

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-051

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3
2. ANDA # 75-051
3. NAME AND ADDRESS OF APPLICANT
UDL Laboratories, Inc.
Attention: Dina Kostakis
7265 Ulmerton Road
Largo, Fl 33771
4. LEGAL BASIS FOR SUBMISSION
The reference product is Reglan Syrup, manufactured by A.H. Robins Company, Inc. The applicant states that the drug product is not entitled to a period of marketing exclusivity.
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Metoclopramide HCl
8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:

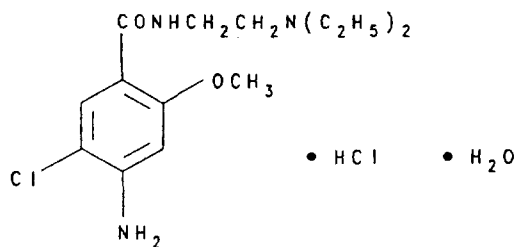
Orig. Submission	12/30/96
Acknowledgment	3/17/97
New Correspondence	3/26/97
NA Letter	5/19/97
Amendment	9/08/97
Amendment	3/31/00
Amendment	10/09/00
Telephone amendment	12/8/00
10. PHARMACOLOGICAL CATEGORY
Antiemetic
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Oral Soln.
14. POTENCY
1 mg/mL

15. CHEMICAL NAME AND STRUCTURE

Metoclopramide Hydrochloride USP

$C_{14}H_{22}ClN_3O_2 \cdot HCl \cdot H_2O$; M.W. = 354.28



4-Amino-5-chloro-N- [2-(diethylamino) ethyl]-o-anisamide
Monohydrochloride monohydrate. CAS [54143-57-6]

16. RECORDS AND REPORTS

N/A

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

Apporvable

19. REVIEWER:

Mahnaz Farahani Ph.D.

DATE COMPLETED:

06/21/00 and 1/8/01

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

Chen Rev 3
6/21/00