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Title: **Gabapentin extended release tablets in healthy subjects under fed conditions: A randomized, open-label, two-treatment, two-period, two-sequence, single dose, crossover, comparative bioavailability study**

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Supplementary Information 1: Inclusion/Exclusion Criteria

Inclusion Criteria

1. Adult human male in the age range of 18-50 years.
2. Provided voluntarily signed written informed consent to participate in this study.
3. Were determined to be healthy based on a medical history and physical examination conducted within 28 days prior to the commencement of the study.
4. Had clinically acceptable results for all the screening parameters and laboratory investigations.
5. Had non-vegetarian diet habit.
6. Had body mass index (BMI) ≥18.50 and < 30.00 kg/m^2
7. Had hemoglobin level ≥12.0 g/dL (Deciliter).

Exclusion Criteria

1. The subject had a history of hypersensitivity to Gabapentin or other related drugs.
2. The subject had a chronic history of dizziness.
3. Subject with a history of depression, suicide attempts, suicidal ideation, and psychosis.
4. The subject had a history of seizures.
5. Subject had a history of drug-induced rash and/or pruritus.
6. The subject had any evidence of organ dysfunction or any clinically significant abnormality as determined from physical or clinical examinations.
7. Subject had a history of serious medical illnesses including but not limited to gastrointestinal, hepatic, renal, cardiovascular, pulmonary, neurological or haematological disease, etc., systemic diseases including but not limited to diabetes, hypertension, sarcoidosis, rheumatic diseases & thyroid abnormalities, diseases like immunosuppression, glaucoma and/ or any serious, potentially life-threatening illness.
8. Subject had inability to communicate well (i.e. language problem, poor mental development, psychiatric illness or poor cerebral function) that might impair the ability to provide, written informed consent.
9. Subject was a regular smoker, who smoked more than 10 cigarettes daily or had difficulty abstaining from smoking for the duration of the study period.

10. The subject had a history of drug dependence or excessive alcohol intake on a habitual basis or had difficulty in abstaining or was found positive in urine alcohol test before admission.
11. Subject had used any medication within 30 days prior to admission to this study.
12. Subject had donated blood (1 unit or 350 mL) or received an investigational medicinal product within 90 days prior to receiving the first dose of the study drug. The elimination of half-life of the study drug was taken into consideration for his inclusion in the study.

Note: If a subject had participated in a study at CPU New Delhi in which blood loss was ≤ 200 mL, a subject could be dosed 60 days after the last pharmacokinetic sample of the previous study.

13. Subject had consumed alcohol 48 hours before admission.
14. The subject had consumed grapefruit juice and/or grapefruit supplements containing products 48 hours before admission.

Supplementary Information 2: Subject Screening Procedure for Other Tests

Table 1: List of other tests performed during the subject screening procedure

Haematology	Biochemistry	Urinalysis	Serology
• Haemoglobin • Total leukocyte count • Differential leukocyte count • Platelet count	• BUN (Blood Urea Nitrogen) • Creatinine • Total Bilirubin • ALP (Alkaline Phosphatase) • AST (Aspartate aminotransferase) • ALT (Alanine aminotransferase) • Glucose • Cholesterol	• Routine Examination - Colour - Appearance - pH - Specific gravity - Protein - Glucose • Microscopic Examination - RBC (Red Blood Corpuscles) - WBC (White Blood Corpuscles) - Epithelial Cells - Crystals - Casts - Others	- HIV I & II - HBsAg (Hepatitis B Surface Antigen) - HCV (Hepatitis C Virus) - RPR (Rapid Plasma Reagin) **Others** • ECG