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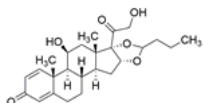
Web site: www.chemimpex.com

Manufacturing site:

825 Dillon Drive

Wood Dale, IL 60191

Product Specifications



Catalogue Number	37654
Product	Budesonide (+)-16a,17a-Butyridenedioxy-11β,21-dihydroxy-1,4-
CAS Number	51333-22-3
Molecular Formula	C ₂₅ H ₃₄ O ₆
Molecular Weight	430.54

Appearance	White to light yellow powder to crystal
Mould and Yeast	≤ 100 cfu/g
Infrared Spectrum	Conforms to structure
Loss on Drying	≤ 0.3%
Residual Solvents	Methanol : ≤ 3000 ppm Ethanol : ≤ 5000 ppm Acetone : ≤ 5000 ppm Acetonitrile : ≤ 410 ppm Methylene chloride : ≤ 600 ppm N-butyraldehyde : ≤ 150 ppm
Microbial Count	≤ 1000 cfu/g (TAMC)
Particle Size	100% thr 10 μm 95% thr 5 μm
Related Substances	16α-Hydroxyprednisolone : ≤ 0.2% Budesonide acetaldehyde acetal : ≤ 0.1% Budesonide d-homo analog : ≤ 0.1% Desonide : ≤ 0.1% Budesonide glyoxal : ≤ 0.07% Budesonide related compound E : ≤ 0.1% Budesonide related compound L : ≤ 0.2%
Assay	98 - 102%
Grade	Meets USP specification
Storage	Store at 2 - 8 °C

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Additional Information	Identification B : To pass test Epimer : 40 - 51% Related substances : Budesonide related compound G : $\leq 0.1\%$ Budesonide 21-acetate : $\leq 0.1\%$ Budesonide 21-butyrate : $\leq 0.1\%$ Any other individual impurity : $\leq 0.1\%$ Total specified impurities : $\leq 0.4\%$ Total unspecified impurities : $\leq 0.4\%$
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For Laboratory Use Only