


**CENTER FOR DRUG EVALUATION AND RESEARCH**

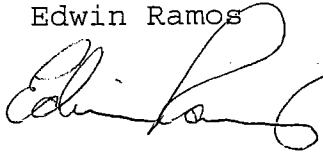
*APPLICATION NUMBER:*

**ANDA 65-024**

**CHEMISTRY REVIEW(S)**

1. CHEMISTRY REVIEW NO. 1
2. ANDA 65-024
3. NAME AND ADDRESS OF APPLICANT  
Altana Inc.  
Attention:  
60 Baylis Road  
Melville, NY 11747
4. BASIS OF SUBMISSION  
The RLD is Garamycin manufactured by Schering Corp. (NDA 50-425).  
To the best of the applicant knowledge there are no existing patents  
and/or exclusivities.
5. SUPPLEMENT(s)  
N/A
6. PROPRIETARY NAME  
N/A
7. NONPROPRIETARY NAME  
Gentamicin Sulfate Ophthalmic  
Ointment USP
8. SUPPLEMENT(s) PROVIDE(s) FOR:  
N/A
9. AMENDMENTS AND OTHER DATES:  
August 4, 1998-- Original Submission  
August 24, 1998-- Telecom from Reg. Support  
August 27, 1998-- New Correspondence  
September 17, 1998-- Acknowledgment letter  
October 27, 1998-- Bio review, acceptable  
January 29, 1999-- Labeling review, unacceptable
10. PHARMACOLOGICAL CATEGORY  
Antibacterial
11. Rx or OTC  
Rx
12. RELATED DMFs  

13. DOSAGE FORM  
Ophthalmic Ointment
14. POTENCY  
0.3%
15. CHEMICAL NAME AND STRUCTURE  
N/A
16. RECORDS AND REPORTS  
N/A

17. COMMENTS  
Drug product has compendial monograph. Microbiology review is pending. ANDA 64-093 was used for specifications comparison.
18. CONCLUSIONS AND RECOMMENDATIONS  
Recommend not approvable letter to issue (Major).
19. REVIEWER: DATE COMPLETED:  
Edwin Ramos March 20, 1999

 3/23/99

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CHEMISTRY REVIEW #1

CC: ANDA #65-024  
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DIVISION FILE  
FIELD COPY

Endorsements:

HFD-643/ERamos/3/22/98

HFD-643/Radams; S Rosencrance/3/23/99

HFD-617/MAnderson/3/22/99

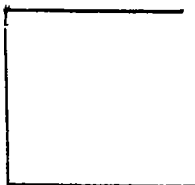
HFD-641/Ffang

F/T by pah/3/23/99

V:\[redacted].65024cr1.f

*[Handwritten signatures and dates]*  
3/23/99  
3/24/99  
3/24/99

1. CHEMISTRY REVIEW NO. 2
2. ANDA 65-024
3. NAME AND ADDRESS OF APPLICANT  
Altana Inc.  
Attention: Virginia Carman  
60 Baylis Road  
Melville, NY 11747
4. BASIS OF SUBMISSION  
The RLD is Garamycin manufactured by Schering Corp. (NDA 50-425). To the best of the applicant's knowledge there are no existing patents and/or exclusivities.
5. SUPPLEMENT (s)  
N/A
6. PROPRIETARY NAME  
N/A
7. NONPROPRIETARY NAME  
Gentamicin Sulfate Ophthalmic Ointment USP
8. SUPPLEMENT (s) PROVIDE (s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:  
August 4, 1998-- Original Submission  
August 24, 1998-- Telecom from Reg. Support  
August 27, 1998-- New Correspondence  
September 17, 1998-- Acknowledgment letter  
October 27, 1998-- Bio review, acceptable  
January 29, 1999-- Labeling review, unacceptable  
Reminder 4/17/00 asking Firm to respond to N/A letter 3/30/99  
Amendment 9/29/00 to Major N/A letter 3/30/99
10. PHARMACOLOGICAL CATEGORY  
Antibacterial
11. Rx or OTC  
Rx
12. RELATED DMFs

