





**Study BN002 0305**

**Study Type:** Pivotal bioequivalence – post menopausal women with confirmed osteoporosis.

**Active:** Capsitonin™ oral calcitonin - final dosage form; GMP manufactured.

**Active Comparator:** Nasal calcitonin (200 I.U. per 0.09 ml activation)

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**Number of Patients:** **Days Treatment:** 7 – 14 Days  
The trial will be powered to determine equivalence between nasal and oral calcitonin. Initial powering indicates approx. 60 – 100.

**Study Location:** Two to three academic centres (Australia & USA or EU)

**Primary Endpoint:** ±20% equivalence bound of the mean reduction in serum C-telopeptide levels compared to nasal calcitonin (90% confidence interval).

**Secondary Endpoints:** Blood calcitonin levels, serum calcium levels, safety and tolerability.

**Outcome:** To demonstrate bioequivalence with nasal calcitonin.

**Timescale:**

Set-up	Q2-2005
Start	Q3-2005
Completion	Q4-2005
Report	Q4-2005