

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-566

Chemistry Review(s)

03/26/04

CHEMISTRY REVIEW

Chemistry Review Data Sheet

NDA 21-566

PREVACID[®] I.V. (lansoprazole) for Injection, 30 mg/Vial

TAP PHARMACEUTICAL PRODUCTS INC.

**Ali Al-Hakim, Ph.D., DNDCII, ONDC
For
Division of Gastrointestinal and Coagulation Drug Products
HFD-180**

Chemistry Review Data Sheet

1. NDA 21-566 Prevacid® I.V. (lansoprazole) for injection

2. REVIEW #: 3

3. REVIEW DATE: March 25, 2004

4. REVIEWER: Ali Al-Hakim, Ph.D.

5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
Original	December 23, 2002
Amendment	April 21, 2003
Amendment	August 12, 2003
IR letter/Fax	August 20, 2003
Amendment	August 28, 2003
Amendment	September 04, 2003
Amendment	September 08, 2003
Teleconference/Fax	September 15, 2003
Amendment	September 17, 2003
IR letter/Fax	September 25, 2003
Amendment	September 24, 2003
Amendment	September 26, 2003
Amendment	October 13, 2003 (fax)
Amendment	October 17, 2003
Amendment	October 20, 2003 (fax)
Amendment	October 20, 2003 (fax)
Amendment	October 20, 2003

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Amendment	January 10, 2004

CHEMISTRY REVIEW

Chemistry Review Data Sheet

7. NAME & ADDRESS OF APPLICANT:

Name: TAP Pharmaceutical Products Inc.

Address 675 North Field Drive
Lake Forest, IL 60045

Representative: Nancianne Knipfer, Ph.D., Regulatory Manager

Telephone: 847 236 2193

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name:	Prevacid® IV
b) Non-Proprietary Name (USAN):	Lansoprazole
c) Code Name/	# AG-1749
d) Chem. Type/Submission Priority (ONDC only):	Standard
• Chem. Type:	3
• Submission Priority:	S

9. LEGAL BASIS FOR SUBMISSION: N/A

10. PHARMACOL. CATEGORY: Proton Pump Inhibitor

11. DOSAGE FORM: Solution for Injection

12. STRENGTH/POTENCY: 30mg

13. ROUTE OF ADMINISTRATION: I.V. Infusion

14. Rx/OTC DISPENSED: Rx OTC

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

SPOTS product – Form Completed

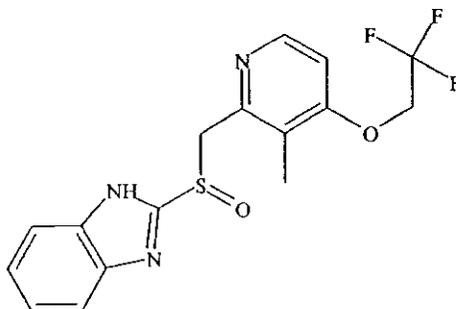
Not a SPOTS product

CHEMISTRY REVIEW

Chemistry Review Data Sheet

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

2-[[[3-methyl-4-(2,2,2-trifluoroethyl)-pyridyl]methyl]sulfinyl]bezimidazole



Molecular Formula: $C_{16}H_{14}F_3O_2S$

Molecular Weight: 369.37

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE1	STATUS2	DATE REVIEW COMPLETED	COMMENTS
1	III			1	Adequate	12/01/01	
2	III			7	N/A	N/A	2 does not require review

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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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:

CHEMISTRY REVIEW

Chemistry Review Data Sheet

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND		Investigational New Drug
IND	41,938	Investigational New Drug
NDA	20-406	Delayed Release Capsules
NDA	21-281	Delayed Release Oral suspension
NDA	21-428	Oral Disintegrating Tablets

18. STATUS:

ONDC:

CONSULTS/CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	Satisfactory	10-22-03 and 03/19/04	Ali Al-Hakim
Pharm/Tox	Approved	09-08-03	Ke Zhang
Biopharm	Approved	09-22-03	Tien-Mien Chen
LNC	N/A		
Methods Validation	Pending		Ali Al-Hakim
DEMTS	Approved	08-18-03	Carol Holquist
EA (Categorical Exclusion)	Acceptable	09-23-03	Ali Al-Hakim
Microbiology	Approved	04-03-03	Paul Stinavage

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The Chemistry Review for NDA 21-566

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The NDA applicant provided adequate information to demonstrate that Pall Supor 1.2 μm in-line filter reduced the particulates in the admixtures to below the USP <788> limits regardless of the material of construction, size or manufacturer of the I.V. bags and infusion sets.