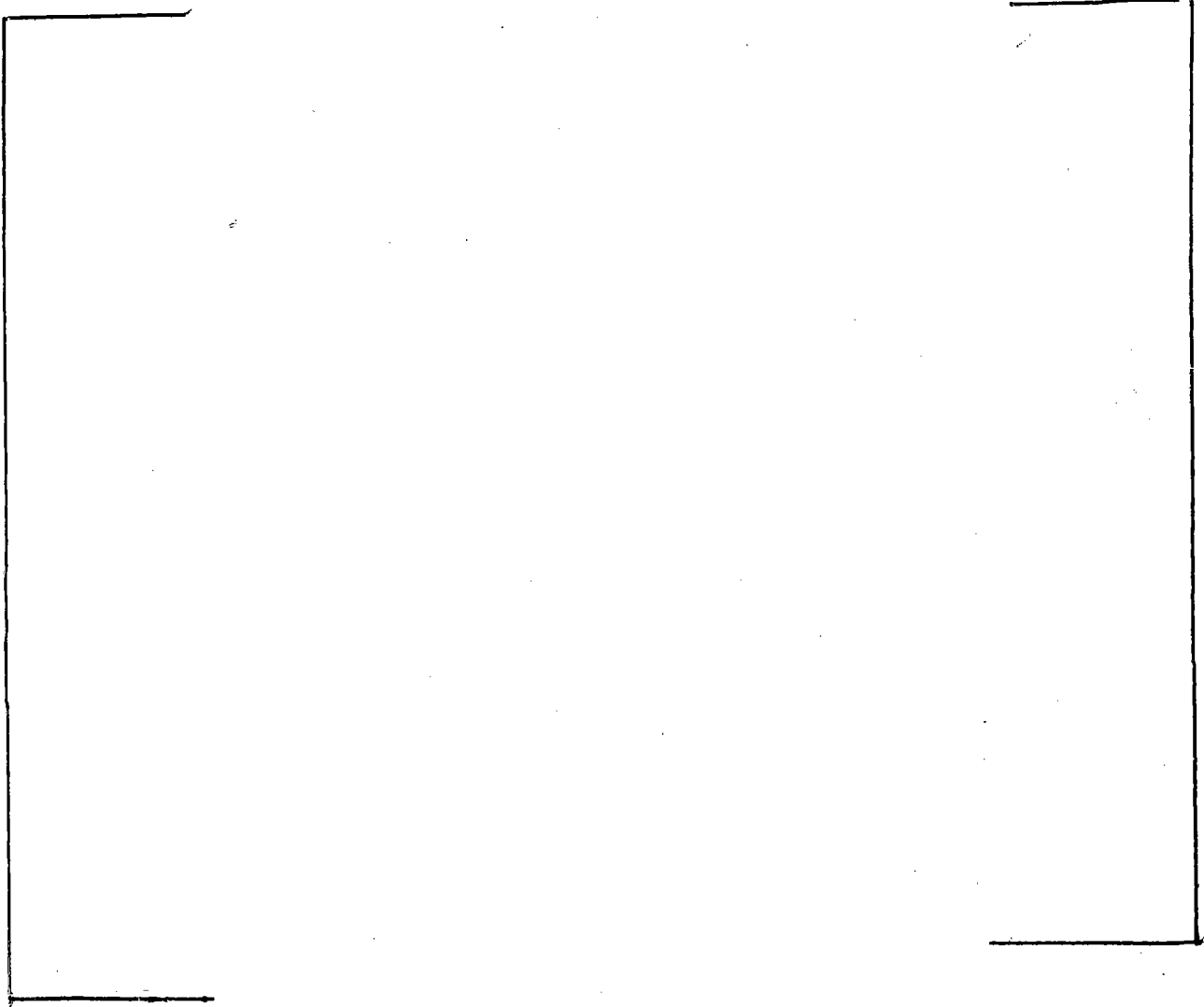


- 13. DOSAGE FORM  
Ophthalmic Ointment
- 14. POTENCY  
0.3%
- 15. CHEMICAL NAME AND STRUCTURE
- 16. RECORDS AND REPORTS N/A
- 17. COMMENTS

This application was reassigned to me January 2001. The first review was done by E. Ramos.

ANDA 64-093 was used for specification comparison in CR #1.

In Amendment 9/29/00, Firm answers as follows:



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*CHEMISTRY REVIEW #2*

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**General comments:**

Answers to concerns raised in CR #1 are all acceptable at present. Due to the issue of currently unacceptable API manufacturer, a major review will be conducted when Firm submits updated information and complete performance data from a new exhibit batch using a new API source.

