

OZL0301-R02-a

江苏红豆杉药业有限公司

JIANGSU YEW PHARMACEUTICAL CO., LTD.

江苏红豆杉药业有限公司检验报告

Analysis Certificate of Jiangsu Yew Pharmaceutical Co., LTD

Sample Name	ALLOPURINOL	Come From	Workshop 2
Specification	Bulk Drug 25Kg/bar	Quantity	500Kg
Batch No.	H20120314	Reference std.	EP7.0
Manufacturing Date	03-14-2012	Test Date	03-19-2012
Expiry Date	02-2016	Report Date	03-20-2012
TEST	SPECIFICATIONS		RESULTS
Appearance	White or almost white powder		White powder
Identification	Conform with IR ref. Standard		Conforms
	The ratio of the absorbance measured at minimum at 231nm to that measured at maximum at 250nm is 0.52-0.62		0.56
	Meets the requirements		Conforms
	The principal spot in the test solution is similar in position and size to that in the reference solution		Conforms
impurity	impurity A $\leq 0.2\%$		0.01%
	impurity B $\leq 0.1\%$		Conforms
	impurity C $\leq 0.1\%$		Conforms
	Unspecified impurity $\leq 0.1\%$		0.03%
	Total impurities other than A,B,C $\leq 0.3\%$		0.08%
	impurity D $\leq 0.1\%$		Conforms
	impurity E $\leq 0.1\%$		Conforms
Heavy metals	$\leq 20\text{ppm}$		Conforms
Loss on drying	$\leq 0.5\%$		$< 20\text{ppm}$
Sulphated ash	$\leq 0.1\%$		0.03%
Residual Formamide	$\leq 200\text{ppm}$		0.07%
Assay(NT)	97.0—102.0%		$< 200\text{ppm}$
Conclusion	The product Compiles with the Standard 98.7%		
Analyst: 胡元明	Checker: 孙文	QA Auditing: 孙文	Auditing Date: 2012.03.20
Quality Chief: 孙文	FAGRON IBÉRICA, Date: 2012.03.20		
Corresponde al lote de Fagron. U3021501			
 Director Técnico S.			