

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-977

20-978

CHEMISTRY REVIEW(S)

DIVISION OF ANTIVIRAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

AUG 20 1999

NDA #: 20-977 **CHEMISTRY REVIEW #:** 1 **REVIEW DATE:** 12-4-98

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
CMC Pre-submission	3-27-98	3-30-98	4-13-98
Original	6-24-98	6-24-98	6-29-98
Amendment BC	7-10-98	7-13-98	7-20-98
Amendment BC	8-28-98	8-31-98	9-16-98
Amendment BC	10-30-98	11-2-98	11-2-98
Amendment BC	11-10-98	11-12-98	11-12-98
Amendment BL	11-12-98	11-13-98	11-13-98
Amendment BL	12-3-98	12-4-98	12-4-98

NAME & ADDRESS OF APPLICANT:

Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

DRUG NAME:Proprietary:

ZIAGENTM

Nonproprietary:

Abacavir Sulfate (USAN, BAN, and INN)

Code Name/#:

1592U89 Hemisulfate

CAS Registry Number:

188062-50-2

PHARMACOLOGICAL CATEGORY:

Antiviral

INDICATION:

Anti-HIV

DOSAGE FORM:

Film coated tablets

STRENGTH:

300 mg of abacavir as abacavir sulfate per tablet.

ROUTE OF ADMINISTRATION:

Oral

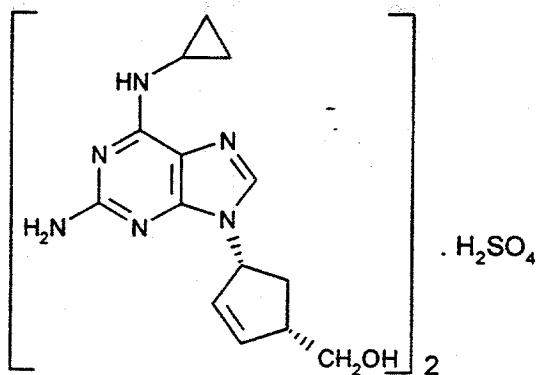
**CHEMICAL NAME, STRUCTURAL FORMULA,
MOLECULAR FORMULA, MOL. WT. :**

Chemical Name:

CAS: (1*S*, *cis*)-4-[2-Amino-6-(cyclopropylamino)-9*H*-
purin-9-yl]-2-cyclopentene-1-methanol sulfate
(salt) (2:1)

IUPAC: [4*R*-(2-Amino-6-cyclopropylamino-purin-9-yl)-
cyclopent-2-en-1*S*-yl]-methanol sulfate (2:1)

Structural Formula:



Molecular Formula:

 $(C_{14}H_{18}N_6O)_2 \cdot H_2SO_4$

Molecular Weight:

670.76

Chirality/Stereochemistry:

abacavir sulfate is a single enantiomer with 1*S*, 4*R* configuration.**SUPPORTING DOCUMENTS:**

DMF No.	Holder	Description	LOA Provid
[Redacted Content]			

CONCLUSIONS & RECOMMENDATIONS:

From the CMC stand point the NDA 20-977 for Ziagen™ (abacavir sulfate) tablets is approved. An expiration dating period of 18 months is recommended for abacavir sulfate tablets that are packaged in bottles of 60 and 180 counts or in unit dose PVC blisters and, stored at controlled room temperature of 20° to 25°C (68° to 77° F) (see USP). In the NDA Action Letter a statement should be included indicating that the analytical methods validation by the FDA District Laboratories is pending.

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Rao V. Kambhampati, Ph.D.
Senior Regulatory Review Scientist

Concurrence:

HFD-530/Chem. TL/SMiller

CONSULT #943

LNC TRADEMARK REVIEW

TO: HFD-530

ATTN:

~~Dan Boring~~

Rao Khambampati

PROPOSED NAME(S): ZIAGEN

ESTABLISHED NAME: abacavir sulfate tablets

COMMITTEE'S COMMENTS:

A review revealed no names which sound like or look like the proposed name.

The Committee has no reason to find the proposed name unacceptable.

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Dan Boring, Ph.D., Chairman
Labeling and Nomenclature Committee