



ABSTRACT

An accurate, distinctive and rapid reverse phase HPLC-DAD analytical procedure was established and validated for determination of legal and illegal drugs in skin whitening products which are classified as illicit drugs. Different manufacturing companies add illicit drugs in skin whitening products to gain popularity, increase the effectiveness of the product. Analysis of arbutin, betamethasone valerate (BMV) and kojic acid dipalmitate (KAD) was done using HPLC-DAD in gradient mode. Mobile phase A consisted of methanol (MeOH) and tetrahydrofuran (THF) used as an organic modifier as mobile phase B. The percent concentration of tetrahydrofuran (B) was selected as 30,30,70,30. Good chromatographic separations between arbutin, betamethasone valerate (BMV) and kojic acid dipalmitate (KAD) and stress induced degradations products were accomplished within 11 minutes using C18 column. The flow rate was set as 1.0 ml/min. On the basis of λ max of arbutin, betamethasone valerate and kojic acid dipalmitate, detection was done at 290, 240 and 260nm respectively, by using DIODE ARRAY detector. Validation of the developed method was done using ICH guidelines. Linearity of the developed method ranges from (15 to 300 $\mu\text{g m}^{-1}$) for arbutin, (12.5-250 $\mu\text{g ml}^{-1}$) for betamethasone valerate (BMV) and (15 to 300 $\mu\text{g ml}^{-1}$) for kojic acid dipalmitate (KAD) respectively. The LOD values were found to be 0.8 $\mu\text{g/ml}$ for arbutin, 1.3 $\mu\text{g/ml}$ for betamethasone valerate and 0.3 $\mu\text{g/ml}$ for kojic acid dipalmitate, The LOQ values were found to be 2.4 $\mu\text{g/ml}$ for arbutin, 1.7 $\mu\text{g/ml}$ for betamethasone valerate and 3.1 $\mu\text{g/ml}$ for kojic acid dipalmitate. All the analytes including the degradation products were separated with acceptable peak tailing and resolution. The established method can successfully be used for the routine and simultaneous determination of legal and illegal drugs (arbutin, betamethasone valerate and kojic acid dipalmitate) in different skin whitening preparations.

Key words: Arbutin, betamethasone dipalmitate (BMV), Kojic acid dipalmitate (KAD), stress induced degradation, DIODE ARRAY detector and HPLC-DAD.