

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-689

CHEMISTRY REVIEW(S)

02/18/05

NDA 21-689

NEXIUM[®] I.V. (esomeprazole sodium) for injection

AstraZeneca

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



Chemistry Review Data Sheet

1. NDA 21-689 Nexium IV (esomeprazole sodium) for injection

2. REVIEW #: 2

3. REVIEW DATE: February 16, 2005

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

5. PREVIOUS DOCUMENTS:

Original

September 10, 2003

Amendment

March 29, 2004

Amendment

April 01, 2004

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Amendment BC

Amendment (response to the approvable letter)

Amendment AZ

Document Date

August 05, 2004

September 23, 2004

September 30, 2004



CHEMISTRY REVIEW



Executive Summary Section

7. NAME & ADDRESS OF APPLICANT:

Name: AstraZeneca

Address 1800 Concord Pike
Wilmington, DE 19850

Representative: Michael Angioli, Director of regulatory affairs

Telephone: 302 885-1389

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name:	Nexium® IV
b) Non-Proprietary Name (USAN):	esomeprazole sodium
c) Code Name	H 199/18 sodium
d) Chem. Type/Submission Priority (ONDC only):	Standard
• Chem. Type:	3
• Submission Priority:	S

9. LEGAL BASIS FOR SUBMISSION: Not Applicable

10. PHARMACOL. CATEGORY: Proton Pump Inhibitor

11. DOSAGE FORM: IV infusion solution prepared form
freeze-dried powder

12. STRENGTH/POTENCY: 20 mg and 40 mg

13. ROUTE OF ADMINISTRATION: IV Infusion

14. Rx/OTC DISPENSED: ☒ Rx ☐ OTC

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

☐ SPOTS product – Form Completed

☒ Not a SPOTS product

Executive Summary Section

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

Approved name(s)International Nonproprietary Name Modified (INN^M): Esomeprazole sodium

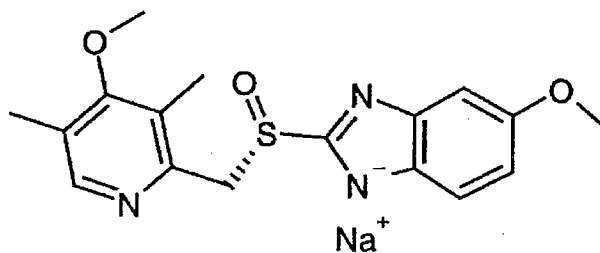
International Nonproprietary Name (INN): Esomeprazole (parent compound)

US Approved Name (USAN): Esomeprazole sodium

Chemical name(s)IUPAC name: sodium 5-methoxy-2-[(*S*)[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1*H*-benzimidazol-1-ateChemical Abstract (CA) Index Name: 1*H*-Benzimidazole, 5-methoxy-2-[(*S*)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-, sodium saltChemical name: (*S*)-5-methoxy-2-[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1*H*-benzimidazole sodium**CAS registry number**

161796-78-7

Chemical Structure

Molecular Formula: C₁₇H₁₈N₃O₃SNa

Molecular Weight: 367.4

NoteEsomeprazole is the *S*-isomer of omeprazole; omeprazole is mixture containing both *S* and *R* isomers.



CHEMISTRY REVIEW



Executive Summary Section

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF	TYPE	HOLDER	ITEM REFERENCED	CO DE1	STATUS2	DATE REVIEW COMPLETED	COMMENTS
	III						Review is not required for Glass type I USP
	III						Review is not required for Glass type I USP
	III						Review is not required for Glass type I USP
	III			1	Adequate	08/22/02	
	III			1	Adequate	09/15/03	
	III			1	Adequate	02/04/04	

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)



CHEMISTRY REVIEW



Executive Summary Section

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	64,865	Nexium Esomeprazole Sodium
NDA	21-153	Nexium Delayed Release Capsules

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	Satisfactory	June 23, 2004	Stella Grosser
EES	Acceptable	May 19, 2004	Ali Al-Hakim
Pharm/Tox	Acceptable	June 24, 2004	Yash Chopra
Biopharmaceutics	Satisfactory	June 18, 2004	Suliman Al-Fayoumi
LNC	N/A		
Methods Validation	Submitted	August 05, 2004	Ali Al-Hakim
DEMTS	Acceptable	January 28, 2004	L. M. Wisniewski
EA	Acceptable	May 30, 2004	Ali Al-Hakim
Microbiology	Acceptable	June 22, 2004	Pawar Vinayak

**APPEARS THIS WAY
ON ORIGINAL**



The Chemistry Review for NDA 21-689

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The application is recommended for approval from CMC point of view.

