

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-226**

**21-251**

**CHEMISTRY REVIEW(S)**

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

**NDA #:** 21-226

**CHEMISTRY REVIEW #:** 1

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
Pre-submission	31-MAR-00		
Original NDA	31-MAY-00	01-JUN-00	06-JUN-00
BZ	28-JUN-00	29-JUN-00	30-JUN-00
BC	07-SEP-00	08-SEP-00	12-SEP-00
BC	13-SEP-00	14-SEP-00	
NC	14-SEP-00	15-SEP-00	
NC	15-SEP-00	18-SEP-00	

**NAME/ADDRESS OF APPLICANT:** Abbott Laboratories  
D-491/AP6B-1  
100 Abbott Park Road  
Abbott Park, IL 60064-3500

**DRUG PRODUCT NAME:**

Proprietary:

Nonproprietary:

Code Name/#:

KALETRA™  
Lopinavir/Ritonavir  
Abbott-84387, ABT-378

**CHEM. TYPE/THER. CLASS:**

1P

**PHARMACOLOGICAL CATEGORY:**

Antiviral

**INDICATION:**

In Combination with Other Antiretroviral Agents for the Treatment of HIV Infection

**DOSAGE FORM/STRENGTH:**

Soft Gelatin Capsules, 133.3 mg/33.3 mg

**ROUTE OF ADMINISTRATION:**

PO

**Rx/OTC:**

Rx  OTC

**SPECIAL PRODUCT:**

Yes  No

**CHEMICAL NAME / STRUCTURAL FORMULA:**

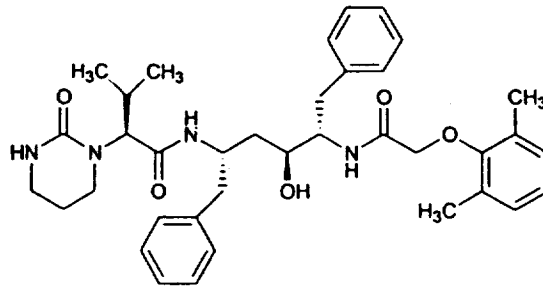
Lopinavir

[1S-[1R\*, (R\*), 3R\*, 4R\*]]-N-[4-[[[(2,6-dimethylphenoxy)acetyl]amino]-3-hydroxy-5-phenyl-1-(phenylmethyl)pentyl]tetrahydro-alpha-(1-methylethyl)-2-oxo-1(2H)-pyrimidineacetamide

CAS Registry Number 192725-17-0

Formula C<sub>37</sub>H<sub>48</sub>N<sub>4</sub>O<sub>5</sub>

M.W. 628.80



### Ritonavir

10-Hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatriodecan-13-oyl acid, 5-thiazolylmethyl ester, [5S-(5R\*, 8R\*, 10R\*, 11R\*)]-

CAS Registry Number

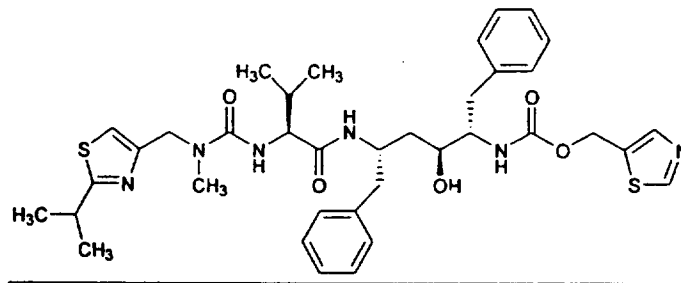
155213-67-5

Formula

C<sub>37</sub>H<sub>48</sub>N<sub>6</sub>O<sub>5</sub>S<sub>2</sub>

M.W.

720.95



### SUPPORTING DOCUMENTS:

