



# CERTIFICATE OF ANALYSIS

20 Martin Ross Ave., Toronto, ON. M3J 2K8 Canada Tel: (416) 665-9696 E-mail: Orders.TRC@LGCGroup.com Website: www.trc-canada.com

## 1. Identification

**CAS Number:**

51333-05-2

**Catalogue Number:**

TRC-A165740

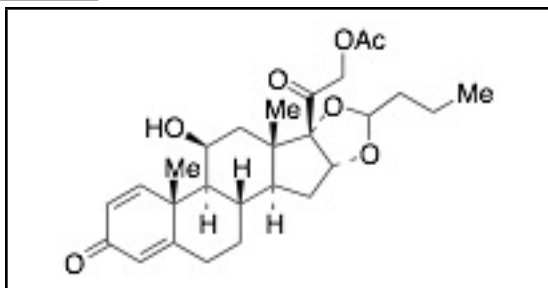
**Product:**

21-Acetoxy-11 $\beta$ -hydroxy-16 $\alpha$ ,17 $\alpha$ -propylmethylenedioxy-1,4-diene-3,20-dione

**Synonyms:**

(11 $\beta$ ,16 $\alpha$ )-21-(Acetyloxy)-16,17-[butylidenebis(oxy)]-11-hydroxy-pregna-1,4-diene-3,20-dione; Budesonide 21-acetate; 21-Acetyloxy Budesonide; Budesonide Impurity K (EP); Budesonide EP Impurity K

**Structure:**



**Molecular Formula:**

C<sub>27</sub>H<sub>36</sub>O<sub>7</sub>

**Molecular Weight:**

472.57

**Source of Product:**

Synthetic

## 2. Analytical Information

**Lot Number:**

2-KHI-62-1

**Atmosphere:**

Air

**Melting Point:**

156 - 158°C (dec.)

**Solubility**

Chloroform (Slightly), Methanol (Slightly)

**Appearance of Product:**

White to Off-White Solid

**Stability**

Not Determined

**Method for Determining Identity:**

<sup>1</sup>H NMR (CDCl<sub>3</sub>) and MS

**Long Term Storage Condition:**

4°C

**Purity:**

97%

**Shipping Condition**

This Product Is Stable To Be Shipped At Room Temperature

97.87% by UPLC

**Additional Information:**

TLC Conditions: SiO<sub>2</sub>; Dichloromethane : Methanol = 9 : 1; Visualized with UV and AMCS; Single Spot, R<sub>f</sub> = 0.65.

<sup>1</sup>H NMR and MS conform to structure.

Specific Rotation: +90.1° (c = 0.3, Chloroform)

Purity is based on the analytical results of the tests performed. NMR and Elemental Analysis (if available) may have an accuracy of  $\pm 2\%$ . Isotopic purity is based on mass distribution observed.

The contents of the specifications are subject to change without advance notice, and the specification values displayed here are the most up to date values.

Philip Chan, Head of Quality Assurance

**QC Test Date**

September 21, 2017

**Retest Date**

September 19, 2021