2. **SYNOPSIS**

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<tr>
<th><strong>Name of Sponsor/Company</strong></th>
<th>McNeil Consumer Products Company</th>
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<tbody>
<tr>
<td><strong>Name of Finished Product:</strong></td>
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<tr>
<td><strong>Name of Active Ingredient:</strong></td>
<td>acetaminophen, aspirin</td>
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<th><strong>Individual Study Table Referring to Part of the Dossier</strong></th>
<th><strong>Volume:</strong></th>
<th><strong>Page:</strong></th>
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**Investigators:**

**Study Centers:**

**Publication (reference):**

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

**Phase of Development:**

**Objective:**

**Methodology:** Double Blind, Placebo-Controlled, Multicenter, Parallel

**Number of Subjects (planned and analyzed):** 74 subjects were included in the efficacy analysis and 74 subjects were included in the safety analysis. Of the 74 subjects, 23 subjects were treated with acetaminophen, 25 subjects were treated with aspirin, and 26 subjects were treated with placebo.

**Diagnosis and Main Criteria for Inclusion:** Children with a rectal temperature $\geq 102^\circ\text{F}$. 
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acetaminophen, aspirin

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Test Product, Dose and Mode of Administration, Batch Number:
- Acetaminophen (5 m - < 2 y: 80 mg, 2 y - < 4 y: 160 mg), liquid oral
- Aspirin (5 m - < 2 y: 80 mg, 2 y - < 4 y: 160 mg), tablet (chewable), oral

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

Reference Therapy, Dose and Mode of Administration, Batch Number:
- Placebo, oral

Criteria for Evaluation:

Efficacy:

Safety:

Statistical Methods:

SUMMARY - CONCLUSIONS

Efficacy Results: The age range of the subjects was 5 months to 4 years. The mean age of subjects treated with acetaminophen was 17.3 months. There were 39.13% females and 60.87% males. The mean age of subjects treated with aspirin was 19.8 months. There were 40% females and 60% males. The mean age of subjects treated with placebo was 18.42 months. There were 61.54% females and 38.46% males.

Mean 6 h SUMDIFF (sum of the differences from baseline in temperature): APAP - 7.51, ASA - 10.26, Pbo - 3.31; APAP or ASA vs Pbo, p < 0.05; APAP vs ASA, p=NS. Mean MAXDIFF (maximum difference from baseline in temperature): APAP - 2.64, ASA - 3.10, Pbo - 1.38; APAP or ASA vs Pbo, p < 0.05; APAP vs ASA, p=NS. Percent of subjects receiving supplemental measures: APAP - 30%, ASA - 24%, Pbo - 62%, p=NS.
### Individual Study Table

**Referring to Part of the Dossier**

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| Name of Active Ingredient: | acetaminophen, aspirin | | |

**Safety Results:** There were no AEs. Over the 6-h study, the ASA group had significant differences (decreases from baseline) in pulse rate, $p=0.0069$; the APAP group had borderline significant differences (decreases from baseline) in mean pulse rate, $p=0.0526$. These differences were not considered to be medically important. None of the groups had statistically significant differences in respiratory rate over time, $p=NS$.

**Conclusions:** Acetaminophen and aspirin were both significantly superior to placebo for all parameters, but were not significantly different from each other.

**Date of the Report:** August 1982