**Status Summary for #65-024:**

**DMF:** Pending (new API source needed)  
**Labeling:** Not acceptable (11/13/00)  
**EER:** pending  
**Sample:** Not requested (USP drug)  
**Bio:** Waiver granted 10/21/98  
**Micro:** Pending

18. CONCLUSIONS AND RECOMMENDATIONS  
 Not approvable (MAJOR Amendment)
19. REVIEWER: DATE COMPLETED:  
 Maria C. Shih 1/17/00

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CHEMISTRY REVIEW # 2

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Endorsements:

HFD-643/M. Shih/1/17/01/

HFD-643/R. Adams/

HFD-617/M. Anderson/

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*MSH 1/26/01*  
*1/25/01* as modified  
*by MA*  
*R.C. Adams 1/17/01*  
*M. Anderson 1/22/01*

F/T by:


NOT APPROVABLE - MAJOR AMENDMENT

1. CHEMISTRY REVIEW NO. 3
2. ANDA 65-024
3. NAME AND ADDRESS OF APPLICANT  
Altana Inc.  
Attention: Virginia Carman  
60 Baylis Road  
Melville, NY 11747
4. BASIS OF SUBMISSION  
The RLD is Garamycin manufactured by Schering Corp. (NDA 50-425).  
To the best of the applicant knowledge there are no existing  
patents and/or exclusivities.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME N/A
7. NONPROPRIETARY NAME  
Gentamicin Sulfate Ophthalmic Ointment USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:  
August 4, 1998-- Original Submission  
August 24, 1998-- Telecom from Reg. Support  
August 27, 1998-- New Correspondence  
September 17, 1998-- Acknowledgment letter  
October 27, 1998-- Bio review, acceptable  
January 29, 1999-- Labeling review, unacceptable  
Reminder 4/17/00 asking Firm to respond to N/A letter 3/30/99  
Amendment 9/29/00 to Major N/A letter 3/30/99  
Amendment 6/18/02 to Major N/A letter 1/30/01  
Amendment 8/7/02 (Labeling)
10. PHARMACOLOGICAL CATEGORY  
Antibacterial
11. Rx or OTC  
Rx
12. RELATED DMFs



- 13. DOSAGE FORM  
Ophthalmic Ointment
- 14. POTENCY  
0.3%
- 15. CHEMICAL NAME AND STRUCTURE
- 16. RECORDS AND REPORTS N/A
- 17. COMMENTS

1) This application was reassigned to me January 2001. The first review was done by E. Ramos.

2) 

2) 

**Status Summary for #65-024:**

**DMF:** \_\_\_\_\_ is adequate  
**Labeling:** Pending  
**EER:** pending  
**Sample:** Not requested (USP drug)  
**Bio:** Waiver granted 10/21/98  
**Micro:** Pending

- 18. CONCLUSIONS AND RECOMMENDATIONS  
Not approvable (MINOR Amendment)
- 19. REVIEWER: Maria C. Shih                      DATE COMPLETED: 10/9/02

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CHEMISTRY REVIEW #3

CC: ANDA #65-024  
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Endorsements:

HFD-643/M.Shih/10/9/02 *M Shih 10/11/02*  
HFD-643/R.Adams/10/9/02 *R-Adams 10/15/02*  
HFD-617/M.Anderson/10/11/02 *M Anderson 10/16/02*  
V:\FIRMSAM/ALTANA/LTRS&REV/65024RV3.NAD.DOC *mda 10/21/02*

F/T by: mda/10/11/02  
NOT APPROVABLE - MINOR AMENDMENT

1. CHEMISTRY REVIEW NO. 4
2. ANDA 65-024
3. NAME AND ADDRESS OF APPLICANT  
Altana Inc.  
Attention: Virginia Carman  
60 Baylis Road  
Melville, NY 11747
4. BASIS OF SUBMISSION  
The RLD is Garamycin manufactured by Schering Corp. (NDA 50-425).  
To the best of the applicant knowledge there are no existing  
patents and/or exclusivities.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME N/A
7. NONPROPRIETARY NAME  
Gentamicin Sulfate Ophthalmic Ointment USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:  
August 4, 1998-- Original Submission  
August 24, 1998-- Telecom from Reg. Support  
August 27, 1998-- New Correspondence  
September 17, 1998-- Acknowledgment letter  
October 27, 1998-- Bio review, acceptable  
January 29, 1999-- Labeling review, unacceptable  
Reminder 4/17/00 asking Firm to respond to N/A letter 3/30/99  
Amendment 9/29/00 to MAJOR N/A letter 3/30/99  
Amendment 6/18/02 to MAJOR N/A letter 1/30/01  
Amendment 8/7/02 (Labeling)  
Amendment 12/9/02 to MINOR N/A letter 10/24/02
10. PHARMACOLOGICAL CATEGORY  
Antibacterial
11. Rx or OTC  
Rx
12. RELATED DMFs





