

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-574

Chemistry Review(s)



NDA 21-574

Fortamet™ Extended-Release Tablets

Metformin HCl, USP ER Tablets

**Andrx Labs, Inc.
(Andrx)**

CMC Review # 2

**Xavier Ysern, PhD
HFD-510**



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CHEMISTRY REVIEW



Chemistry Review Data Sheet

Chemistry Review Data Sheet

1. **NDA** 21-574
2. **REVIEW #** 2
3. **REVIEW DATE:** 01-AUG-2003 (review # 2)
4. **REVIEWER:** Xavier Ysern
5. **PREVIOUS DOCUMENTS:**
- | <u>Document(s)</u> | <u>Document Date</u> |
|--------------------|----------------------|
| -- | -- |
6. **SUBMISSION(S) BEING REVIEWED:**
- | <u>Submission(s) Reviewed</u> | <u>Document Date</u> |
|-------------------------------|----------------------|
| Original | 17-DEC-2002 |
| Amendment | 29-JAN-2003 |
| | 17-MAR-2003 |
| | 15-MAY-2003 |
| | 28-JUL-2003 |
7. **NAME & ADDRESS OF APPLICANT:**
- Name:** Andrx Labs, Inc. phone (201) 883-1898
- Address:** 401 Hackensack Avenue
Hackensack, NJ 07601
- Representative:** Nicholas J. Farina, Vice President Regulatory Affairs
- Telephone:** (610) 428-2417 Fax: (201) 883-1893
8. **DRUG PRODUCT NAME/CODE/TYPE:**
- a) Proprietary Name: Fortamet™ ER Tablets
- b) Non-Proprietary Name (USAN): Metformin HCl Extended-Release Tablets
- c) Code Name: --
- d) Chem. Type/Submission Priority:
- Chem. Type: Type 4
 - Submission Priority: S
9. **LEGAL BASIS FOR SUBMISSION:** --
10. **PHARMACOLOGICAL CATEGORY:** Proposed for the treatment of Type 2 diabetes mellitus as an adjunct to diet and exercise
11. **DOSAGE FORM:** Tablets
12. **STRENGTH/POTENCY:** 500-mg and 1000-mg
13. **ROUTE OF ADMINISTRATION:** Oral
14. **Rx/OTC DISPENSED:** Rx
15. **SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):** Not a SPOTS product



CHEMISTRY REVIEW



Chemistry Review Data Sheet

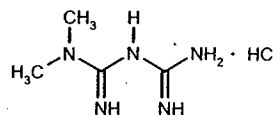
16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WEIGHT:

Metformin Hydrochloride

$C_4H_{11}N_5 \cdot HCl$

MW = 129.17 + 36.46 = 165.63

CAS 657-25-9 (free base) 1115-70-4 (hydrochloride)



N,N-Dimethylimidodicarbonimidic diamine monohydrochloride or *N,N*-Dimethylbiguanide HCl

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	LOA date	Holder	Item Referenced	Code ¹	Status ²	Date Review Completed	Comments
Type II							
	05.Nov.2001		Metformin HCl (DS)	1	Adequate	23-JAN-2002	ANDA 75961
Type III							
	16.Mar.2001			4	Adequate		
	08.Oct.2002			4	Adequate		
	02.May.2002			4	Adequate		
	06.Aug.2002			4	Adequate		
	01.Mar.1999			4	Adequate		
	20.Dec.2001			3	Adequate	01-APR-1999	
	03.May.2000			4	Adequate		
	25.May.2001			4	Adequate		
	02.May.2002			4	Adequate		
	07.Jun.2002			4	Adequate		
	18.Dec.1997			4	Adequate		
	06.Jun.2002			4	Adequate		
	29.Mar.2001			4	Adequate		
	12.Sep.2002			4	Adequate		
	11.Oct.2002			4	Adequate		
	1.Oct.2002			4	Adequate		
Type IV							
	13.Feb.2002			4	Adequate	Part of this review	
	13.Feb.2002						
	27.Dec.2000						

¹ Action codes for DMF Table:

1 - DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 - Type I 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)

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