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*APPLICATION NUMBER:*

**205552Orig2s000**

**CHEMISTRY REVIEW(S)**

**NDA 205-552****Imbruvica (ibrutinib) capsules, 140 mg****Pharmacyclics, Inc.****Xiao-Hong Chen, Ph.D.  
Donghao (Robert) Lu, Ph.D.****Office of New Drug Quality Assessment  
Division of New Drug Quality Assessment I****CMC Review of NDA 205-552****For the Division of Oncology Drug Products I (HFD-150)**

# Table of Contents

<b>Table of Contents .....</b>	<b>2</b>
<b>Chemistry Review Data Sheet.....</b>	<b>3</b>
<b>The Executive Summary .....</b>	<b>7</b>
<b>I. Recommendations .....</b>	<b>7</b>
<b>A. Recommendation and Conclusion on Approvability.....</b>	<b>7</b>
<b>B. Recommendation on Post Marketing Requirements, Post Marketing Commitments, Agreements, and/or Risk Management Steps, if Approvable.....</b>	<b>7</b>
<b>II. Summary of Chemistry Assessments .....</b>	<b>7</b>
<b>A. Description of the Drug Product(s) and Drug Substance(s) .....</b>	<b>7</b>
<b>B. Description of How the Drug Product is Intended to be Used .....</b>	<b>9</b>
<b>C. Basis for Approvability Recommendation.....</b>	<b>9</b>
<b>III. Administrative .....</b>	<b>9</b>
<b>A. Reviewer's Signature .....</b>	<b>9</b>
<b>B. Endorsement Block .....</b>	<b>9</b>
<b>C. CC Block.....</b>	<b>9</b>
<b>Chemistry Assessment .....</b>	<b>10</b>
<b>Appendix.....</b>	<b>11</b>

# Chemistry Review Data Sheet

1. NDA 205-552
2. REVIEW #2:
3. REVIEW DATE: 17-OCT-2013
4. REVIEWER: Donghao (Robert) Lu, Ph.D. (Drug substance)  
Xiao-Hong Chen, Ph.D. (Drug product)
5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Document Date

Original NDA submission	28-Jun-2013
Amendment SN0018	09-Aug-2013
Amendment SN0021	13-Aug-2013
Amendment SN0027	23-Aug-2013
Amendment SN0029	29-Aug-2013

7. NAME & ADDRESS OF APPLICANT:

NAME:

Pharmacyclics, Inc.

ADDRESS:

995 East Arques Avenue,  
Sunnyvale, CA 94085

REPRESENTATIVE:

Christine Salido, Exec. Director,  
Regulatory Affairs

TELEPHONE:

(408) 215-3476

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Imbruvica®
- b) Non-Proprietary Name (USAN): ibrutinib

- c) Code Name/# PCI-32765, JNJ 54179060  
 d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: 1
  - Submission Priority: P

9. LEGAL BASIS FOR SUBMISSION: Filed 505(b)(1)

10. PHARMACOL. CATEGORY: A potent small-molecule covalent inhibitor of Bruton's tyrosine kinase

11. DOSAGE FORM: Capsule

12. STRENGTH/POTENCY: 140 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED:  Rx  OTC

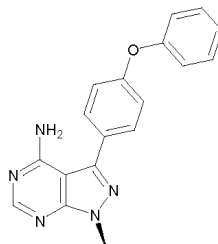
**15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):**

SPOTS product – Form Completed

Not a SPOTS product

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

Name (USAN, INN): Ibrutinib  
 Name (CAS): 1-{(3R)-3-[4-amino-3-(4-phenoxyphenyl)-1Hpyrazolo[3,4-d]pyrimidin-1-yl]piperidin-1-yl}prop-2-en-1-one  
 Other Name: 1-[(3R)-3-[4-amino-3-(4-phenoxyphenyl)-1Hpyrazolo[3,4-d]pyrimidin-1-yl]-1-piperidinyl]-2-propen-1-one  
 (CAS) Registry Num: 936563-96-1  
 Mol. Formula: C<sub>25</sub>H<sub>24</sub>N<sub>6</sub>O<sub>2</sub>  
 Mol. Wt.: 440.50  
 Structural Formula:



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