Therefore, from the CMC point of view, the application is recommended for approval pending labeling revision described below.

Based on the [] real-time satisfactory stability data for 6 drug product batches stored at recommended temperature (25°C/60%RH), an expiration dating of 36 months is recommended.

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

1. Conduct studies to identify the cause of instability of the drug product in some admixture solutions. This should include a full chemical characterization of the particulates.
2. Reformulate the product so that it is compatible with admixture solutions, independent of the composition of the diluent container or administration kit.

C. Basis for Approvability or Not-Approval Recommendation

Test data provided by the applicant indicated that admixtures of the drug product with the different diluents have been shown to be stable for the following time periods:

- 9% Sodium Saline for injection (NS) for up to 24 hours
- 5% Dextrose (D5W) for up to 12 hours
- Lactated Ringer's (LR) for up to 24 hours

The use of these diluents is acceptable provided they are infused through the Pall Supor 1.2 μm in-line filter, to remove potential particulates. The filter was effective regardless of the bag type, bag size, infusion set or diluent, for the periods indicated above.

Therefore, based on the above satisfactory information provided by the NDA applicant, the application is recommended for approval.

Most of the changes appears to be acceptable, however, the applicant should delete the information related to the use of Y-site because Y-sites may be used to deliver two drugs and therefore, this may lead to medication error.

III. Administrative

A. Reviewer's Signature

Ali Al-Hakim, Ph.D.

B. Endorsement Block

CC:

HFD-180/Ali Al-Hakim/03/22/04

HFD-180/Liang Zhou/Date

HFD-180/Melissa Furness/Date

NDA 21-566 Division Files

HFD-180/R.Justice and J.Korvick

HFD-820/E.Duffy

21 Page(s) Withheld



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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Ali Al-Hakim
3/26/04 10:44:02 AM
CHEMIST

Liang Zhou
3/26/04 11:09:15 AM
CHEMIST

Approval is recommended from a CMC point of view
pending a labeling review issue

10/23/03

MEMORANDUM

From: Ali Al-Hakim, Ph.D.
Through: Liang Zhou, Ph.D.
Date: 10/23/03
To: NDA 21-566 (lansoprazole)
Applicant: TAP Pharmaceutical products Inc.
Subject: Concern regarding particulates in IV solutions

Based on the teleconference meeting this morning between the division and Tap (October 23, 2003), we understand the sponsor arguments that the drug product was within the USP specification limits for particulates using only [] bags. However, the product failed USP limits when other bags/solutions were used []

Historical data and previous regulatory and scientific review experience obtained with similar drug products point out the fact that these products susceptible to particulates formation when dissolved in IV bags solutions. The problem may be related, but not limited, to bags, solutions, tubing, connectors, syringes, etc.

Further discussion between Drs. Marie Kowblansky, Joyce Korvick, Robert Justice, Julie Beitz and Bronwyn Collier resulted in the decision that this application should be approvable and the following recommendations should be included in the regulatory action letter

1. Conduct studies to identify the cause of the instability of the drug product in some admixture solutions. This should include a full chemical characterization of the particulates []
2. Reformulate the product so that it is compatible with admixture solutions, independent of the composition of the diluent container or administration kit.
3. As an interim solution, you may be able to market the product co-packaged with an in-line filter for removal of particulates from the admixture on administration. This will require the submission of data to demonstrate that there is no loss of potency when the admixture is filtered.

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/s/

Ali Al-Hakim
10/23/03 03:18:54 PM
CHEMIST

Liang Zhou
10/23/03 03:30:31 PM
CHEMIST

10/21/03

CHEMISTRY REVIEW

Chemistry Review Data Sheet

NDA 21-566

PREVACID® I.V. (lansoprazole) for Injection, 30 mg

TAP PHARMACEUTICAL PRODUCTS INC.