The sponsor provided satisfactory responses to the approvable letter dated April 23, 2004.

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

None at this time

APPEARS THIS WAY
ON ORIGINAL

Executive Summary Section

II. Summary of Chemistry Assessments

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

The drug product

Nexium IV, (esomeprazole) was developed by AstraZeneca to be used as an alternative to the oral formulation. The sponsor reported that the IV formulation is intended for short-term (up to 10 days) _____ (GERD) patients _____ not possible or not appropriate.

Esomeprazole is the single (*S*)-enantiomer of the proton pump inhibitor (PPI) omeprazole, and acts through inhibition of the proton pumping enzyme H⁺/K⁺-ATPase located in the parietal cells of the gastric oxyntic mucosa, thus preventing hydrochloric acid secretion to the gastric lumen.

The proposed IV formulation contains an esomeprazole sodium salt, in place of the esomeprazole magnesium salt in the oral formulation. The sponsor reported that the sodium salt was selected because the water solubility of esomeprazole magnesium was insufficient for the IV formulation.

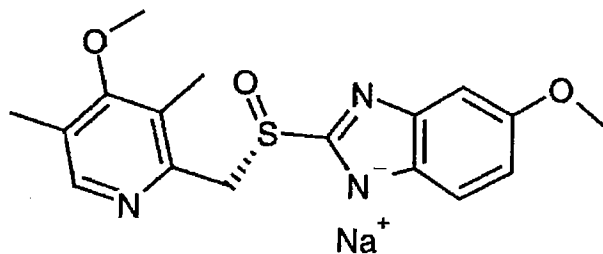
The drug product is formulated as a freeze-dried esomeprazole sodium salt in a 5 mL vial _____ powder) containing two strengths of 20 mg and 40 mg of Nexium IV per single-use vial. The infusion solution is prepared by dissolving the content of one vial in 50 mL 0.9% sodium chloride and should be given as an infusion over a period from 10 to 30 minutes.

The stability of esomeprazole in solution is strongly dependent on the pH (like any other PPI products). The NDA reported that in acidic aqueous solutions at pH 4 (20°C) and below, the substance is rapidly degraded with a half-life of 15 minutes or less. At pH 7 (20°C) the half-life is approximately 30 hours, and at pH 9 the half-life is more than a week. At higher pH esomeprazole is reasonably stable in solution. This is one of the main reasons for formulating the drug product at a higher pH (>10) at injection/reconstitution solutions. The high pH appears to have a great impact on the stability and solubility of the drug product.

The half-life in 0.1 M sodium hydroxide (37°C) is approximately one year.

The drug substance,

Esomeprazole sodium, is a white or almost white powder which contains _____





CHEMISTRY REVIEW



Executive Summary Section

Initial manufacturing process for the synthesis was developed using _____
_____. However, the sponsor reported that an improved
method was developed (_____) _____ This is
the proposed method for the drug substance. Details and _____ regarding these two methods
are discussed in this review in the manufacturing section.
The manufacturing process starts by (_____)



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

As indicated in the label, the drug product is supplied in 5 mL single used vials contain 20 and 40mg of sterilized freeze-dried powder. The drug product can be used either for injection or for infusion by the using the following preparation procedures:

- For injection:
The freeze-dried powder should be reconstituted in 5 mL _____
0.9% sodium chloride _____. Withdraw 5 mL of the reconstituted solution and
administer as an injection over no less than 3 minutes.
- For infusion
A solution for infusion is prepared by _____ the content of one vial in 5 mL 0.9%
Sodium Chloride Injection, USP; Lactated Ringer's Injection, USP or 5% Dextrose
Injection, USP _____ infusion over a period from 10 to 30 minutes.

Note

The applicant reported that NEXIUM I.V. for Injection should not be administered concomitantly with any other medications through the same intravenous site and or tubing. The intravenous line should always be flushed both prior to and after administration of NEXIUM I.V. for Injection.

