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RESEARCH**

APPLICATION NUMBER:

21-450

CHEMISTRY REVIEW(S)

NDA 21-450

Zomig® (zolmitriptan) Nasal Spray

**AstraZeneca Pharmaceuticals LP as U.S. agent for:
IPR Pharmaceuticals**

**Martha R. Heimann, Ph.D.
Division of Neuropharmacological Drug Products**

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Chemistry Review Data Sheet

1. **NDA #:** 21-450
2. **REVIEW #:** 1
3. **REVIEW DATE:** 09-DEC-2002
4. **REVIEWER:** Martha R. Heimann, Ph.D.
5. **PREVIOUS DOCUMENTS:**(This is review #1.)
6. **SUBMISSION(S) BEING REVIEWED:**

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original NDA	06-MAR-2002
CMC Update	27-JUN-2002
Revised Package Insert	22-NOV-2002

7. **NAME and ADDRESS OF APPLICANT:**

Name: IPR Pharmaceuticals, Inc
Address: P.O. Box 1967
Carolina, PR 00984-1967
Representative: Kevin McKenna, Executive Director-Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike, P.O. Box 8355
Telephone: (302)886-2742

8. **DRUG PRODUCT NAME/CODE/TYPE:**

- a) Proprietary Name: Zomig®
- b) Non-Proprietary Name (USAN): zolmitriptan
- c) Code Name/#: 311C90
- d) Chem. Type/Submission Priority:
 - Chem. Type: 3
 - Submission Priority: S

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