

**CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**50-444/S-036**

**50-445/S-019**

**50-649/S-011**

**CHEMISTRY REVIEW(S)**

## NDA SUPPLEMENT REVIEW

<b>CHEMIST'S REVIEW</b>	<b>1. ORGANIZATION.</b>	<b>2. NDA NUMBER</b>
1	DAIDP (HFD-520)	50-444
<b>3. NAME &amp; ADDRESS OF APPLICANT</b>	<b>4. AF NUMBER</b>	
Wyeth Pharmaceuticals P. O. Box 8299 Philadelphia, PA 19101-8299		
		<b>5. SUPPLEMENT (s) NUMBER (s) DATE (s.)</b>
		SLR-036 3/26/02
<b>6. NAME OF DRUG</b>	<b>7. NONPROPRIETARY NAME</b>	
Minocin Intravenous	Minocin Hydrochloride	
<b>8. SUPPLEMENT (s) PROVIDES FOR: adding "Geriatric Use"</b> Subsection to the Precaution Section on the labeling and information on Sodium and Potassium content.		
<b>AMENDMENTS AND OTHER (REPORTS, etc.) DATES</b>		
None		
<b>10. PHARMACOLOGICAL CATEGORY</b>	<b>11. HOW DISPENSED</b>	<b>12. RELATED IND/NDA/DMF (s)</b>
Antibiotic	Rx XX OTC	
<b>13. DOSAGE FORM (s)</b>	<b>14. POTENCY (ies)</b>	
Injection	equiv 100 mg base/vial	
<b>15. CHEMICAL NAME AND STRUCTURE</b>		
		<b>16. RECORDS AND REPORTS</b>
m.w.		CURRENT
CAS Registry No.	- -	x Yes X No
		REVIEWED
		Yes X No
<b>17. COMMENTS</b>		
This drug is the subject of a compendial monograph, USP 24, pg.1117. Reviewed for Sodium and Potassium content.		
<b>18. CONCLUSIONS AND RECOMMENDATIONS:</b>		
According to the firm, it contains neither Sodium nor Potassium.		
cc: Orig: NDA 50-444 ;HFD-520 HFD-520/Div File HFD-520/MO/Moledina HFD-520/Pharm/Ellis HFD-520/CSO/Milstein HFD-520/Shetty HFD-520/D. Katague:R/D initialed		
<b>19. REVIEWER</b>		
NAME: B. Vithal Shetty, Ph.D.		4/15/02
SIGNATURE		DATE COMPLETED
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/s/

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B.V. Shetty  
4/17/02 08:44:50 AM  
CHEMIST

Shrikant Pagay  
4/18/02 10:28:34 PM  
CHEMIST  
Signed for dr. Katague

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW 1. ORGANIZATION. 2. NDA NUMBER  
1 DAIDP (HFD-520) 50-649

3. NAME & ADDRESS OF APPLICANT 4. AP NUMBER  
Wyeth Pharmaceuticals  
P. O. Box 8299  
Philadelphia, PA 19101-8299

5. SUPPLEMENT(s)  
NUMBER(s) DATE(s)  
SLR-011 3/26/02

6. NAME OF DRUG NONPROPRIETARY NAME  
Minocin Pellet-Filled Capsules Minocin Hydrochloride

8. SUPPLEMENT(s) PROVIDES FOR: adding "Geriatric Use"  
Subsection to the Precaution Section on the labeling and  
information on Sodium and Potassium content.

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES  
NONE

10. PHARMACOLOGICAL CATEGORY 11. HOW DISPENSED 12. RELATED IND/NDA/DMF(s)  
Antibiotic Rx XX OTC

13. DOSAGE FORM(s) 14. POTENCY(ies)  
capsule equiv 50 mg base, 75mg base, 100mg  
base

15. CHEMICAL NAME AND STRUCTURE

m.w.  
CAS Registry No. - -  
REVIEWED

16. RECORDS AND REPORTS  
CURRENT  
x Yes X No  
REVIEWED  
Yes X No

17. COMMENTS  
This drug is the subject of a compendial monograph,  
USP 24, p.1117. Reviewed for Sodium and Potassium content.