C. Basis for Approvability or Not-Approval Recommendation

The sponsor provided satisfactory Responses to the Agency's Information Request letter dated April 23, 2004 delineated in the Chemistry review number 1. The responses were related to the CMC issues regarding compatibility studies with other diluents and IV bags and other CMC queries.

- This drug product will be used in hospital emergency setting. From CMC risk management point of view, the comparability study for this type of product is a critical requirement for this application..



III. Administrative

A. Reviewer's Signature

Ali Al-Hakim, Ph.D.

B. Endorsement Block

CC:

HFD-180/Ali Al-Hakim/February 16, 2005

HFD-180/Liang Zhou/Date

HFD-180/Melissa Furness/Date

NDA 21-689 Division Files

HFD-180/J.Korvick

HFD-820/E.Duffy

**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
2/18/05 02:47:15 PM
CHEMIST

Liang Zhou
2/18/05 04:33:21 PM
CHEMIST

12 Page(s) Withheld

X Trade Secret / Confidential

 Draft Labeling

 Deliberative Process

Withheld Track Number: Chemistry- 1

06/10/04

NDA 21-689

NEXIUM[®] I.V. (esomeprazole sodium)

AstraZeneca

Ali Al-Hakim, Ph.D., DNDCII, ONDC

For

Division of Gastrointestinal and Coagulation Drug Products

HFD-180



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Chemistry Review Data Sheet

1. NDA 21-689 Nexium IV (esomeprazole) for injection

2. REVIEW #: 1

3. REVIEW DATE: June 5, 2004

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

5. PREVIOUS DOCUMENTS:

Previous Documents

None

Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Original

Amendment

Amendment

Document Date

September 10, 2003

March 29, 2004

April 01, 2004



CHEMISTRY REVIEW



Executive Summary Section

7. NAME & ADDRESS OF APPLICANT:

Name: AstraZeneca

Address 1800 Concord Pike
Wilmington, DE 19850

Representative: Michael Angioli, Director of regulatory affairs

Telephone: 302 885-1389

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name:	Nexium® IV
b) Non-Proprietary Name (USAN):	esomeprazole sodium
c) Code Name	H 199/18 sodium
d) Chem. Type/Submission Priority (ONDC only):	Standard
• Chem. Type:	3
• Submission Priority:	S

9. LEGAL BASIS FOR SUBMISSION: Not Applicable

10. PHARMACOL. CATEGORY: Proton Pump Inhibitor

11. DOSAGE FORM: IV infusion solution prepared form
freeze-dried powder

12. STRENGTH/POTENCY: 20 mg and 40 mg

13. ROUTE OF ADMINISTRATION: IV Infusion

14. Rx/OTC DISPENSED: ☒ Rx ☐ OTC

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

☐ SPOTS product – Form Completed

☒ Not a SPOTS product

Executive Summary Section

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

Approved name(s)International Nonproprietary Name Modified (INN^M): Esomeprazole sodium

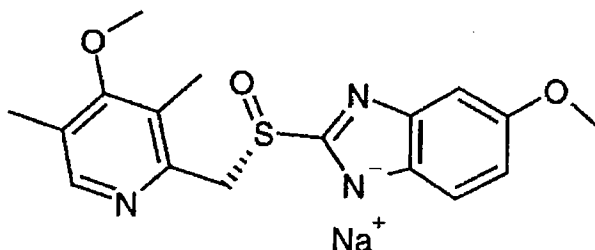
International Nonproprietary Name (INN): Esomeprazole (parent compound)

US Approved Name (USAN): Esomeprazole sodium

Chemical name(s)IUPAC name: sodium 5-methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1*H*-benzimidazol-1-ateChemical Abstract (CA) Index Name: 1*H*-Benzimidazole, 5-methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-, sodium saltChemical name: (S)-5-methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1*H*-benzimidazole sodium**CAS registry number**

161796-78-7

Chemical Structure

Molecular Formula: C₁₇H₁₈N₃O₃SNa

Molecular Weight: 367.4

Note

Esomeprazole is the S-isomer of omeprazole; omeprazole is mixture containing both S and R isomers.



