World Academy of Science, Engineering and Technology
International Journal of Biomedical and Biological Engineering
Vol:10, No:06, 2016

Developing Stability Monitoring Parameters for NIPRIMAL®: A Monoherbal Formulation for the Treatment of Uncomplicated Malaria

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Abstract : NIPRIMAL® is a mono herbal formulation of Nauclea latifolia used in the treatment of malaria. The stability of extracts made from plant material is essential to ensure the quality, safety and efficacy of the finished product. This study assessed the stability of the formulation under three different storage conditions; normal room temperature, infrared and under refrigeration. Differential Scanning Calorimetry (DSC) and Thin Layer Chromatography (TLC) were used to monitor the formulations. The DSC analysis was done from 0oC to 350oC under the three storage conditions. Results obtained indicate that NIPRIMAL® was stable at all the storage conditions investigated. Thin layer chromatography (TLC) after 6 months showed there was no significant difference between retention factor (RF) values for the various storage conditions. The reference sample had four spots with RF values of 0.47, 0.68, 0.76, 0.82 respectively and these spots were retained in the test formulations with corresponding RF values were after 6 months at room temperature and refrigerated temperature been 0.56, 0.73, 0.80, 0.92 and 0.47, 0.68, 0.76, 0.82 respectively. On the other hand, the RF values (0.55, 0.74, 0.77, 0.93) obtained under infrared after 1 month varied slightly from the reference. The sample exposed to infrared had a lower heat capacity compared to that stored under room temperature or refrigeration. A combination of TLC and DSC measurements has been applied for assessing the stability of NIPRIMAL®. Both methods were found to be rapid, sensitive and reliable in determining its stability. It is concluded that NIPRIMAL® can be stored under any of the tested conditions without degradation. This study is a major contribution towards developing appropriate stability monitoring parameters for herbal products.

Keywords : differential scanning calorimetry, formulation, NIPRIMAL®, stability, thin layer hromatography
Conference Title : ICMPNP 2016 : International Conference on Medicinal Plants and Natural Products
Conference Location : San Francisco, United States
Conference Dates : June 09-10, 2016