**Ali Al-Hakim, Ph.D., DNDCII, ONDC
for
Division of Gastrointestinal and Coagulation Drug Products
HFD-180**

Chemistry Review Data Sheet

1. NDA 21-566 Prevacid® I.V. (lansoprazole) for injection

2. REVIEW #: 2

3. REVIEW DATE: October 21, 2003

4. REVIEWER: Ali Al-Hakim, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents

Original
Amendment
Amendment
IR letter/Fax
Amendment
Amendment
Amendment
Teleconference/Fax
Amendment
IR letter/Fax

Document Date

December 23, 2002
April 21, 2003
August 12, 2003
August 20, 2003
August 28, 2003
September 04, 2003
September 08, 2003
September 15, 2003
September 17, 2003
September 25, 2003

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Amendment
Amendment
Amendment
Amendment
Amendment
Amendment
Teleconference

Document Date

September 24, 2003
September 26, 2003
October 13, 2003 (fax)
October 17, 2003
October 20, 2003 (fax)
October 20, 2003 (fax)
October 20, 2003

CHEMISTRY REVIEW

Chemistry Review Data Sheet

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Name: TAP Pharmaceutical Products Inc.

Address 675 North Field Drive
Lake Forest, IL 60045

Representative: Nancianne Knipfer, Ph.D., Regulatory Manager

Telephone: 847 236 2193

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name:	Prevacid® IV
b) Non-Proprietary Name (USAN):	Lansoprazole
c) Code Name/	# AG-1749
d) Chem. Type/Submission Priority (ONDC only):	Standard
• Chem. Type:	3
• Submission Priority:	S

9. LEGAL BASIS FOR SUBMISSION: N/A

10. PHARMACOL. CATEGORY: Proton Pump Inhibitor

11. DOSAGE FORM: Solution for Injection

12. STRENGTH/POTENCY: 30mg

13. ROUTE OF ADMINISTRATION: I.V. Infusion

14. Rx/OTC DISPENSED: Rx OTC

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

SPOTS product Form Completed

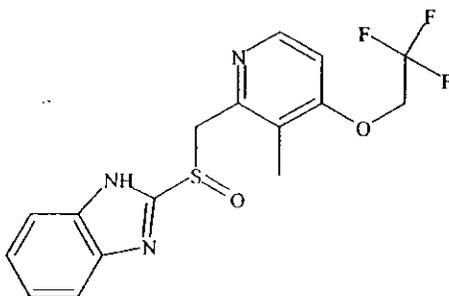
Not a SPOTS product

CHEMISTRY REVIEW

Chemistry Review Data Sheet

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Molecular Formula: $C_{16}H_{14}F_3O_2S$

Molecular Weight: 369.37

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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)

CHEMISTRY REVIEW

Chemistry Review Data Sheet

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND		Investigational New Drug
IND	41,938	Investigational New Drug
NDA	20-406	Delayed Release capsules

18. STATUS:

ONDC:

CONSULTS/CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	Pending		
Pharm/Tox	Approved	09-08-03	Ke Zhang
Biopharm	Approved	09-22-03	Tien-Mien Chen
LNC	N/A		
Methods Validation	Pending		
DEMTS	Approved	08-18-03	Carol Holquist
	Pending () bag issue	09-25-03	
EA (Categorical Exclusion)	Acceptable	09-23-03	Ali Al-Hakim
Microbiology	Approved	04-03-03	Paul Stinavage

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The Chemistry Review for NDA 21-566

Review no. 1 for the above NDA recommended that the application is approvable pending the followings:

1. Additional information regarding the compatibility studies of the drug product solution with other manufactures of [] bags , [] commercial IV bags () and other IV solutions (e.g. Lactated Ringer's Injection, 5% Dextrose Injection).
2. Clarification regarding the storage statement [] 1
3. Satisfactory Establishment Evaluation Report (EER)

The sponsor of the NDA provided responses regarding items 1 and 2 above (Documents/faxes dated October 13 and 20).