CHEMISTRY REVIEW



Executive Summary Section

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE1	STATUS2	DATE REVIEW COMPLETED	COMMENTS
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	III						Review is not required for Glass type I USP
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² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)



CHEMISTRY REVIEW



Executive Summary Section

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	64,865	Nexium Esomeprazole Sodium
NDA	21-153	Nexium Delayed Release Capsules

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	Acceptable	May 19, 2004	
Pharm/Tox	Pending		
Biopharm	N/A		
LNC	N/A		
Methods Validation	Pending		
DEMTS	Acceptable	January 28, 2004	L. M. Wisniewski
EA	Acceptable	May 30, 2004	Ali Al-Hakim
Microbiology	Pending		

**APPEARS THIS WAY
ON ORIGINAL**



The Chemistry Review for NDA 21-689

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The application is approvable pending satisfactory response to the CMC Information Request letter regarding compatibility studies with other diluents and IV bags and other CMC queries. This letter was sent to the sponsor on April 23, 2004. Details of the letter and other CMC queries are delineated in the list of the deficiencies letter at the end of this review and follow up telecom dated April 19, 2004 (refer to telecom meeting minutes).

The compatibility issue is important approvability item because of the following reasons:

- Test data from compatibility studies are using different diluents and bags are useful to determine what types of degradations/particulates that may formed between the drug product with different diluents and infusion bags so that appropriate labeling instruction could be described in dose administration section as per similar PPI approved products.
- To be regulatory/scientific consistent with similar requirements requested by the Agency on previous API products
- Compatibility issue is related to the drug product quality and PPI drug products have a tendency to degrades and/or forms particulates with different commercially available bags/diluents. Therefore, test data from compatibility studies are useful from the CMC point of view so that proper labeling and reconstitution instructions can be proposed.
- Similar compatibility problems and issues were encountered with other PPI applications which were eventually resolved after constructive meetings and discussions between the Agency and the applicants.
- This drug product will be used in hospital emergency setting. From CMC risk management point of view, the comparability study for this type of product is a critical requirement for this application..

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

None at this time

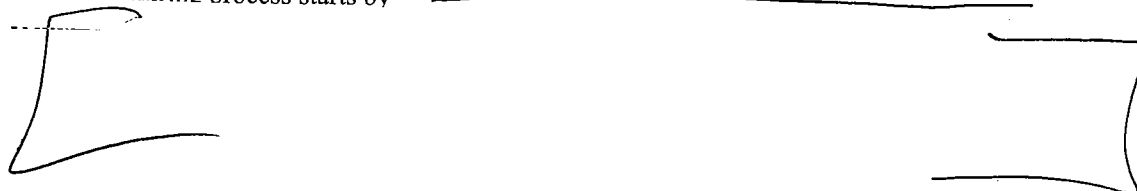


CHEMISTRY REVIEW



Executive Summary Section

Initial manufacturing process for the synthesis was developed using _____
_____. However, the sponsor reported that an improved
method was developed _____. This is
the proposed method for the drug substance. Details and _____ regarding these two methods
are discussed in this review in the manufacturing section.
The manufacturing process starts by _____



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

As indicated in the label, the drug product is supplied in 5 mL single used vials contain 20 and 40mg of sterilized freeze-dried powder. The drug product can be used either for injection or for infusion by the using the following preparation procedures:

- For injection:
The freeze-dried powder should be reconstituted in 5 mL of _____
0.9% sodium chloride _____. Withdraw 5 mL of the reconstituted solution and
administer as an injection over no less than 3 minutes.
- For infusion
A solution for infusion is prepared by _____ the content of one vial in 5 mL 0.9%
sodium chloride _____ over a period from 10 to 30 minutes. _____
_____ temperature up to 30°C (86°F).

Note

The applicant reported that NEXIUM I.V. for Injection should not be administered concomitantly with any other medications through the same intravenous site and or tubing. The intravenous line should always be flushed both prior to and after administration of NEXIUM I.V. for Injection.

C. Basis for Approvability or Not-Approval Recommendation

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CHEMISTRY REVIEW



Executive Summary Section

- To be regulatory/scientific consistent with similar requirements requested by the Agency on previous API products
- Compatibility issue is related to the drug product quality and PPI drug products have a tendency to degrade and/or forms particulates with different commercially available bags/diluents. Therefore, test data from compatibility studies are useful from the CMC point of view so that proper labeling and reconstitution instructions can be proposed.
- Similar compatibility problems and issues were encountered with other PPI applications which were eventually resolved after constructive meetings and discussions between the Agency and the applicants.
- This drug product will be used in hospital emergency setting. From CMC risk management point of view, the comparability study for this type of product is a critical requirement for this application..

