



Chong Da Prostaglandin Fine Chemicals Co., Ltd

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Certificate of analysis

COMMERCIAL NAME: Ruxolitinib phosphate

PRODUCT NAME: (R)-3-(4-(7H-Pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile phosphate

CHEMICAL FORMULA: $C_{17}H_{18}N_6 \cdot H_3PO_4$

CAS No. : 1092939-17-7

Batch No.	Date of Manufacture	Date of Expiry	Date of Analysis	Package
170305	25/03/2017	24/03/2019	31/03/2017	1kg/pack
Items	Specifications			Results
Appearance	White to off-white or light pink powder			Conforms
Solubility	Highly soluble in water, and the solubility is pH dependant.			Conforms
Identification	IR: The IR absorption spectrum of the sample must be concordant with Test Standard			Conforms
	HPLC: The retention time of the major peak in the chromatogram conforms to the characteristic peak of R.S.			Conforms
Melting Point	194°C~198°C			Conforms
pH	2.0~3.0			2.8
Water Content	Not more than 1.0%			0.48%
Enantiomer	≤1.0%			0.82%
Related Substances	Any other impurity: Not more than 0.5%			0.26%
	Total impurities: Not more than 1.0			0.75%
Assay (on anhydrous basis)	98.0%~102.0%			99.1%
Conclusion	Qualified			

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F