With respect to item no. 1, the applicant performed initial studies using the following bags and solutions configuration:

Table 1. I.V. Bags, Suppliers and I.V. Solutions Available in 50 mL Size

I.V. Bag Material	Commercial Supplier	Solution
[
]

Testing were performed on 3 lots using the following conditions:

- Vials will be reconstituted with 5 mL of water and the product will be held for 1 hour prior to further dilution.
- The solution is further diluted in each of the above listed bags with 50mL of either dextrose or 0.9% sodium chloride. Testing was performed at initial, 8 hours and 24 hours time point.

The following test were performed:

Chemistry Assessment Section

- Particulate Testing (visual and sub-visuals) was performed according to USP limits:
 Particulates $\geq 10 \mu\text{m}$ is NMT 6000
 Particulates $\geq 25 \mu\text{m}$ is NMT 600
- pH

Results for the tests indicated that — bags from two manufactures using saline and dextrose solutions were within the USP specifications and pH proposed limit during the above testing period. However, [redacted] were showing higher levels of particles which sometimes exceeding USP limits. Therefore, as per USP instruction, stage 2 microscopy is to be performed before drawing final conclusion regarding these — bags.

Regarding item 2; [redacted], the sponsor listed and argued that several approved drug have used similar statement. However, the applicant reported that because of the agency concern, the following statement will be added to the package insert:

"Use carton to protect content from light"

The above labeling revision appears to be justified.

Recommendation and Conclusion on Approvability

After reviewing the data received yesterday morning (Oct. 20) thoroughly, the submitted data do not conclusively demonstrate that the — bags are the cause of precipitation. Our scientific judgement is that the solutions in these bags are the cause of particulates formation. To ensure that the particulates do not occur and whether they are related to bags, solutions or drug product, identification of the particulates is required. Additionally, completeness of the proposed studies which include potency and related substance and subsequent data may shed more light on the compatibility issue. Therefore, the application remains approvable pending completion of these studies and acceptable EER.

Chemistry Deficiencies

- 1- Provide test data for the identification and/or cause of the particulates which were detected in the IV bags during compatibility studies in order to ensure that the particulates do not occur and whether they are related to bags, solutions or drug product
- 2- Provide test data and complete your proposed compatibility studies which include potency and related substance that may provide scientific explanation for the formation of particulates.
- 3- Satisfactory inspection for the manufacturing facilities (EER)

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/s/

Ali Al-Hakim
10/21/03 05:23:12 PM
CHEMIST

Liang Zhou
10/21/03 05:36:58 PM
CHEMIST

Addendum

From: Ali Al-Hakim
Subject: NDA 21-566 (lansoprazole) IV injection
To: NDA 21-566
Date: September 29, 2003

Your responses to our diffidence requests regarding compatibility studies with IV bags and diluents (manufactured by different manufacturers using various diluents other than the — bag and the 0.9% NaCl described in the application) are not acceptable. The issue of particulates formation remained as a potential safety risk from the CMC point of view. At this time, we do not negotiate phase IV commitment as stated in your fax letters dated September 17 and 26, 2003. Please note that these studies can be performed in a relatively short time and we do not think that they require such lengthy time as suggested in your responses.

Please note the following Chemistry Deficiencies which remained unresolved. These issues should be conveyed in the Disciplinary Review Letter to the applicant.

1. Compatibility studies should be conducted using commonly used diluents even if they are not identified in the proposed drug product labeling (e.g. Lactated Ringer's Injection, 5% Dextrose Injection, etc). The study should include:
 - A- IV bags of all commercial compositions, supplied by different manufacturers, that contain various solutions
 - B- These studies should be performed because there is a high probability that IV bags and solutions not identified in package insert may be used in a clinical setting.

The studies are required because the possibility of particulate formation will result in potential potency loss and safety concerns.

2. Three copies of methods validation should be provided. These copies should be prepared as per FDA guideline "GUIDELINE FOR SUBMITTING SAMPLES AND ANALYTICAL DATA FOR METHODS VALIDATION". Refer to 21 CFR 314.50

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/s/

Ali Al-Hakim
9/29/03 05:03:38 PM
CHEMIST

Liang Zhou
9/29/03 05:12:48 PM
CHEMIST

The compatibility studies don't require more than few days
to generate the required test data. The DR
Letter needs to be issued based on this
Chemist's Addendum. Further negotiations with the applicant to
discuss and resolve these issues may be needed.

