



瑾 岚 医 药 技 术 开 发 有 限 公 司

JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED

Hangzhou ROYAL Import & Export Co.,Ltd.

Certificate of Analysis

Product name	Crisaborole		
Batch No.	18RY0102	CAS No.	906673-24-3
Mfg. Date	2018-01-16	Exp. Date	2020-01-15

Tests	Specifications	Result
Appearance	White to pale yellow solid	Off-white solid
Identity(IR)	IR: The IR absorption spectrum of the sample must be concordant with test standard	Complies
	HPLC: the retention time of the major peak in the chromatogram conforms to the characteristic peak of R.S.	Complies
Loss on drying	$\leq 2.0\%$	1.2%
Related substances	Any other impurity: $\leq 0.5\%$	0.08%
	Total impurities: $\leq 1.0\%$	0.15%
Heavy metal	≤ 20 ppm	Complies
Residual Solvents	Comply with ICH guidelines	Complies
Assay(on anhydrous basis)	98.0%~102.0%	99.7%
Conclusion : Conforms to In-house specification.		

Tested by: Alice

Checked by: Penny

Approved by: Michelle

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