

Chem-Impex International, Inc.

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Certificate of Analysis

Catalogue Number	37654
Lot Number	002260-20220401
Product	Budesonide (+)-16 α ,17 α -Butylidenedioxy-11 β ,21-dihydroxy-1,4-
CAS Number	51333-22-3
Molecular Formula	C ₂₅ H ₃₄ O ₆
Molecular Weight	430.54
Appearance	White to almost white crystalline powder
Odor	Odorless
Mould and Yeast	< 100 cfu/g
Infrared Spectrum	Conforms to structure
Loss on Drying	0.18%
Residual Solvents	Ethanol : 661 ppm Methanol, Acetone, Acetonitrile, Methylene chloride, N-Butyraldehyde : Not detected
Microbial Count	< 1000 cfu/g (TAMC)
Particle Size	100% thr 10 μ m 95% thr 5 μ m
Related Substances	Any other individual impurity : Not detected Total specified impurities : 0.33% Total unspecified impurities : 0.29%
Assay	99.3%
Grade	Meets USP specification
Storage	Store at 2 - 8 °C
Additional Information	Budesonide acetaldehyde acetal, Desonide : Not detected Budesonide 21-acetate, Budesonide 21-butyrate : Not detected 16 α -Hydroxyprednisolone : 0.01%, Budesonide d-homo analog : 0.05%, Budesonide glyoxal, Budesonide related compound E, G : 0.06% Budesonide related compound L : 0.19% Epimer : 50.89%

Certificate of Analysis

Catalog Number: 37654

Lot Number: 002260-20220401

Remarks

See material safety data sheet for additional information

For laboratory use only

The foregoing is a copy of the Certificate of Analysis as provided by our supplier

A handwritten signature in black ink, appearing to read 'Bala Kumar', with a stylized flourish at the end.

Bala Kumar
Quality Control Manager