



Estimation of Acetaminophen and Ibuprofen in Tablets by a Derivative UV Method: Characterization of *In Vitro* Release Using USP Apparatuses 2 and 4

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SUMMARY. The aim of this work was to develop and validate a derivative UV method for estimation of acetaminophen and ibuprofen in fixed-dose combination formulations and to demonstrate its application in dissolution studies. Studies were carried out in an USP paddle apparatus at 75 rpm and 900 mL of 0.1 M phosphate buffer pH 7.4. Flow-through cell method with laminar flow at 16 mL/min was used. Samples were taken at 5, 10, 20, 30, 45, and 60 min. The reference and a generic formulation were tested (325/200 mg). Dissolution profiles were compared by model-independent and dependent approaches. The UV method was linear ($R^2 > 0.99$), accurate ($100 \pm 3\%$) and precise (RSD $< 2.14\%$). Dissolution profiles between generic and reference formulations were similar ($f_2 > 50$) however, significant differences in MDT, DE, $t_{50\%}$, $t_{63.2\%}$ and Td values were found ($p < 0.05$).

RESUMEN. El objetivo de este trabajo fue desarrollar y validar un método UV derivativo para estimar paracetamol e ibuprofeno en formulaciones combinadas de dosis fija y demostrar su aplicación en estudios de disolución. Los estudios se llevaron a cabo en el Aparato USP de paletas a 75 rpm y 900 mL de solución amortiguadora de fosfato 0.1 M pH 7.4. En el Aparato 4 USP se utilizó flujo laminar a 16 mL/min. Se tomaron muestras a los 5, 10, 20, 30, 45 y 60 min. Se evaluó la formulación de referencia y una genérica (325/200 mg). Los perfiles se compararon con métodos modelo-independiente y dependiente. El método UV fue lineal ($R^2 > 0.99$), exacto ($100 \pm 3\%$) y preciso (RSD $< 2.14\%$). Los perfiles entre genérico y referencia fueron similares ($f_2 > 50$) sin embargo, se encontraron diferencias significativas en los valores de TMD, ED, $t_{50\%}$, $t_{63.2\%}$ y Td ($p < 0.05$).

KEY WORDS: acetaminophen, derivative spectroscopy, fixed-dose combination formulations, flow-through cell method, ibuprofen, USP paddle apparatus.

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