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CHEMISTRY REVIEW #4 pages 2-8

Status Summary for #65-024:

DMF: \_\_\_\_\_ is adequate  
Labeling: Acceptable 1/3/03  
EER: pending  
Sample: Not requested (USP drug)  
Bio: Waiver granted 10/21/98  
Micro: Pending

18. CONCLUSIONS AND RECOMMENDATIONS  
Not approvable (MINOR Amendment)

19. REVIEWER: DATE COMPLETED:  
Maria C. Shih 1/22/03

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CHEMISTRY REVIEW #4 pages 10-22

CC: ANDA #65-024  
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Endorsements:

HFD-643/M. Shih/1/22/03/

HFD-643/R. Adams/2/1/03

HFD-617/M. Anderson/2/5/03

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*[Handwritten signature]* 2/5/03

*R. c. Adams 2/9/03*

*M Anderson 2/10/03*

F/T by: EW 2/5/03

NOT APPROVABLE - MINOR AMENDMENT

1. CHEMISTRY REVIEW NO. 5

2. ANDA 65-024

3. NAME AND ADDRESS OF APPLICANT

Altana Inc.  
Attention: Virginia Carman  
60 Baylis Road  
Melville, NY 11747

4. BASIS OF SUBMISSION

The RLD is Garamycin manufactured by Schering Corp. (NDA 50-425).  
To the best of the applicant knowledge there are no existing  
patents and/or exclusivities.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME

Gentamicin Sulfate Ophthalmic Ointment USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

August 4, 1998-- Original Submission  
August 24, 1998-- Telecom from Reg. Support  
August 27, 1998-- New Correspondence  
September 17, 1998-- Acknowledgment letter  
October 27, 1998-- Bio review, acceptable  
January 29, 1999-- Labeling review, unacceptable  
Reminder 4/17/00 asking Firm to respond to N/A letter 3/30/99  
Amendment 9/29/00 to MAJOR N/A letter 3/30/99  
Amendment 6/18/02 to MAJOR N/A letter 1/30/01  
Amendment 8/7/02 (Labeling)  
Amendment 12/9/02 to MINOR N/A letter 10/24/02  
Amendment 5/7/03 to MINOR N/A letter 2/20/03

10. PHARMACOLOGICAL CATEGORY

Antibacterial

11. Rx or OTC

Rx

12. RELATED DMFs

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CHEMISTRY REVIEW #5 PP. 2-4

Status Summary for #65-024:

DMF: \_\_\_\_\_ is adequate  
Labeling: Acceptable 1/3/03  
EER: pending  
Sample: Not requested (USP drug)  
Bio: Waiver granted 10/21/98  
Micro: Pending

18. CONCLUSIONS AND RECOMMENDATIONS  
Not approvable (MINOR Amendment)

19. REVIEWER: Maria C. Shih                      DATE COMPLETED: 6/17/03

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CHEMISTRY REVIEW #5 pages 6-19



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Endorsements:

