Application Note

747008X

High Speed Separation of Steroid Drug Cortisone Acetate utilizing Extreme High Pressure Liquid Chromatography System (X-LC®)

Introduction

Cortisone acetate, a steroid, is administered to reduce tissue inflammation or to suppress the human immune system. The U.S. Pharmacopeia (USP)[1] method requires that HPLC analysis of components of a cortisone acetate drug should have a resolution, R, between the analyte and internal standard peaks to be greater than 2.2 and the relative standard deviation for replicate injections to be not greater than 2.0%.

We examined the utility of an X-PressPak C18S column (2.1 mm I.D. x 50 mm L.) packed with 2 µm diameter packing material for the ultra-high speed separation of the above steroid drug. The results were examined to determine whether the performance of the column and chromatography separation meets the USP requirements.

Experimental

The chromatography system utilized in this experiment was a JASCO X-LC system consisting of a 3185PU HPLC pump, 3080DG degasser, 3067CO column oven, 3070UV UV/Vis detector, 3059AS auto sampler and a chromatography data system.

Results and Discussion

Figure 1 shows the separation of a standard mixture of propyl paraben (0.03 mg/mL), butyl paraben (0.03 mg/mL) and cortisone acetate (0.1 mg/mL). The X-LC system provides an analysis time 4 times shorter than conventional HPLC while the resolution between the propyl paraben and cortisone acetate elutions was 12.2; the reproducibility of the peak ratio is 0.44%. These results well exceed the USP requirements for the analysis.

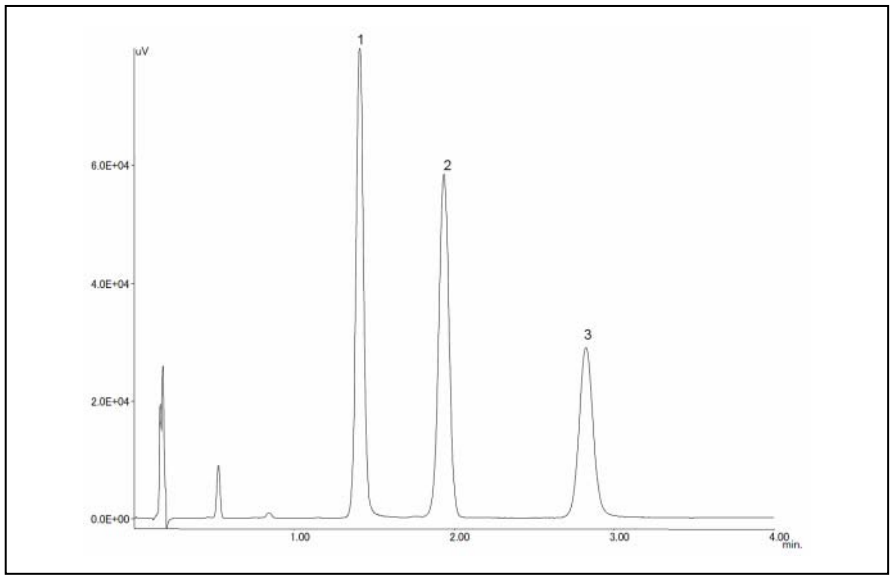

Figure 1 X-LC chromatogram of a standard mixture of propyl paraben, butyl paraben, and cortisone acetate Peak: 1=propyl paraben (0.03 mg/mL), 2=butyl paraben (0.03 mg/mL), 3=cortisone acetate (0.1 mg/mL) Chromatographic conditions: Column=X-PressPak C18S (2.1 mm I.D. x 50 mmL.), Mobile phase=CH_3CN/H_2O (35/65), Column temperature=25 ºC, Flow rate=0.7 mL/min, Detection wavelength=254 nm, Injection volume=1 µL

References

1) US Pharmacopeia 29, 266 (2006)

JASCO INTERNATIONAL CO., LTD
4-21, Sennin-cho 2-chome, Hachioji, Tokyo 193-0835, Japan
Tel: +81-42-666-1322, Fax: +81-42-665-6512