

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-976**

**CHEMISTRY REVIEW(S)**



**NDA #21-976**

**PREZISTA™  
(darunavir)  
Tablets  
300 mg**

**Tibotec, Inc.**

**CMC Review  
Rao V. Kambhampati, Ph.D.  
Senior Regulatory Review Scientist  
ONDQA, DPA II, Branch IV**



# Chemistry Review Data Sheet

1. NDA# 21-976
2. REVIEW #: 1
3. REVIEW DATE: 6/23/2006
4. REVIEWER: Rao V. Kambhampati, Ph.D.
5. PREVIOUS DOCUMENTS: N/A
6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Pre-submission RRZ 002	4/Nov/2005
Original N 000	22/Dec/2005
Amendment N 000 BC	27/Feb/2006
Amendment N 000 BL	1/Jun/2006
Amendment N 000 BC	19/Jun/2006
Amendment N 000	21/Jun/2006
Amendment N 000 BL	22/Jun/2006

7. NAME & ADDRESS OF APPLICANT:

Name:	Tibotec, Inc.
Address:	1020 Stony Hill Road, Ste 300 Yardley, PA 19067
Representative:	Jenny Z. Lin, Pharm. D. Manager, Regulatory Affairs
Telephone:	609-730-7516

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: PREZISTA™
- b) Non-Proprietary Name (USAN): darunavir
- c) Code Name/#: TMC 114, TMC 114 ethanolate, TMC 114 monoethanolate, R319064, JNJ-25875382, darunavir ethanolate.
- d) Chem. Type/Submission Priority (ONDQA only):
  - Chem. Type: 1



# CHEMISTRY REVIEW



## Chemistry Review Data Sheet

- Submission Priority: P

9. LEGAL BASIS FOR SUBMISSION: N/A

10. PHARMACOL CATEGORY: Antiviral (protease inhibitor)

11. DOSAGE FORM: Tablet

12. STRENGTH/POTENCY: 300 mg (each tablet contains darunavir ethanolate equivalent to 300 mg of the free form of darunavir)

13. ROUTE OF ADMINISTRATION: Oral

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:

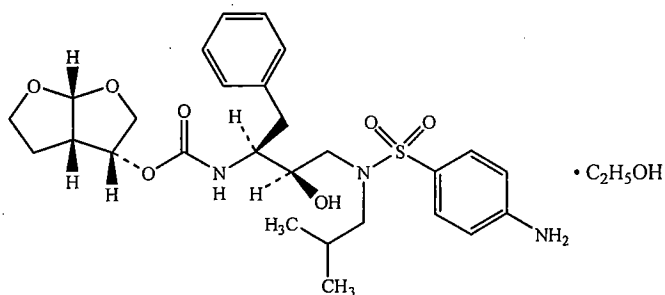
Chemical Name: [(1*S*,2*R*)-3-[[[4-aminophenyl]sulfonyl](2-methylpropyl)amino]-2-hydroxy-1-(phenylmethyl)propyl]-carbamic acid (3*R*,3*aS*,6*aR*)-hexahydrofuro[2,3-*b*]furan-3-yl ester monoethanolate

CAS Reg. No.: N/A (206361-99-1 for free darunavir)

Molecular Formula:  $C_{27}H_{37}N_3O_7S \cdot C_2H_5OH$

Molecular Weight: **██████████**

Structural Formula:





# CHEMISTRY REVIEW



## Chemistry Review Data Sheet

### 17. RELATED/SUPPORTING DOCUMENTS:

#### A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	COMMENTS
				Adequate
				Adequate
				Adequate
				Adequate
				Adequate
				Adequate
				Adequate
				Adequate
				Adequate

#### B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	62,477	TMC 114 (darunavir) Tablets

### 18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
EER	Acceptable	3/29/06	J.D. Ambrogio (HFD-322), DMPQ, OC
Trademark Review	Acceptable	4/7/06	DMETS (HFD-420), ODS
EA	Acceptable (Categorical Exclusion)	6/21/06	Rao Kambhampati, Ph.D.
Biopharm for Dissolution Method including acceptance criteria	Acceptable	6/21/06	Vikram Arya, Ph.D.
Methods Validation	Not necessary	6/21/06	Rao Kambhampati, Ph.D.

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