2. SYNOPSIS

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<th>Name of Sponsor/Company</th>
<th>Individual Study Table Referring to Part of the Dossier</th>
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<td>McNeil Consumer Products Company</td>
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Name of Finished Product:

Name of Active Ingredient: ibuprofen, aspirin, caffeine

Title of Study: A double-blind single dose evaluation of the comparative analgesic efficacy of aspirin 800 mg/caffeine 64 mg, ibuprofen 400 mg, and placebo in the treatment of post-operative pain following third molar extraction. Stat Rpt 87. Protocol 7-713B, Unpublished Report 212.

Investigators:

Study Centers:

Publication (reference):

Study Period: Date of first enrollment: Date of last completed:

Phase of Development:

Objective:

Methodology: Randomized, Double Blind, Placebo-Controlled, Parallel, Single Investigator

Number of Subjects (planned and analyzed): 124 subjects were included in the efficacy analysis and 124 subjects were included in the safety analysis. Of the 124 subjects, 41 were treated with ibuprofen, 41 with aspirin + caffeine, and 42 with placebo.

Diagnosis and Main Criteria for Inclusion: Subjects ≥ 16 y with at least moderate pain following third molar extraction.
**Name of Sponsor/Company:** McNeil Consumer Products Company  

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### Test Product, Dose and Mode of Administration, Batch Number:  

- Ibuprofen 400 mg, capsule oral  
- Aspirin 800 mg + caffeine 64 mg, capsule oral  

### Duration of Treatment:  
This was a single-dose study.  

### Reference Therapy, Dose and Mode of Administration, Batch Number:  

- Placebo, capsule oral  

### Criteria for Evaluation:  

**Efficacy:**  

**Safety:**  

**Statistical Methods:**  

### SUMMARY - CONCLUSIONS  

**Efficacy Results:** Overall, there were 61 females and 63 males. The mean age of the subjects treated with ibuprofen was 25.7 years. There were 21 females and 20 males. The mean age of subjects treated with aspirin + caffeine was 25.0 years. There were 19 females and 22 males. The mean age of subjects treated with placebo was 23.9 years. There were 21 females and 21 males.  

All values are presented as least squares means.  

- 4 h SPID (sum of the pain intensity differences from baseline, 4-point categorical scale): IBU-4.5, ASA+caffeine-2.5, Pbo-0.8.  
- 4 h TOTPAR (total pain relief scores, 5-point categorical scale): IBU-8.8, ASA+caffeine-5.9, Pbo-3.3.  
- MAXPID (maximum pain intensity difference, 4-point categorical scale): IBU-1.6, ASA+caffeine-1.0, Pbo-0.6.  
- MAXPAR (maximum pain relief, 5-point categorical scale): IBU-3.0, ASA+caffeine-2.2, Pbo-1.4.  

Hours (the number of hours in
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which initial pain was at least one-half relieved): IBU-2.3, ASA+caffeine-1.6, Pbo-0.6. Subject’s overall evaluation (5-point categorical scale): IBU-2.4, ASA+caffeine-1.5, Pbo-0.7. For above summary measures, IBU vs Pbo, p<0.0036. ASA+caffeine vs Pbo, p=0.0451 for Hours only. IBU was better than ASA+caffeine, p=0.0373. Number of subjects remedicating over 4 h: IBU-8, ASA+caffeine-14, Pbo-22, p=0.007.

**Safety Results:** Number of subjects with AEs: IBU-5 (asthenia, dizziness, nausea, stomach pain, somnolence); ASA+caffeine-6 (dizziness, dyspepsia, headache, nausea, somnolence); Pbo-4 (asthenia, headache, nausea, somnolence); p=NS.

**Conclusions:** Conclusions were not provided in the clinical study report.

**Date of the Report:** February 1988