ABSTRACT

OPTIMIZATION AND VALIDATION OF HPLC METHOD FOR SIMULTANEOUS ASSAY OF METHYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN, AND 2-PHENOXYETHANOL IN SEPICIDE HB®

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The aim of the present study was to optimize and validate HPLC methods for the simultaneous assay of methylparaben, ethylparaben, propylparaben, butylparaben, and 2-phenoxyethanol preservatives in Sepicide HB. Chromatographic separation for the five compounds was achieved on a C-18 endcapped high pure silica (125 x 4 mm, 5µ) column using mixture of acetonitrile-methanol-waters as mobile phase in gradient system at flow rate of 1mL/min. The analysis was performed with the ultraviolet (UV) detection at 258nm and temperature of column was set at 30°C. The analysis time was 17 minutes. The method was validated with respect to specificity, linearity, accuracy, precision, and robustness. The methods showed good result and met all validation requirements. The calibration curve showed good linearity over the concentration 16.20-64.80 mg/mL for methylparaben, 3.22-12.88 mg/mL for ethylparaben, 2.66-10.64 mg/mL for propylparaben, 5.32-22.72 mg/mL for butylparaben, and 64.00-260.00 mg/mL for 2-phenoxyethanol. The coefficient correlation were > 0.999 and Vxo were < 5% in each case. Average recovery for each compounds was between 98% and 102%. The relative standard deviation (RSD) values was less than 2% for each compounds. The method was proved to be selective and robust with respect changes. Assay of methylparaben, ethylparaben, propylparaben, butylparaben, and 2-phenoxyethanol in sample met requirement of the range of labeled amount in each compounds.

Keywords : alkyl paraben, 2-phenoxyethanol, HPLC, validation methods, sepicide HB