

Certificate of Analysis

Inspection number QC- C05B3- 202010004

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Product name	Promestriene	Product Specifications	API	Product code	C05B3
Product batch	2009002	Manufacturing date	2020.10.10	Product weight	10.74KG
Packaging specification	5kg/barrel				
Report date	2020.10.19		Re- test date	2022.04.09	
Manufacturing address	West District and east side of Jingsi Road, Lingang Economic and Technological Development Zone, Cangzhou City, Hebei Province, China.				

Test item	specification	Results
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Conclusion
Characters

Appearance	White or almost white crystalline powder; Odorless. It is very soluble in chloroform, normally soluble in dioxane and acetone, slightly soluble in anhydrous ethanol and acetonitrile, almost insoluble in water.	White crystalline powder, Odorless. It is very soluble in chloroform, normally soluble in dioxane and acetone, slightly soluble in anhydrous ethanol and acetonitrile, almost insoluble in water.	Complied
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Melting point	64~68℃	66.5~66.9℃	Complied
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Specific rotation	+65° to +75°	+68°	Complied
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Identification

Color reaction	It reacts with sulfuric acid to form light yellow green liquid, which shows yellow green fluorescence at 365nm of ultraviolet lamp, and it is orange yellow flocculent precipitate after diluted with water	approach	Complied
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UV spectra	Absorption at 279nm and 287nm	Absorption at 279nm and 287nm	Complied
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IR	Complied with that of the reference spectrum	Complied with that of the reference	Complied
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Test		spectrum	
Related Substances	Total impurities NMT 1.0%	0.064%	Complied
Loss on drying	NMT 0.5%	0.07%	Complied
Residue on ignition	NMT 0.1%	0.04%	Complied
Heavy metals	NMT 10ppm	Complied	Complied
Residual solvents	Methanol NMT 0.3%, Ethanol NMT 0.5%	Methanol is not detected, Ethanol 0.2%	Complied
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Assay	Calculated on dried basis NLT 98.5%	100.0%	Complied
Microbial limit	Total aerobic: NMT 10 ³ cfu per 1 g; Total mould and yeast: NMT 10 ² cfu per 1 g	Total aerobic: NMT 10cfu/g; Total mould and yeast: NMT 10cfu/g	Complied

Test conclusion: According to <Promestriene analysis operating procedures>(SCZ- IS- PF- A004) &< Promestriene quality standard>(SCZ- QS- PF- A004), this product is analyzed, and the results are complied.

Reporter: Miao Yang
Liu

Reviewer: Dongxue Liu

Director: Weiqing

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