18. CONCLUSIONS AND RECOMMENDATIONS:  
It contains neither Sodium nor Potassium.  
cc: Orig: NDA 50-649 HFD-520  
HFD-520/Div File HFD-520/MO Moledina Nasim  
HFD-520/Pharm/Ellis HFD-520/CSO/Milstein  
HFD-520/Shetty HFD-520/D. Katague:R/D initialed

19  
REVIEWER  
NAME: B. Vithal Shetty, Ph.D. 4/15/02

DATE COMPLETED  
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/s/  
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B.V. Shetty  
4/17/02 08:51:48 AM  
CHEMIST

Shrikant Pagay  
4/18/02 10:32:55 PM  
CHEMIST  
Signed for Dr. Katague

## NDA SUPPLEMENT REVIEW

<b>CHEMIST'S REVIEW</b>	<b>1. ORGANIZATION.</b>	<b>2.NDA NUMBER</b>
<u>1</u>	DAIDP (HFD-520)	50-445
<b>3. NAME &amp; ADDRESS OF APPLICANT</b>	<b>4. AF NUMBER</b>	
Wyeth Pharmaceuticals P.O Box 8299 Philadelphia, PA 19101-8299		
		<b>5. SUPPLEMENT</b>
		<b>NUMBER(s) DATE(s)</b>
		SLR-019 3/26/02
<b>6. NAME OF DRUG</b>	<b>7. NONPROPRIETARY NAME</b>	
Minocin Oral Suspension	Minocin Hydrochloride	
<b>8. SUPPLEMENT(S) PROVIDES FOR: adding "Geriatric Use"</b> Subsection to the Precaution Section on the labeling and information on Sodium and Potassium content.		
<b>AMENDMENTS AND OTHER(REPORTS, etc.) DATES</b>		
None		
<b>10. PHARMACOLOGICAL</b>	<b>11. HOW DISPENSED</b>	<b>12. RELATED</b>
<b>CATEGORY</b>		<b>IND/NDA/DMF(S)</b>
Antibiotic		
	Rx XX	OTC
<b>13. DOSAGE FORM(S)</b>	<b>14. POTENCY(ies)</b>	
Liquid Suspension	equiv 50mg base/5mL	1
<b>15. CHEMICAL NAME AND STRUCTURE</b>		
		<b>16. RECORDS AND REPORTS</b>
m.w.		CURRENT
CAS Registry No.	- -	X Yes X No
-		REVIEWED
		Yes X No
<b>17. COMMENTS</b>		
This drug is the subject of a compendial monograph, USP 24, pg.1117 . See items 27 for detailed comments. <u>Reviewed for Sodium and Potassium content.</u>		
<b>18. CONCLUSIONS AND RECOMMENDATIONS:</b>		
According to the firm, the Total mEq of Na/5mL in Minocin Oral Suspension = 0.189 and the Total mg Na/5mL in Minocin Oral Suspension = 4.31		
cc: Orig: NDA 50-444;HFD-520		
HFD-520/Div File HFD-520/MO/Moledina		
HFD-520/Pharm/Ellis HFD-520/CSO/Milstein		
HFD-520/Shetty HFD-520/D. Katague:R/D initialed		
<b>19</b>		<b>REVIEWER</b>
NAME: B.Vithal Shetty, Ph.D.		4/15/02
SIGNATURE		DATE COMPLETED
DISTRIBUTION	ORIGINAL JACKET	REVIEWER March 9, 2002

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/s/

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B.V. Shetty  
6/3/02 01:04:08 PM  
CHEMIST

Shrikant Pagay  
6/3/02 01:10:14 PM  
CHEMIST

David Katague  
6/3/02 01:47:01 PM  
CHEMIST