CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-428

CHEMISTRY REVIEW(S)

NDA 21-428

Lansoprazole Tablets, 15 & 30 mg.

Tap Pharmaceutical Products, Inc.

Joseph Sieczkowski, Ph.D.
Division of Gastrointestinal and Coagulation Drug Products

Table of Contents

Chemistry Review Data Sheet

1. NDA 21-428

2. REVIEW #2

3. REVIEW DATE: 29-AUG-2002

4. REVIEWER: Joseph Sieczkowski, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
IND 60,103	03-May-2000
NDA 20-406	12-NOV-1993
NDA 21-281	30-JUN-2000

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date

Original	30-OCT-2001
Correspondence	20-NOV-2001
Correspondence	07-DEC-2001
BC	13-DEC-2001
BC	22-FEB-2002
BC	27-FEB-2002
BC	21-MAR-2002
BC	12-APR-2002
BL	26-APR-2002
Correspondence	20-JUN-2002
BZ	20-JUN-2002
BC	28-JUN-2002
BL	11-JUL-2002
BC	14-AUG-2002
BZ	21-AUG-2002
BL	29-AUG-2002

7. NAME & ADDRESS OF APPLICANT:

Name:	TAP Pharmaceutical Products, Inc.
Address:	675 North Field Drive, Lake Forest, IL 60045
Representative:	Nancy Knipfer, Assistant Director, Regulatory Affairs
Telephone:	847-236-2193

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Prevacid SoluTab™

b) Non-Proprietary Name (USAN): (Division's name decision)
lansoprazole delayed-release orally disintegrating tablets

[USP Nomenclature and Labeling committee meeting with FDA Labeling and Nomenclature committee decided the appropriate dosage form name as being, "delayed-release orally-disintegrating tablets". (June 26-27, 2002)]

c) Code Name/# (ONDC only): AG-1749; A-65006; CAS 103577-45-3

d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: S

- Submission Priority: 3

9. LEGAL BASIS FOR SUBMISSION:
   a. Correspondence 20-NOV-01-"Takeda Chemical Industries, Ltd., of Japan has licensed or sublicensed lansoprazole as covered by these patents to TAP".

U.S. Patent No.	Expiration Date	Coverage
4,628,098	05/10/09	Compound
4,689,333	07/29/05	Pharmaceutical formulations containing lansoprazole, and a method of treating gastritis
5,013,743	02/12/10	Use of lansoprazole for combating disease caused by the genus *Campylobacter*
5,026,560	06/25/08	Formulation (spherical granules)
5,045,321	09/03/08	Formulation (spherical granules or tablets stabilized with inorganic salt)
5,093,132	09/03/08	Formulation stabilized with inorganic salt
5,433,959	09/03/08	Stabilized pharmaceutical composition
5,464,632	03/22/2013	Formulation (disintegrating tablet)

b. TAP Pharmaceutical's ownership of NDA 20-406, Prevacid (lansoprazole) Delayed-Release Capsules and NDA 21-281, Prevacid (lansoprazole) for Delayed- Release Suspension.

10. PHARMACOL. CATEGORY: gastric acid-pump inhibitor

11. DOSAGE FORM: tablet (additional TAP terminology: fast disintegrating tablet; disintegrating tablet; fast dissolving tablet) see item 8b. above.

12. STRENGTH/POTENCY: 15 & 30 mg / tablet

13. ROUTE OF ADMINISTRATION: oral

14. Rx/OTC DISPENSED: xxx Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note22]:

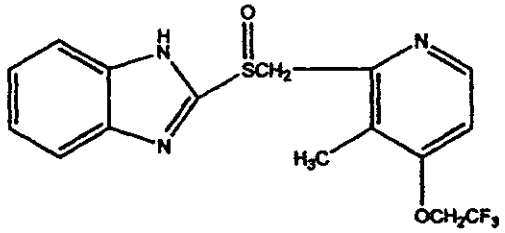
_____SPOTS product – Form Completed

__xxx__Not a SPOTS product

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

Lansoprazole is a substituted benzimidazole, 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl]benzimidazole. Its empirical formula is $C_{16}H_{14}F_3N_3O_2S$ with a molecular weight of 369.37. The structural formula is

LANSOPRAZOLE



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
[redacted]	IV	[redacted]		1	Adequate	7/15/2002 by J.Sieczkowski	Chemist DMF Review # 1
	IV			3	Adequate	05/03/2000 by Arthur Shaw, Ph.D. HFD-180	IND 60,103 lansoperazole tablet, rapidly disintegrating
	III			4	Adequate		DMF LOA Corresp. of 07-DEC-2001
	III			4	Adequate		DMF LOA Corresp. of 07-DEC-2001

[1] Action codes for DMF Table:

1 - DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
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)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
Prevacid Delayed-Release Capsules	NDA 20-406	Refcrenced for drug substance manufacture.

