

分析证明书

CERTIFICATE OF ANALYSIS

Product name: Ruxolitinib 鲁索利替尼	
Batch no. 批号: 20220215	Quantity 数量: 500grs
Manuf. date 生产日期: 2022/02/10	Expiry date 有效期: 2022/02/09

ITEMS	STANDARD	RESULTS
Appearance	White to light-yellow crystalline powder	light-yellow crystalline powder
Identification	HPLC	Conforms
Related substances	Impurity B $\leq 0.1\%$	0.01%
	Impurity C $\leq 0.1\%$	ND
	Impurity D $\leq 0.1\%$	ND
	Impurity E $\leq 0.1\%$	0.01%
	Any single unknown impurity $\leq 0.1\%$	0.17%
	Total impurities $\leq 1.0\%$	0.24%
Optical isomers	Impurity A $\leq 1.0\%$	0.57%
Loss on Dryings	$\leq 0.50\%$	0.4%
Residual Solvents	Methanol $\leq 0.3\%$	Conforms
	Isopropyl alcohol $\leq 0.5\%$	Conforms
	MTBE $\leq 0.5\%$	Conforms
	EA $\leq 0.5\%$	Conforms
	THF $\leq 0.072\%$	Conforms
	1,4-dioxane $\leq 0.038\%$	Conforms
	DMSO $\leq 0.5\%$	Conforms
Purity	$\geq 99.0\%$	99.7%
CONCLUSION: The results conform to this specification.		

复核人 Checker:

化验人 Analyst:

