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Chemical Stability of Sublingual Glyceryl Trinitrate Tablets in Outpatient Settings

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Background: Sublingual Glyceryl Trinitrate (GTN) tablets are essential in managing angina. However, their chemical stability can be compromised by evaporation of the active pharmaceutical ingredient (API), especially when patients do not follow appropriate handling and storage practices.

Objective: To compare the chemical stability of sublingual GTN tablets issued at Teaching Hospital Jaffna (THJ), and after one month outpatient use

Methods: A descriptive cross-sectional study was conducted among 50 patients receiving GTN at the Cardiology Clinic, THJ. Patients were randomly selected from the three dispensing counters in the Pharmacy in which first set of medication sample (three tablets from each counter) was collected. The second set of samples were collected from the selected outpatients, who received GTN from respective counters during home visits after one month of typical outpatient use. Chemical stability was assessed by determining the amount of API using a UV-visible spectrophotometer at a wavelength of 260 nm based on the BP. The statistical significance of the difference in API levels of the samples obtained from counters and patients were evaluated by a paired sample *t*-test at 5% significance level using the software SPSS version 23.0.

Results: The initial mean±SD API content in tablets from counters 1, 2, and 3 was 0.4116±0.0884 mg, 0.4067± 0.0933 mg, and 0.3824±0.1176 mg, respectively, which were below the pharmacopeial limit of 90% (0.45 mg). After four weeks of outpatient use, the mean±SD API levels in patient samples further declined to 0.1797±0.0883 mg, 0.1424±0.0980 mg, and 0.2086±0.0744 mg for counters 1, 2, and 3, respectively. A significant difference ($p<0.05$) was observed between the API levels in the counter and the patients' sample and significantly deviating from the pharmacopeial standards.

Conclusions: The study demonstrates that the API levels of sublingual GTN tablets were already below pharmacopeial limits at the point of dispensing and further declined significantly after four weeks of outpatient storage. Further investigation is required to assess the patients' practices related to handling and storage of GTN tablets.

Keywords: *Active pharmaceutical ingredient, Chemical stability, Glyceryl trinitrate*