III. Administrative

A. Reviewer's Signature

Ali Al-Hakim, Ph.D.

B. Endorsement Block

CC:

HFD-180/Ali Al-Hakim/June 05, 2004

HFD-180/Liang Zhou/Date

HFD-180/Melissa Furness/Date

NDA 21-689 Division Files

HFD-180/R.Justice

HFD-820/E.Duff

85 Page(s) Withheld

X Trade Secret / Confidential

 Draft Labeling

 Deliberative Process

Withheld Track Number: Chemistry-2

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this page is the manifestation of the electronic signature.**

/s/

Ali Al-Hakim
6/10/04 02:09:16 PM
CHEMIST

Liang Zhou
6/10/04 02:13:37 PM
CHEMIST

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : NDA 21689/000

Sponsor: ASTRAZENECA

Org Code : 180

NO CITY, , XX

Priority : 3S

Brand Name : NEXIUM IV

Stamp Date : 10-SEP-2003

Estab. Name:

PDUFA Date : 31-MAR-2005

Generic Name: ESOMEPRAZOLE SODIUM

Action Goal :

Dosage Form: (POWDER)

District Goal: 11-MAY-2004

Strength : 20 AND 40 MG

FDA Contacts: M. FURNESS

Project Manager (HFD-180)

301-827-7310

A. AL HAKIM

Review Chemist (HFD-180)

301-827-7467

L. ZHOU

Team Leader (HFD-180)

301-827-1251

Overall Recommendation: ACCEPTABLE on 19-MAY-2004by J. D AMBROGIO(HFD-322) 301-827-

9049

Establishment : CFN : 9615803

FEI : 3003063819

ASTRA ZENECA

224 AVENUE DE LA DORDOGNE

DUNQUERQUE, , FR

DMF No:

AADA:

Responsibilities: INTERMEDIATE MANUFACTURER

Profile : CRU

OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 19-MAY-04

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN :-9610565

FEI : 3002806411 -

APPEARS THIS WAY
ON ORIGINAL

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER

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

APPEARS THIS WAY
ON ORIGINAL

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : NDA 21689/000

Sponsor: ASTRAZENECA

Org Code : 180

NO CITY, , XX

Priority : 3S

Brand Name : NEXIUM IV

Stamp Date : 10-SEP-2003

Estab. Name:

PDUFA Date : 10-JUL-2004

Generic Name: ESOMEPRAZOLE SODIUM

Action Goal :

Dosage Form: (POWDER)

District Goal: 11-MAY-2004

Strength : 20 AND 40 MG

FDA Contacts: M. FURNESS

Project Manager (HFD-180) 301-827-7310

A. AL HAKIM

Review Chemist (HFD-180) 301-827-7467

L. ZHOU

Team Leader (HFD-180) 301-827-1251

Overall Recommendation: ACCEPTABLE on 19-MAY-2004by J. D AMBROGIO(HFD-322) 301-827-9049

Establishment : CFN : 9615803

FEI : 3003063819

ASTRA ZENECA

224 AVENUE DE LA DORDOGNE

DUNQUERQUE, , FR

DMF No:

AADA:

Responsibilities: INTERMEDIATE MANUFACTURER

Profile : CRU

OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 19-MAY-04

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 9610565

FEI : 3002806411

ASTRAZENECA BULK & LIQUID PRODUCTION SWEDEN

KVARNBERGAGATAN 12 (STRANGNASVAGEN 20)

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

sponsibilities: FINISHED DOSAGE MANUFACTURER
 FINISHED DOSAGE RELEASE TESTER
 FINISHED DOSAGE STABILITY TESTER

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

**Appears This Way
On Original**

DMF No:

AADA:

sponsibilities: DRUG SUBSTANCE MANUFACTURER
 DRUG SUBSTANCE RELEASE TESTER
 DRUG SUBSTANCE STABILITY TESTER

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

Establishment : CFN : 1220331 FEI : 1220331
 ASTRAZENECA LP
 50 OTIS ST
 WESTBOROUGH, MA 01581

DMF No:

AADA:

APPEARS THIS WAY
ON ORIGINAL