

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

Address: No.1 Zhiqing Road, Railway Station Economic Development Zone

Huangzhou District China-438011 Huanggang, Hubei province



CERTIFICATE OF ANALYSIS

Product : Budesonide Micronized

Batch No. : HG-BD241102M2

Quantity : 5kg

Specification: USP2024

Mfg. date: 2024.11.06

Retest date: 2027.11.05

Item	Specifications	Results
Appearance	White to off-white, odorless, crystalline powder	Off-white, odorless, crystalline powder
Identification	A:IR.Comparison: Budesonide CRS.	Sample spectrum is similar to that of reference standard.
	UV:Comparison: Budesonide CRS.	Sample spectrum is similar to that of reference standard.
Loss on drying	≤0.3%	0.10%
Related substances	16α-Hydroxyprednisolone ≤0.2%	0.01%
	Budesonide acetaldehyde acetal ≤0.10%	Not detected
	Budesonide d-homo analog ≤0.10%	Not detected
	Desonide ≤0.10%	0.04%
	Budesonide glyoxal ≤0.07%	0.03%
	Budesonide related compound E ≤0.10%	0.01%
	Budesonide related compound L ≤0.2%	0.09%
	Budesonide related compound G ≤0.10%	0.02%
	Budesonide 21-acetate ≤0.10%	Not detected
	Budesonide 21-butyrate ≤0.10%	Not detected
	Any other individual impurity ≤0.10%	0.03%
	Total specified impurities ≤0.4%	0.16%
	Total unspecified impurities ≤0.4%	0.11%
Epimer A	40.0~51.0%	47.8%
Residual Solvents	Ethanol ≤5000ppm	631ppm
Assay	98.0 ~ 102.0 %	100.5%
Microbial control	The total aerobic microbial count is NMT 10 ³ cfu/g	<10cfu/g
	The total combined molds and yeast count is NMT 10 ² cfu/g	<10cfu/g
Particle Size	D90<5μm, D50<3μm	D90: 4.6μm, D50: 2.1μm

Conclusion: Complies with the requirements of USP2024

Q.C. director:

QP:

Date: 2025.01.15

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