09/26/03

CHEMISTRY REVIEW

NDA 21-566

PREVACID® I.V. (lansoprazole) for Injection, 30 mg

TAP PHARMACEUTICAL PRODUCTS INC.

Ali Al-Hakim, Ph.D., DNDCH, ONDC
for
Division of Gastrointestinal and Coagulation Drug Products
HFD-180

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Chemistry Review Data Sheet

1. NDA 21-566 Prevacid® I.V. (lansoprazole) for injection

2. REVIEW #: 1

3. REVIEW DATE: September 25, 2003

4. REVIEWER: Ali Al-Hakim, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

Original

December 23, 2002

Amendment

April 21, 2003

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September 25, 2003

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• Chem. Type:	3
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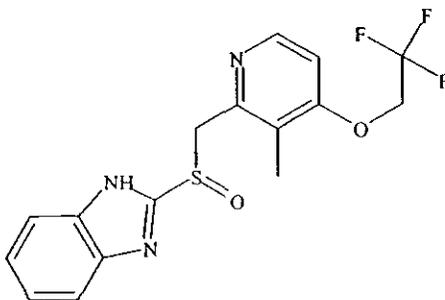
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LNC	N/A		
Methods Validation	Pending		
DEMTS	Approved Pending — bag issue	08-18-03 09-25-03	Carol Holquist
EA (Categorical Exclusion)	Acceptable	09-23-03	Ali Al-Hakim
Microbiology	Approved	04-03-03	Paul Stinavage

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On Original*

The Chemistry Review for NDA 21-566

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The application is approvable pending:

- Satisfactory results obtained from the compatibility studies of the drug product solution with other, [] commercial IV bags.
- Compatibility studies should be also performed using commonly used diluents even if they are not identified in the drug product labeling e.g. Lactated Ringer's Injection, 5% Dextrose Injection, etc. These studies should be performed because it is likely that the diluents will be used whether or not they are specifically discussed in the labeling.
- Pending EER

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

II. Summary of Chemistry Assessments

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

lansoprazole is available commercially for oral administration (15 and 30mg strengths; capsules, tablets and suspension). Therefore, lansoprazole IV was developed as an alternative to the oral dosage form.

Lansoprazole (Prevacid I.V.) for injection, 30 mg, is a lyophilized drug product packaged in 17 mL single dose [] The vial is sealed with stopper []

In addition to the 30 mg lansoprazole active ingredient, the drug product contains inactive ingredients which include mannitol [] (60mg), meglumine [] (10mg) and sodium hydroxide [] The drug product contains an access [] solution which is added to each vial during filling because complete withdrawal of the reconstituted solution from the vial is not possible (see justification for this [] later in this review).

The vial []

For patients use, 30 mg of lansoprazole, 30 mg lansoprazole is reconstituted with 5 mL of sterile water for injection (pH 11) and further diluted in 50 mL of 0.9%

CHEMISTRY REVIEW

Executive Summary Section

sodium chloride injection (pH 10.2). The reconstituted solution can be held for 1 hour when stored at 25 °C prior to further dilution. The diluted solution stored at 25°C, should be administered within 24 hours. The diluted solution should be administered to the patient over 30 minutes.

Lansoprazole drug substance is a white to brownish-white powder; [] . Lansoprazole is a stable

] It also []

Lansoprazole drug substance manufactured for the commercial scale process is []

The drug substance [] becoming slightly soluble at pH 11 and sparingly soluble []

The followings are the main issues related to the drug product

-
-
-
-
-

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

Inject 5 mL of sterile water for injection, USP, into a 30 mg vial of Prevacid IV for injection (6mg/mL). Mix gently until the powder is dissolved. The pH of this solution is about 11.2. This reconstituted solution can be held for 1 hour when stored at 25°C prior to further dilution. Dilute with 50 mL of 0.9% sodium hydroxide. The diluted solution stored at 25°C and has a pH of approximately 10.2. This solution should be administered within 24 hours. The diluted solution should be administered to the patient over 30 minutes. Prevacid I.V. for injection should not be mixed with other drugs or diluents as this may cause incompatibilities. Neither use of filter or dedicated line is required. Compatibility studies were performed between the drug product reconstituted solution and infusion set and infusion bag. No compatibility issues were reported.