18. STATUS:
ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A	----------	
EES	Acceptable	06-FEB-2002	J.M. D Ambrogio (HFD-324)
Pharm/Tox	N/A	----------	
Biopharm	Pkg. Insert/ comments to applicant on "Alternative Administrative Options"	07-AUG-2002	Tien Mien (Albert) Chen, PhD
LNC	dosage form name defined	01-JUL-2002	Meeting June 27-28/ Yana Mille
Methods Validation	Pending/ MV Package	Phase IV	Joseph Sieczkowski, PhD
DMETS	Acceptable/ "SoluTab™"	28-MAY-2002	Denise Toyer, Pharm. D.
EA	Deficient/ Acceptable Chemistry Review 2	21-MAY-2002	Nancy B Sager-OPS/QIS
Microbiology	Acceptable	17-MAR-2002	James McVey, PhD

OGD: N/A

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology			

EES			
Methods Validation			
Labeling			
Bioequivalence			
EA			
Radiopharmaceutical			

19. ORDER OF REVIEW (OGD Only)

The application submission(s) covered by this review was taken in the date order of receipt. ____ Yes ____ No If no, explain reason(s) below:

REVIEW NOTES

A. DRUG SUBSTANCE

B. DRUG PRODUCT

9 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Joe Sieczkowski
8/29/02 03:17:55 PM
CHEMIST

Liang Zhou
8/30/02 01:09:33 PM
CHEMIST

NDA 21-428

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Joseph Sieczkowski, Ph.D.
Division of Gastrointestinal and Coagulation Drug Products

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3. REVIEW DATE: 15-JUL-2002

4. REVIEWER: Joseph Sieczkowski, Ph.D.

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[USP Nomenclature and Labeling committee meeting with FDA Labeling and Nomenclature committee decided the appropriate dosage form name as being, "delayed-release orally-disintegrating tablets". (June 26-27, 2002)]

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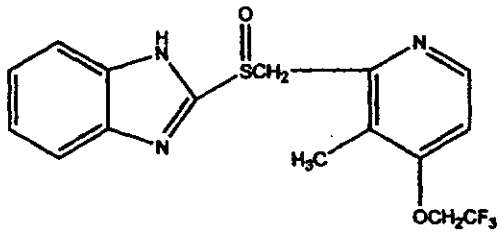

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B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
Prevacid Delayed-Release Capsules	NDA 20-406	First lansoprazole dosage form to market. Referenced for drug substance manufacture.

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A	----------	
EES	Acceptable	06-FEB-2002	J.M. D Ambrogio (HFD-324)
Pharm/Tox	N/A	----------	
Biopharm	Pending/ Consult	*	Tien Mien (Albert) Chen, PhD
LNC	Recommend/dosage form	01-JUL-02	Meeting June 27-28/ Yana Mille
Methods Validation	Pending/ MV Package	Phase IV	Joseph Sieczkowski, PhD
DMETS	Acceptable/ "SoluTab™"	28-MAY-2002	Denise Toyer, Pharm. D.
EA	Deficient	21-MAY-2002	Nancy B Sager-OPS/QIS
Microbiology	Acceptable	17-MAR-2002	James McVey, PhD

OGD: N/A

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology			
EES			
Methods Validation			
Labeling			

Bioequivalence			
EA			
Radiopharmaceutical			

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REVIEW NOTES

A. DRUG SUBSTANCE

[redacted]

B. DRUG PRODUCT

[redacted]

APPEARS THIS WAY
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✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Joe Sieczkowski
7/24/02 10:54:40 AM
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Liang Zhou
7/24/02 01:02:58 PM
CHEMIST