

## Sedative, anxiolytic and analgesic effects of the ethanolic extract of *Leea indica* (Burm. f.) Merr. leaf

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The analgesic potential of *Leea indica* (Burm. f.) Merr., a Bangladeshi tribal medicinal plant was studied for the first time. The crude ethanol extract of *Leea indica* (Burm. f.) Merr. leaves was evaluated for its central nervous system (CNS) depressant effect using rodent behavioral models, such as hole cross, open field and thiopental sodium induced sleeping time tests for its sedative properties and an elevated plus-maze (EPM) test for its anxiolytic potential, respectively. The ethanol extract of *L. indica* at doses of 200 mg/kg, p. o., displayed a dose-dependent suppression of motor activity, exploratory behavior (in hole cross and open field tests) and prolongation of thiopental induced sleeping time in mice. In the EPM test, the dose of ethanol extract significantly ( $p < 0.05$ ) increased exploration to and time spent by the treated mice in EPM open arms in a dose dependent manner. In addition, analgesic potential of *L. indica* was evaluated for centrally acting analgesic property using formalin induced licking response model and peripheral pharmacological actions using acetic acid-induced writhing test. In acetic acid-induced writhing test, all extracts at 200 mg/kg dose exhibited significant ( $p < 0.05$ ) reduction of writhing response in a dose dependent manner; in formalin induced licking response model a significant ( $p < 0.05 - 0.001$ ) result was comparable to the standard drug diclofenac sodium. These results provide in vivo evidence that leaves of *L. indica* in general have significant sedative and analgesic effects.

**Keywords:** Neuropharmacology, open field, elevated plus-maze (EPM), medicinal plant, *L. indica*, analgesic.

### Biography

Mr. Talha Bin Emran has been working as a Lecturer, in the Department of Pharmacy, BGC Trust University, Bangladesh from January 2012 to till the date. Mr. Emran has published more than 20 research and review papers in reputed International and national Journal. He participated in many seminars and conferences in home to present his research activities. His research work based on Phytochemistry, Pharmacology, Molecular biology, Oncology and Bioinformatics. He is a fellow of Academy of General Education, India (FAGE) and a fellow of Ministry of Science, Information & Communication Technology (MOSICT) in the Session 2011-2012 for MS Thesis. He is a life member in Graduate Biochemist Association (GBA) and also a life member of Association of Pharmacy Professionals (APP), India. He is interested in Clinical Research, Protein Engineering, Immunology and Molecular Medicine.

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## QbR - Aims to assure product quality through design

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QbR is a new quality assessment system that focuses on critical pharmaceutical quality attributes. It is transforming the ANDA CMC review into a modern, science- and risk-based pharmaceutical quality assessment system. QbR contains the important scientific and regulatory review questions to Comprehensively assess critical formulation and manufacturing process variables, to Set regulatory specifications relevant to quality, to determine the level of risk associated with the manufacture and to design the product. QbR helps in building Quality by design, development and manufacture which is eventually confirmed by testing. By following QbR time, effort, and resources for developing the product can be minimized. The main objective of this review article is to put forth the aspect of the Question based review by incorporating design to obtain approvals assuring product quality through design and performance -based specification eventually reduces the review time. The QbR identifies and incorporates the best practices of the current CMC review system and makes these practices common for the entire FDA OGD. As such, the new QbR questions will provide a standardized method of delivering a comprehensive CMC review. Many of the questions require critical analysis by reviewers and will encourage reviewers to link deficiencies sent to the applicant to scientifically justified quality concerns. QbR ensures that FDA quality reviewers are asking the right questions at the right time and in the most efficient manner. The QbR also provides for an efficient review of low-risk products and an in-depth review of complex dosage forms. The formalized QbR questions transparently expose the logic used in drug product quality assessment. Such transparency should result in more first-cycle approvals and minimize the inefficient and time-consuming process associated with multiple-cycle approvals.

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