



Analytical Method Validation for *In Vitro* Permeation of *Calendula officinalis* L. Gel

Kariane M. NUNES ¹, Elanne S. BANDEIRA ², Eliana F. OZELA ¹,
Wagner L.R. BARBOSA ³, Roseane M. RIBEIRO-COSTA ², José O.C. SILVA JÚNIOR ^{1*}

¹ *Laboratory of Pharmacotechnical Research and Development, College of Pharmacy,
Federal University of Pará, PA, Brazil*

² *Laboratory of Quality Control of Medicines, College of Pharmacy,
Federal University of Pará, PA, Brazil*

³ *Laboratory of Phytochemistry, College of Pharmacy, Federal University of Pará, PA, Brazil*

SUMMARY. The objective of this study was to evaluate preliminary stability, as well as to validate an analytical method for *in vitro* skin permeation study of a gel containing tincture of *Calendula officinalis* L., aiming at the implementation and consolidation of methodologies to be used as prototype for future development of herbal medicine in the Brazilian Amazon region. The gel showed a satisfactory result during the assessment of its preliminary stability considering that the formulation remained stable throughout cycles at temperatures of 45 °C and 25 °C. Parameters obtained in the validation of the analytical method presented satisfactory results for specificity, linearity ($r > 0.99$), precision (intra-day and inter-day) with relative standard deviation values (R.S.D. %) below the required maximum of 5 %. Accuracy and robustness were consistent with both the objectives of the work and recommendations of the existing laws, providing the reliability of the data obtained during the skin permeation study, evidenced by the gel tendency to promote the permeation of flavonoids, expressed in rutin, through models of synthetic and biological membrane. However, it was observed that the gel had a higher permeability ratio through synthetic membrane, due to greater cumulative mass of rutin quantified after permeation.

KEY WORDS: Analytical method validation, *Calendula officinalis* L., *In vitro* cutaneous permeation, Rutin.

* Author to whom correspondence should be addressed. E-mail: carrera@ufpa.br