Introduction

The combination of ambroxol (mucolytic) and clenbuterol (bronchodilator) in a syrup have a complementary action and is designed to facilitate the elimination of excess mucus and phlegm. Due to the fact that validated analytical methods are of vital importance for the assurance of the composition of the drug as necessary requirement for its commercialization, the aim of this work was to develop and validate an analytical procedure by HPLC for the simultaneous determination of ambroxol hydrochloride and clenbuterol in syrups, giving rise to an analytical methodology that allows both components to be determined simultaneously, using the high-performance liquid chromatography (HPLC) technique.

Validation of the Analytical Procedure

The following parameters were evaluated: linearity and range, precision and accuracy, as established by the ICH and USP 42. Precision was evaluated as repeatability and intermediate precision, performed by the same analyst, same instrument, on different days.

Methodology

Mobile phase acetonitrile, methanol, buffer / ionic pair (KH₂PO₄ and 1-octanesulfonic acid) (15:20:65)% v/v at pH 3.70

Flow 1.5 mL / min

Volume of injection 15 μL / min

Column C18 (L1) 4.5 mm X 100 mm, 3.5 μm

wavelength 245 nm

Results

A high tendency to linearity was found between the response of the areas by variation of the concentration for ambroxol and clenbuterol, with R values in ranges of (0.9993-0.9995) and (0.9989-0.9992), respectively.

The results of RSDR were less than 2%, which indicates that the precision evaluated through the repeatability of the method is within the limits established for chromatographic.

Accuracy measured as percentage of recovery for ambroxol was found between 67.76% and 127.71% and for clenbuterol between 69.34% and 129.69% for fortified concentration levels between 70% and 130%, results that are within the limits of the acceptance criteria ranging from 98.0% to 102.0% for each level, as established in the ICH.

The results of the validation process were successfully met, indicating that the developed analytical method is suitable for the determination of ambroxol and clenbuterol in syrups.

References

1. Laboratory Boehringer - Ingelheim S.A. Project leaflet for the product mucosolvan. Approval project. Argentina. [2013].
2. Pharmacopoeia of the United States of America (USP) <1225> USP 42 NF37, United States. [2019].