a [redacted] 8 fl oz (240 mL) [redacted] bottles. [redacted]

Chemistry Assessment Section

C. Basis for Approvability or Not-Approval Recommendation

The application is approvable. An acceptable EER for all cited sites should be received from OC and the pending deficiencies listed at the end of the review should be addressed to gain approval.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block

Chemist: Chong Ho Kim/ 28-SEP-2004
Chemistry Team Leader: Richard Lostritto/
ProjectManager: Anthony Zeccola/

C. CC Block

Orig. NDA #21-734
HFD-570/Division File
HFD-570/CHKim
HFD-570/RLostritto
HFD-570/AZeccola
R/D Init. by:

Doc: N21-734r1.928

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Chong-Ho Kim
10/20/04 05:04:18 PM
CHEMIST

Richard Lostritto
10/21/04 03:31:26 PM
CHEMIST