

Item Number	B4040
Item	Budesonide, Micronized, USP
CAS Number	51333-22-3
Molecular Formula	C ₂₅ H ₃₄ O ₆
Molecular Weight	430.59
MDL Number	
Synonyms	16,17-Butylidenebis[oxy]-11,21-dihydroxypregna-1,4-diene-3,20-dione

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS, BOTH EPIMERS)	98.0	102.0 %
ASSAY (DRIED BASIS, EPIMER A)	40.0	51.0 %
LOSS ON DRYING		0.3 %
ORGANIC IMPURITIES:		
16a-HYDROXPREDNISOLONE		0.2 %
BUDESONIDE ACETALDEHYDE ACETAL (EPIMERS)		0.10 %
BUDESONIDE D-HOMO ANALOG		0.10 %
DESONIDE		0.10 %
BUDESONIDE GLYOXAL (EPIMERS)		0.07 %
BUDESONIDE RELATED COMPOUND E		0.10 %
BUDESONIDE RELATED COMPOUND L		0.2 %
BUDESONIDE RELATED COMPOUND G (EPIMERS)		0.10 %
BUDESONIDE 21-ACETATE (EPIMERS)		0.10 %
BUDESONIDE 21-BUTYRATE		0.10 %
ANY OTHER INDIVIDUAL IMPURITY		0.10 %
TOTAL SPECIFIED IMPURITIES		0.4 %
TOTAL UNSPECIFIED IMPURITIES		0.4 %
ELEMENTAL IMPURITIES	AS REPORTED	
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		10 ³ cfu/g
TOTAL MOLDS AND YEASTS COUNT (TMYC)		10 ² cfu/g
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B	SPECTRUM MATCHES STANDARD	

Test	Specification	
	Min	Max
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

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