C. Basis for Approvability or Not-Approval Recommendation

The major issue which remained unresolved and deemed this application approvable is the compatibility of the drug product solution with other IV bags [] There is a tendency for this type of drug product to form particulate if it comes in contact with some IV bags. The applicant should provide satisfactory

CHEMISTRY REVIEW

Executive Summary Section

results from compatibility/stability studies obtained from the drug product solution with other, [] commercial IV bags. However, the applicant may investigate other alternatives such as co-packaging of [] bags with the drug product. In an amendment dated September 15, 2003, the applicant reported that such studies will take about [] before it can be submitted to the NDA. Therefore, the application remains approvable pending satisfactory response to the this issue.

III. Administrative

A. Reviewer's Signature

Ali Al-Hakim, Ph.D.

B. Endorsement Block

CC:
HFD-180/Ali Al-Hakim/09/25/03
HFD-180/Liang Zhou/Date
HFD-180/Melissa Furness/Date

NDA 21-566 Division Files
HFD-180/R.Justice
HFD-820/E.Duffy

73 Page(s) Withheld



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

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

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

/s/

Ali Al-Hakim
9/26/03 11:24:24 AM
CHEMIST

Liang Zhou
9/26/03 11:32:17 AM
CHEMIST

CHEMISTRY REVIEW TEMPLATE

Chemistry Assessment Section

B. Environmental Assessment Or Claim Of Categorical Exclusion

A categorical exclusion for from preparing Environmental Assessment for Prevacid was submitted in volume 7. The exclusion was based on the fact that the estimated concentration of lansoprazole at the point of entry into the aquatic environment [Expected Introduction Concentration (EIC)] will be below or equal to [] The 5 years production estimate to be [] Therefore, calculated EIC in the fourth year of production is expected to [] This amount is the cut-off limit specified in 21 CFR 25.31 (a)1993) and the FDA Guidance for Industry "Environmental assessment of Human Drugs and Biologics Application (1998).

Evaluation

Adequate information is provided regarding the Claim Of Categorical Exclusion for the NDA.

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Establishment : CFN : [] FEI :
[]
[]
[]

DMF No: AADA:

Responsibilities: []

Profile : SVT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 18-MAR-04
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : [] FEI : []
[]
[]

JMF No: AADA:

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ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Responsibilities:	C	J
	[J
	[J
	C	J

Profile : CSN OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 19-MAR-04

Decision : ACCEPTABLE

Reason : BASED ON PROFILE

Profile : SVT OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 22-OCT-03

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

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ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application : NDA 21566/000 Sponsor: TAP PHARM
Org Code : 180 675 NORTH FIELD DR
Priority : 3S LAKE FOREST, IL 60045

Stamp Date : 23-DEC-2002 Brand Name : PREVACID IV (LANSOPRAZOLE) INJ
PDUFA Date : 23-OCT-2003 30MG
Action Goal : 23-OCT-2003 Estab. Name:
District Goal: 24-AUG-2003 Generic Name: LANSOPRAZOLE
Dosage Form: (INJECTION)
Strength : 30MG

FDA Contacts: M. FURNESS Project Manager (HFD-180) 301-827-7310
A. AL HAKIM Review Chemist (HFD-820) 301-827-7467
L. ZHOU Team Leader (HFD-180) 301-827-1251

Overall Recommendation: ACCEPTABLE on 22-OCT-2003 by S. ADAMS (HFD-322) 301-827-9051

Establishment : CFN : [] FEI :
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[]]

DMF No: AADA:

Responsibilities: []
[]]

Profile : SVT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 20-AUG-03
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : [] FEI : []]

[] J

DMF No:

AADA:

Responsibilities:

[] J
[] J
[] J
[] J

Profile : SVT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-OCT-03
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

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