# 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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<td>Name of Finished Product:</td>
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<td>Name of Active Ingredient:</td>
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| ibuprofen, aspirin, caffeine | |

**Title of Study:** A double-blind single dose evaluation of the comparative analgesic efficacy of aspirin 1000 mg/caffeine 64 mg, ibuprofen 400 mg, and placebo in the treatment of post-operative pain following third molar extraction. Stat Rpt 81.  Protocol 7-714B, Unpublished Report 206.

**Investigators:**

**Study Centers:**

**Publication (reference):**

**Study Period:**  
*Phase of Development:*

**Date of first enrollment:**

**Date of last completed:**

**Objective:**

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

**Number of Subjects (planned and analyzed):** 123 subjects were included in the efficacy analysis and 125 subjects were included in the safety analysis. In the ibuprofen group, 41 subjects were included in the efficacy analysis and 42 subjects were included in the safety analysis. In the aspirin + caffeine group, 41 subjects were included in the efficacy analysis and 42 subjects were included in the safety analysis. In the placebo group, 41 subjects were included in both the efficacy and safety analyses.
**Name of Sponsor/Company**  
McNeil Consumer Products Company

**Name of Finished Product:**  
Volume:

**Name of Active Ingredient:**  
ibuprofen, aspirin, caffeine

**Diagnosis and Main Criteria for Inclusion:**  
Subjects ≥ 16 y with at least moderate pain following third molar extraction.

**Test Product, Dose and Mode of Administration, Batch Number:**
- Ibuprofen 400 mg, capsule oral
- Aspirin 1000 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 65 females and 58 males. The mean age of subjects treated with ibuprofen was 25.2 years. There were 21 females and 20 males. The mean age of subjects treated with aspirin + caffeine was 25.5 years. There were 25 females and 16 males. The mean age of subjects treated with placebo was 24.0 years. There were 19 females and 22 males.

Values are presented as least squares means. 4 h SPID (sum of the pain intensity differences from baseline, 10 cm VAS): IBU-9.1, ASA+caffeine-5.3, Pbo--2.9. 4 h TOTPAR (total pain relief scores, 10 cm VAS): IBU-23.2, ASA+caffeine-18.7, Pbo-7.2.
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MAXPID (maximum pain intensity difference): IBU-3.4, ASA+caffeine-2.8, Pbo-0.5. MAXPAR (maximum pain relief): IBU-7.9, ASA+caffeine-6.7, Pbo-3.0. Hours (the number of hours in which initial pain was at least one-half relieved): IBU-2.7, ASA+caffeine-2.1, Pbo-0.7. Subject’s overall evaluation (5-point categorical scale): IBU-2.6, ASA+caffeine-2.0, Pbo-0.8. For all of the above summary measures, IBU or ASA+caffeine vs Pbo, \( p=0.0001 \). SPID and overall: IBU vs ASA+caffeine, \( p<0.0432 \). Number of subjects remedicating over 4 h: IBU-5, ASA+caffeine-10, Pbo-23; IBU or ASA+caffeine vs Pbo, \( p \leq 0.05 \); IBU vs ASA+caffeine, \( p=\text{NS} \).

**Safety Results:** Number of subjects reporting AEs: IBU-5, ASA+caffeine-5, Pbo-2; \( p=\text{NS} \). Reported AEs included asthenia (ASA+caffeine-1), dizziness (ASA+caffeine-2), nausea (IBU-1, ASA+caffeine-2, Pbo-2), somnolence (IBU-3), and syncope (IBU-1). The episode of fainting (syncope) was considered remotely related to the study medication since the subject had frequently fainted in the past. The episode lasted about two seconds.

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

**Date of the Report:** October 1987