



## Physicochemical and Microbiological Stabilities of a Sweetened and Calorie-Free Metformin Extemporaneous Formulation for Pediatrics

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**SUMMARY.** A liquid extemporaneous metformin formulation from Glucophage® tablets was prepared in drinking water sweetened with 10 % Splenda®, then stored for 30 days at 25 °C exposed to and protected from light, at 4 and 40 °C. Physicochemical integrity was determined by UPLC-UV using a VARIAN Pursuit C8 column 150 x 3.9 mm at 40 °C, with detection at 236 nm. Mobile phase was 0.1M KH<sub>2</sub>PO<sub>4</sub> (pH = 6.5) : 4.6 mM SDS : acetonitrile (63:7:30 v/v) eluted at 0.8 mL/min. Microbial colony forming units per milliliter (CFU/mL) were determined in soy agar trypticasein (SAT), McConkey agar, and Sabouraud media at 37 and 29 °C for 72 and 96 h. The solution retained over 90 % of the initial amount of metformin, showing zero-growth of enteric or aerobic mesophilic bacteria and was able to restore normal glucose levels in chronically hyperglycemic Wistar rats. This metformin formulation may be helpful managing insulin resistance in pediatric endocrinology.

**KEY WORDS:** Extemporaneous formulation, Individualized dose, Insulin resistance, Metformin, Microbial stability, Physicochemical integrity.

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