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RESEARCH**

APPLICATION NUMBER:

22-301

CHEMISTRY REVIEW(S)



NDA 22-301

**Apriso (mesalamine)
Extended-Release Capsules, 0.375 g**

Salix Pharmaceuticals, Inc.

Gene W. Holbert, Ph.D.

Division of Gastroenterology Products



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Chemistry Review Data Sheet

1. NDA 22-301
2. REVIEW #: 1
3. REVIEW DATE: 29-AUG-2008
4. REVIEWER: Gene W. Holbert Ph.D.
5. PREVIOUS DOCUMENTS:

Previous DocumentsDocument Date

None

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) ReviewedDocument Date

Original

21-DEC-2007

Amendment (BZ)

25-JUL-2008

Amendment (BC)

25-AUG-2008

Amendment (BC)

01-OCT-2008

7. NAME & ADDRESS OF APPLICANT:

Name: Salix Pharmaceuticals, Inc.
Address: 1700 Perimeter Park Drive
Morrisville, NC 27560

Representative: William P. Forbes, Pharm. D.
Telephone: (919) 862-1818

8. DRUG PRODUCT NAME/CODE/TYPE:

Proprietary Name: Apriso
Non-Proprietary Name (USAN/INN/BAN): Mesalamine
Chemical Abstracts Name: Benzoic acid, 5-amino-2-hydroxy-
Other Names: 5-Aminosalicylic acid (5-ASA)
CAS Registry No: 89-57-6
Code Name/#: NA
Chem. Type/Submission Priority:

- Chem. Type: 3 Submission Priority: S



CHEMISTRY REVIEW



Chemistry Review Data Sheet

9. LEGAL BASIS FOR SUBMISSION: 505 (b)(2)
10. PHARMACOL. CATEGORY: Anti-inflammatory (gastrointestinal)
11. DOSAGE FORM: Capsule, extended release Code: 610

The formulation exhibits both delayed and extended release properties. On the advice of the labeling and nomenclature committee, the dosage form name "capsules, extended release" will be used.

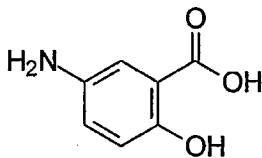
12. STRENGTH/POTENCY: 0.375 g
13. ROUTE OF ADMINISTRATION: Oral Code: 001
14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

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



Molecular Formula: C₇H₇NO₃ Molecular Weight: 153.14

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