HFD-643/M. Shih/6/17/03/

HFD-643/R. Adams/6/18/03

HFD-617/M. Anderson/6/25/03

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 6/25/03

R. C. Adams 6/25/03

M. Anderson 6/26/03

F/T by: EW 6/25/03

NOT APPROVABLE - MINOR AMENDMENT

1. CHEMISTRY REVIEW NO. 6
2. ANDA 65-024
3. NAME AND ADDRESS OF APPLICANT  
Altana Inc.  
Attention: Virginia Carman  
60 Baylis Road  
Melville, NY 11747
4. BASIS OF SUBMISSION  
The RLD is Garamycin manufactured by Schering Corp. (NDA 50-425).  
To the best of the applicant knowledge there are no existing  
patents and/or exclusivities.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME N/A
7. NONPROPRIETARY NAME  
Gentamicin Sulfate Ophthalmic Ointment USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:  
August 4, 1998-- Original Submission  
August 24, 1998-- Telecom from Reg. Support  
August 27, 1998-- New Correspondence  
September 17, 1998-- Acknowledgment letter  
October 27, 1998-- Bio review, acceptable  
January 29, 1999-- Labeling review, unacceptable  
Reminder 4/17/00 asking Firm to respond to N/A letter 3/30/99  
Amendment 9/29/00 to MAJOR N/A letter 3/30/99  
Amendment 6/18/02 to MAJOR N/A letter 1/30/01  
Amendment 8/7/02 (Labeling)  
Amendment 12/9/02 to MINOR N/A letter 10/24/02  
Amendment 5/7/03 to MINOR N/A letter 2/20/03  
Amendment 11/10/03 to MINOR N/A letter 7/17/03
10. PHARMACOLOGICAL CATEGORY  
Antibacterial
11. Rx or OTC  
Rx
12. RELATED DMFs



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CHEMISTRY REVIEW #6 pages 2-5

Status Summary for #65-024:

DMF:

**Labeling:** Acceptable 1/3/03  
**EER:** Pending  
**Sample:** Not requested (USP drug)  
**Bio:** Waiver granted 10/21/98  
**Micro:** Deficient review dated 2/27/04

18. CONCLUSIONS AND RECOMMENDATIONS

Not approvable \_\_\_\_\_ and sterility assurance.

19. REVIEWER:

Maria C. Shih

DATE COMPLETED:

1/13/04; 2/27/04

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CHEMISTRY REVIEW #6 PP. 7-21

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CC: ANDA #65-024  
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Field Copy

Endorsements:

HFD-643/M.Shih/1/13/04; 2/27/04 (as revised)

HFD-643/R.Adams/1/13/04; 3/1/04 *M. Anderson for R.C. Adams*

HFD-617/M.Anderson/3/1/04

V:\FIRMSAM/ALTANA/LTRS&REV/65024RV6.NAD.DOC

F/T by: mda/3/1/04

NOT APPROVABLE - MINOR AMENDMENT

*R.C. Adams 3/1/04*  
*M. Anderson 3/1/04*

1. CHEMISTRY REVIEW NO. 7

2. ANDA 65-024

3. NAME AND ADDRESS OF APPLICANT

Altana Inc.  
Attention: Audrey Zawesky  
60 Baylis Road  
Melville, NY 11747

4. BASIS OF SUBMISSION

The RLD is Garamycin manufactured by Schering Corp. (NDA 50-425).  
To the best of the applicant knowledge there are no existing  
patents and/or exclusivities.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME

Gentamicin Sulfate Ophthalmic Ointment USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

August 4, 1998-- Original Submission  
August 24, 1998-- Telecom from Reg. Support  
August 27, 1998-- New Correspondence  
September 17, 1998-- Acknowledgment letter  
October 27, 1998-- Bio review, acceptable  
January 29, 1999-- Labeling review, unacceptable  
Reminder 4/17/00 asking Firm to respond to N/A letter 3/30/99  
Amendment 9/29/00 to MAJOR N/A letter 3/30/99  
Amendment 6/18/02 to MAJOR N/A letter 1/30/01  
Amendment 8/7/02 (Labeling)  
Amendment 12/9/02 to MINOR N/A letter 10/24/02  
Amendment 5/7/03 to MINOR N/A letter 2/20/03  
Amendment 11/10/03 to MINOR N/A letter 7/17/03  
Amendment 4/2/04 to MINOR N/A letter 3/1/04  
Telephone Amendment 5/7/04

10. PHARMACOLOGICAL CATEGORY  
Antibacterial

11. Rx or OTC  
Rx

12. RELATED DMFs  

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CHEMISTRY REVIEW #7 pages 2-6



**Status Summary for #65-024:**

**DMF:** \_\_\_\_\_ is adequate

**Labeling:** Acceptable 6/26/03  
**EER:** Acceptable 4/28/03  
**Sample:** Not requested (USP drug)  
**Bio:** Waiver granted 10/21/98  
**Micro:** Acceptable 6/29/04

18. **CONCLUSIONS AND RECOMMENDATIONS**

Approval recommended

19. **REVIEWER:** DATE COMPLETED:  
Maria C. Shih 7/07/04

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CHEMISTRY REVIEW #7 pages 8-21