1. **Title of research project:** Studies on stability aspects of herbals of medicinal interest
2. **Name of PI:** Mr. Sandeep S. Pathare
3. **Funding Agency:** University Grants Commission
4. **Project Reference number/ File number:** 47-1522/10 (WRO) Dated 28/09/2010
5. **Executive summary of the project along with output:**

SUMMARY

Project has been completed successfully and summary of findings are as follows:

1. *Andrographis paniculata* (Family: Acanthaceae) is a plant that has been effectively used in traditional Asian medicines for centuries. It's perceived "blood purifying" property results in its use in diseases where bloods "abnor -malities" are considered causes of disease, such as skin eruptions, boils, scabies, and chronic undetermined fevers.
2. Gastrointestinal stability of Andrographolide was evaluated in vitro in simulated gastric (SGF) and intestinal (SIF) fluids using a validated HPLC-PDA method or by using analytical techniques.
3. The method was validated using a 5µm Thermo Hypersil GOLD C18column (250 mm × 4.0 mm) and mobile phase consisting of water: acetonitrile; 70: 30 (v/v) delivered isocratically at a flow rate of 1 mL/min with UV detection at 228 nm.
4. Andrographolide in pure form and in extract *Andrographis paniculata* was incubated at 37°C in an incubator shaker in USP simulated gastric and intestinal fluids with and without enzymes.
5. The gastric stability study samples were assayed at 0, 15, 30 and 60 min intervals while sampling for the intestinal stability study was at 0, 15, 30, 60 min 1, 2 and 3 h as FDA Guidance System. Also the stability study was performed upto 24 h to see the degradation pattern in SGF and SIF (with enzyme and without enzyme).
6. The method was shown to be accurate, precise, specific and linear over the analytical range. Andrographolide was stable in SGF (pH~1.2) for the 1-h incubation period and in SIF (pH 6.8) up to 3 h with <3% relative difference (RD) between the amount of drug added and that found for all time points.
7. This stability experiment in simulated gastric and intestinal fluids suggests that drug loss in the gastrointestinal tract takes place by membrane permeation rather than a degradation process.

8. It has been concluded from this study that Significant degradation (>5%) of a drug evaluated in the manner presented in this study could indicate potential drug instability in the gastrointestinal tract. Andrographolide was stable in SGF (pH 1.2) for the 1-h incubation period and in SIF (pH 6.8) up to 3 h with < 3% degradation either as pure drug or in extract of *Andrographis paniculata*. Based upon these results, Andrographolide is considered stable in SGF (1 h) and SIF (3 h) at 37° C in accordance with FDA/CDER's BCS Guidance. This study also suggests that Andrographolide would be stable in the gastrointestinal tract and that drug loss may take place by membrane permeation rather than a gastrointestinal degradation process.

Publication:

One research paper communicated for publication in international journal.

Presentation:

'Determination of *In-vitro* gastrointestinal stability of pure Andrographolide and *Andrographis paniculata* extract by validated HPLC method and accelerated stability of extract and its polyherbal formulation'. Research Paper Presented at National Conference at 64th Indian Pharmaceutical Congress (IPC), hosted by the Association of Pharmaceutical Teachers of India (APTI) at Chennai. India on 7th - 9th December 2012.