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CERTIFICATE OF ANALYSIS

Product : Budesonide Micronized

Batch No. : BD210603M

Quantity : 2kg

Specification: USPNF2021

Mfg. date: 2021.06.20

Retest date: 2024.06.19

Item	Specifications	Results
Appearance	White to off-white, odorless, crystalline powder	Off-white, odorless, crystalline powder
Solubility	Freely soluble in chloroform; sparingly soluble in alcohol; practically insoluble in water and in heptane.	Conform
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%	0.16%
Related substances	16α-Hydroxyprednisolone≤0.2%	0.05%
	Budesonide acetaldehyde acetal≤0.10%	Not detected
	Budesonide d-homo analog≤0.10%	0.06%
	Desonide≤0.10%	Not detected
	Budesonide glyoxal≤0.07%	Not detected
	Budesonide related compound E≤0.10%	0.02%
	Budesonide related compound L≤0.2%	0.08%
	Budesonide related compound G≤0.10%	0.04%
	Budesonide 21-acetate≤0.10%	Not detected
	Budesonide 21-butyrate≤0.10%	Not detected
	Any other individual impurity≤0.10%	0.05%
	Total specified impurities≤0.4%	0.18%
Total unspecified impurities≤0.4%	0.12%	
Epimer A	40.0~51.0%	46.1%
Residual Solvents	Methanol≤3000 ppm	Not detected
	Ethanol ≤5000ppm	1099ppm
	Acetone≤5000ppm	Not detected
	Acetonitrile≤410ppm	Not detected
	Methylene chloride≤600ppm	16ppm
	N-butyraldehyde≤150ppm	33ppm
As(In-house)	≤1.5ppm	<1.5ppm
Pb(In-house)	≤0.5ppm	<0.5ppm
Cd(In-house)	≤0.5ppm	<0.5ppm
Hg(In-house)	≤3ppm	<0.5ppm
V(In-house)	≤10ppm	<3ppm
Co(In-house)	≤5ppm	<5ppm
Ni(In-house)	≤20ppm	<20ppm
Assay	98.0 ~ 102.0 %	99.1%
Microbial control	Total viable microbial count ≤ 1000cfu/g	Conform
	Fungi count ≤100cfu/g	
Particle Size	100% ≤10μm; 95%≤5μm	Conform
Storage Condition	Sealed and protected from light	

Conclusion: Complies with the requirements of USP43

Q.C. director: 吴海敏

QP: 王军

Date: 2021.12.10

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