

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-021

CHEMISTRY REVIEW(S)



NDA 22-021

**Ramipril Tablets
1.25, 2.5, 5, and 10 mg**

Cobalt Pharmaceuticals Inc.

Prafull Shiromani

**Division of Pre-Marketing Assessment 1
Office of New Drug Quality Assessment**



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Chemistry Review Data Sheet

1. NDA 22-021
2. REVIEW #: 1
3. REVIEW DATE: 15-Aug-06
4. REVIEWER: Prafull Shiromani
5. PREVIOUS DOCUMENTS: None (this is the original document)

Previous Documents

Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

NDA 22-021

Document Date

10-Jan-06

7. NAME & ADDRESS OF APPLICANT:

Name: Cobalt Pharmaceuticals Inc.

Address: 6500 Kitimat Road, Mississauga, Ontario, Canada,
L5N 2B8

Representative: James Parker, JD, PhD

Telephone: 978-897-8404

8. DRUG PRODUCT NAME/CODE/TYPE:



CHEMISTRY REVIEW



Chemistry Review Data Sheet

- a) Proprietary Name: N/A
- b) Non-Proprietary Name (USAN): Ramipril
- c) Code Name/# (ONDC only): N/A
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: Type 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505 (b) (2) – Altace Capsules 1.25, 2.5, 5, and 10 mg; Holder: King Pharmaceuticals Inc. – NDA # 19-901

10. PHARMACOL. CATEGORY: Hypertension

11. DOSAGE FORM: Tablet

12. STRENGTH/POTENCY: 1.25, 2.5, 5, and 10 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: Rx OTC

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

SPOTS product – Form Completed

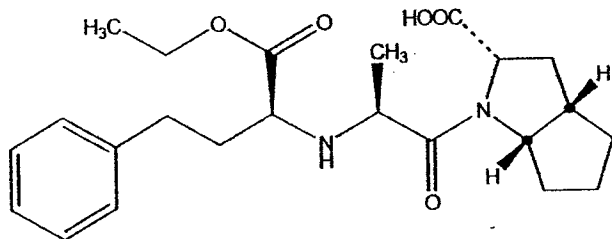
Not a SPOTS product

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

(2S,3aS,6aS)-1-[(S)-N-[(S)-1-carboxy-3-phenylpropyl] alanyl] octahydrocyclopenta [b] pyrrole-2-carboxylic acid, 1-ethyl ester

Chemistry Review Data Sheet

a) Structural Formula:


 b) Molecular Formula: $C_{23}H_{32}N_2O_5$

c) Molecular Mass: 416.5

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
				3	Review (#3) Completed (R. Powers)	6/6/05	Adequate

¹ Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 – Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)



CHEMISTRY REVIEW



Chemistry Review Data Sheet

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A	N/A	None
EES	Pending	8/15/06	
Pharm/Tox	N/A	N/A	None
Biopharm	N/A	N/A	None
LNC	N/A	N/A	None
Methods Validation	Samples not sent to Lab. Since conventional methods	N/A	None
OPDRA	N/A	N/A	None
EA	Acceptable	7/25/05	P. Shiromani
Microbiology	N/A	N/A	None

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§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling

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/s/

Prafull Shiromani
8/21/2006 04:32:31 PM
CHEMIST

Ramesh Sood
8/22/2006 09:56:38 AM
CHEMIST



**NDA 22-021
Second Amendment**

**Ramipril Tablets
1.25, 2.5, 5, and 10 mg**

Cobalt Pharmaceuticals Inc.

Prafull Shiromani Ph.D.

**Division of Pre-Marketing Assessment 1
Office of New Drug Quality Assessment**

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Chemistry Review Data Sheet

1. NDA 22-021-Second Amendment
2. REVIEW #: 2
3. REVIEW DATE: 19-Jan-2007
4. REVIEWER: Prafull Shiromani, Ph.D.
5. PREVIOUS DOCUMENTS: None (this is the original document)

Previous DocumentsDocument Date

NDA 22-021

10-Jan-2006

Review #1

15-Aug-2006

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) ReviewedDocument Date

NDA 22-021 – Second Amendment

17-Nov-2006

Response to Telephone Conference of January 11, 2007

23-JAN-2007

Response to Telephone Conference of January 26, 2007

02-FEB-2007

Response to E-mail request of February 7, 2007 and Response to Telephone Conference of February 8, 2007

13-FEB-2007

Response to Telephone Conference of February 20, 2007

22-FEB-2007

7. NAME & ADDRESS OF APPLICANT:



CHEMISTRY REVIEW



Chemistry Review Data Sheet

Name: Cobalt Pharmaceuticals Inc.

Address: 6500 Kitimat Road, Mississauga, Ontario, Canada,
L5N 2B8

Representative: James Parker, JD, PhD

Telephone: 978-897-8404

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Altace[®] Tablets
- b) Non-Proprietary Name (USAN): Ramipril
- c) Code Name/# (ONDC only): N/A
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: Type 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505 (b) (2) – Altace Capsules 1.25, 2.5, 5, and 10 mg; Holder: King Pharmaceuticals Inc. – NDA # 19-901

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15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):
 SPOTS product – Form Completed

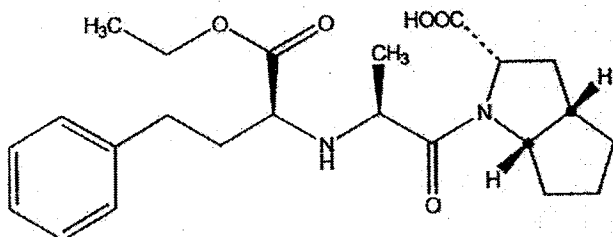
Chemistry Review Data Sheet

X Not a SPOTS product

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

(2S,3aS,6aS)-1-[(S)-N-[(S)-1-carboxy-3-phenylpropyl] alanyl] octahydrocyclopenta [b] pyrrole-2-carboxylic acid, 1-ethyl ester

a) Structural Formula:



b) Molecular Formula: $C_{23}H_{32}N_2O_5$

c) Molecular Mass: 416.5

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A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
_____	II	_____	_____	1	Adequate	15-Feb-2007	

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CHEMISTRY REVIEW

Chemistry Review Data Sheet

- 4 – Sufficient information in application
- 5 – Authority to reference not granted
- 6 – DMF not available
- 7 – Other (explain under "Comments")

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B. Other Documents: N/A

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A	N/A	None
EES	Acceptable	19-Dec-2006	
Pharm/Tox	N/A	N/A	None
Biopharm	Dissolution: Q = _____	01-Jan-2007	Carol Noory
LNC	N/A	N/A	None
Methods Validation	Samples not sent to Lab. Since conventional methods	N/A	None
OPDRA	N/A	N/A	None
EA	Acceptable-No change from original NDA and so not submitted with this amendment	7/25/05 (original)	Prafull Shiromani
Microbiology	N/A	N/A	None

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§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling

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/s/

Prafull Shiromani
2/22/2007 03:00:48 PM
CHEMIST

Ramesh Sood
2/22/2007 03:23:26 PM
CHEMIST