

Separation of Budesonide Epimers per USP Monograph

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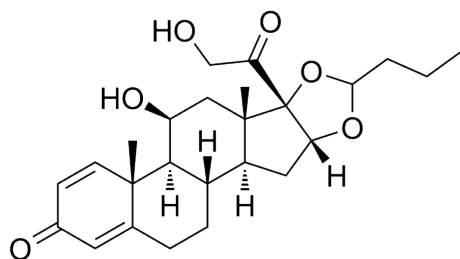
Overview

Budesonide is a corticosteroid that prevents swelling. The development of a quick and efficient analysis of Budesonide and its related organic impurities is of interest for drug manufacturers. In this application note, we report the separation of Budesonide epimers using a Luna™ 3 μm C18(2) column, a Luna Omega 3 μm C18 column, and a Hyperclone™ ODS 3 μm C18 column according to the USP monograph for Budesonide.

System suitability per USP Monograph for the Budesonide Assay is a resolution no less than (NLT) 1.2 between the two Budesonide epimer peaks and a percent relative standard deviation (%RSD) of no more than (NMT) 1.0 % for the sum of the peak areas of the two Budesonide epimers. A minor adjustment to the mobile phase composition was made for the Luna C18(2) and Luna Omega C18 columns. The increase in the acetonitrile (minor component of isocratic mobile phase) of 3 % from 45 to 48 % is allowed per USP <621> and was done in order to meet the system suitability requirement for resolution of the two Budesonide epimer peaks. System suitability requirements for Budesonide Assay were met by the Luna 3 μm C18(2), the Luna Omega 3 μm C18, and the Hyperclone ODS 3 μm C18 columns (**Figure 2**).

All solutions were prepared as indicated in the USP Monograph for Budesonide. USP Budesonide CRS (Catalog No. 1078201) was purchased from USP.

Figure 1. Budesonide



LC-UV Conditions

Column: Luna 3 μm C18(2) ([00G-4251-E0](#))
Luna Omega 3 μm C18 ([00G-4784-E0](#))
Hyperclone ODS 3 μm C18 ([00G-4361-E0](#))

Dimension: 250 x 4.6 mm

Mobile Phase: Acetonitrile/Buffer (45:55, v/v)
Acetonitrile/Buffer (48:52, v/v), for Luna C18(2) and Luna Omega C18

Buffer: 0.5 mL of Glacial Acetic Acid in 1 L of water. Adjust with Potassium Hydroxide to a pH of 3.9.

Flow Rate: 1 mL/min (Isocratic)

Injection Volume: 20 μL

Temperature: 50 °C

Detector: UV @ 240 nm

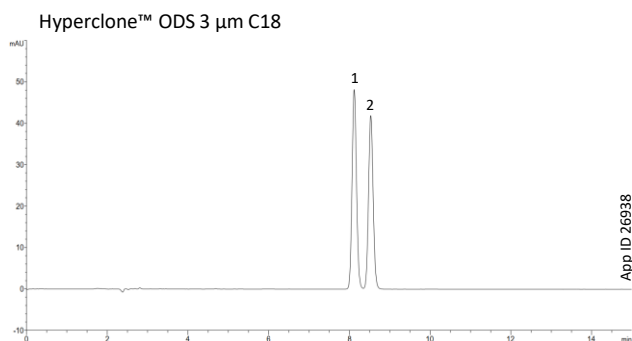
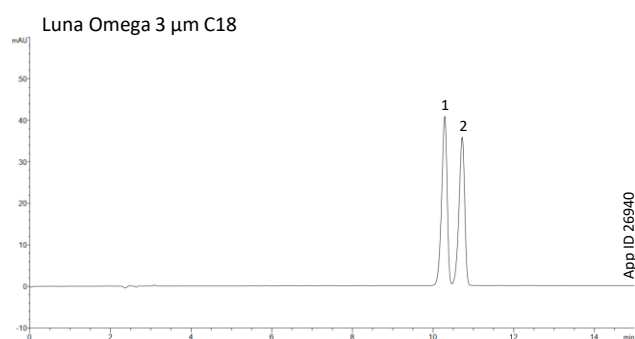
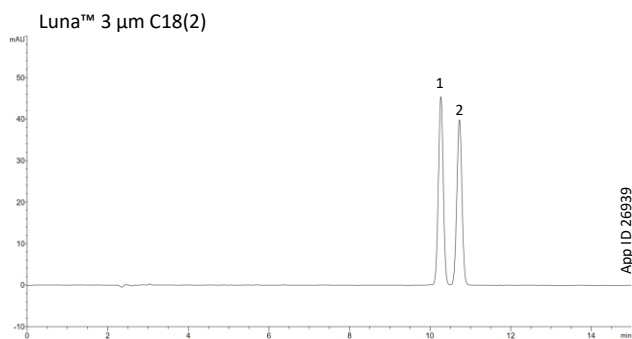
System: Agilent® 1260 Binary UHPLC

Table 1. Preparation of Solutions

Solution	Composition
Diluent	Acetonitrile/Water (3:7, v/v)
Standard Solution	0.06 mg/mL of USP Budesonide CRS in Diluent



Figure 2. Standard Solution



Peak No.	Analyte	Luna 3 μm C18(2)		Luna Omega 3 μm C18		Hyperclone ODS 3 μm C18	
		Resolution	Sum Area %RSD	Resolution	Sum Area %RSD	Resolution	Sum Area %RSD
1	Budesonide Epimer B	2.01	0.083	1.70	0.065	2.00	0.040
2	Budesonide Epimer A						
N = 5 Injections							



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