



## Development and Sedative Effect of a New Formulation of Midazolam in Chocolate Bars

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**SUMMARY.** The aim of this work was to assess the stability and sedative effect of midazolam in chocolate bars. The stability of 5 g chocolate bars containing 6 mg midazolam hydrochloride was evaluated at room temperature ( $25 \pm 2$  °C), at 4 and 40 °C, by HPLC. Drug plasma levels were measured and the sedative effect was confirmed in six healthy volunteers according to the Ramsay's scale. Data regarding chocolate bar administration were compared to those from the apple juice solution. Pharmacokinetic data were processed using the WinNonLin 5.2 software. Midazolam in chocolate bars remained stable for 14 days at room temperature and exposed to light; for 90 days at 4 and 40 °C protected from light, and showed a longer shelf life, better flavour and appearance, inducing the same sedative effect as the apple juice preparation. Raspberry flavour masked midazolam displeasing taste most favourably.

**KEY WORDS:** Chocolate, Extemporaneous formulation, Midazolam, Stability, sedation.

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