

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

ANDA 40-458

CHEMISTRY REVIEW(S)

APPROVAL PACKAGE SUMMARY 40-458

ANDA: 40-458

FIRM: Mikart, Inc.

DRUG: Carbinoxamine Maleate

DOSAGE: _____

STRENGTH: 4 mg/5 mL

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable 1/8/03.

BIO STUDY/BIOEQUIVALENCE: Bio waiver granted 2/14/02

METHOD VALIDATION: The drug substance is compendial.
The drug product method validation is
satisfactory 5/21/02

STABILITY: The firm has provided satisfactory 3 months
accelerated stability data at 40°C/75%RH and 12
months room temperature at 25-30°C/Ambient
Humidity for all packaging sizes. The stability
samples were stored horizontal.

LABELING REVIEW STATUS: Labeling is acceptable 3/31/03.

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided the master manufacturing
formula for the commercial production that
reflected the same batch size as the exhibit
batch. Also included a copy of the executed batch
record #E010309 for _____ liters.
The firm will be using the same drug substance
manufacturer, same equipment and same process.

COMMENTS: The application is approvable.

REVIEWER: *N. Nashed*
Nashed E. Nashed, Ph.D.
SUPERVISOR: James M. Fan

DATE: 1/9/03
1/12/03

JM 1/1/03

411103

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 40-458

3. NAME AND ADDRESS OF APPLICANT

Mikart, Inc.
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318

4. LEGAL BASIS FOR SUBMISSION

The listed drug Clistin Elixir (NDA 8-955) held by McNeil. Clistin Elixir is a discontinued drug product withdrawn by McNeil May 6, 1985. There are no un-expired patents or un-expired exclusivity for this product. There are no NDA specification available for review.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Carbinoxamine Maleate

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

9. AMENDMENTS AND OTHER DATES:

Original 11/15/01

10. PHARMACOLOGICAL CATEGORY

Antihistaminic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

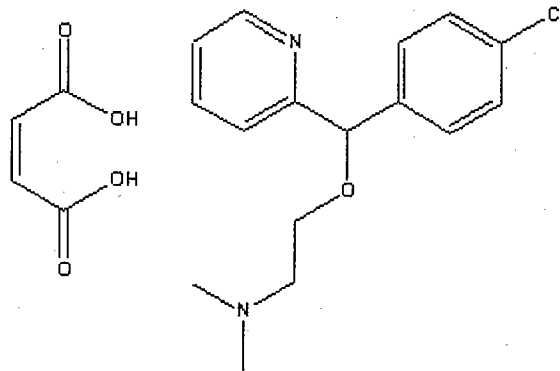
13. DOSAGE FORM

14. POTENCIES

4 mg/5 mL

15. CHEMICAL NAME AND STRUCTURE

Ethanamine, 2-[(4-chlorophenyl)-2-pyi-dinylmethoxy]-N,N-dimethyl-, (Z)-2-butenedioate (1:1)



16. RECORDS AND REPORTS

17. COMMENTS

The firm will be asked to tighten their limits for related substances for the finished drug product based on their observed data.

The firm will be asked to tighten the limits for related substances for stability based on their observed data.

DMF — is deficient.

Please revise your drug substance specifications to include specifications for individual and total impurities.

Please correct footnote on p.86 " — liter tablet batch size".

18. CONCLUSIONS AND RECOMMENDATIONS

The application is deficient.

19. REVIEWER:

Nashed
Nashed E. Nashed, Ph.D.

DATE COMPLETED:

3/6/02
2/20/02

JM Fan
Supervisor: James M. Fan

3/2/02
2/27/02

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1. CHEMISTRY REVIEW NO. 2
2. ANDA # 40-458
3. NAME AND ADDRESS OF APPLICANT

Mikart, Inc.
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318

4. LEGAL BASIS FOR SUBMISSION

The listed drug Clistin Elixir (NDA 8-955) held by McNeil. Clistin Elixir is a discontinued drug product withdrawn by McNeil May 6, 1985. There are no un-expired patents or un-expired exclusivity for this product. There are no NDA specification available for review.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Carbinoxamine Maleate

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

9. AMENDMENTS AND OTHER DATES:

Original 11/15/01
Amendment 10/17/02
Amendment 11/21/02
Telephone Amendment ~~1/8/03~~ 12/4/02

10. PHARMACOLOGICAL CATEGORY

Antihistaminic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

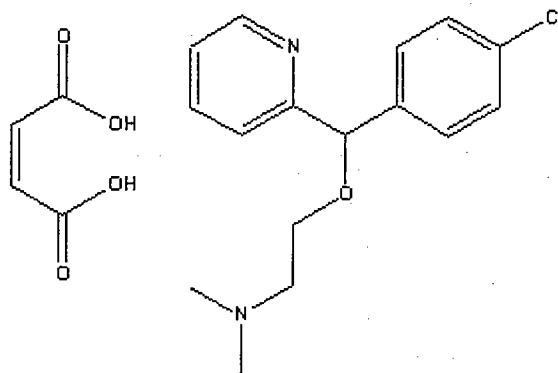
13. DOSAGE FORM

14. POTENCIES

4 mg/5 mL

15. CHEMICAL NAME AND STRUCTURE

Ethanamine, 2-[(4-chlorophenyl)-2-pyridinylmethoxy]-N,N-dimethyl-, (Z)-2-butenedioate (1:1)



16. RECORDS AND REPORTS

17. COMMENTS

None

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

N. Nashed
Nashed E. Nashed, Ph.D.

DATE COMPLETED:

4/1/03
1/9/03

Supervisor: James M. Fan

1/12/03

[Signature]

4/1/03

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