

CERTIFICATE OF ANALYSIS

Product: Desogestrel[CAS:54024-22-5]

Batch No: 20160712

Manufacturing Date: July 2016

Expiry Date: July 2017

Quantity: 20.5 Kgs

Items 项 目	Acceptance Criteria 标准规定	Results 检验结果
Description 性状	White or almost white crystalline powder 本品为白色或类白色结晶性粉末	Almost white Crystalline powder 类白色结晶性粉末
Specific optical rotation 比旋度	+53° ~ +57°	+56°
Identification 鉴别	The infrared Spectrum of the test should be consistent with the standard. 红外光谱收图请与对照品的图谱基本一致。	Qualified 符合
Related substances 有关物质	Impurity A ≤0.2% 杂质 A ≤0.2%	0.10%
	Impurity B ≤0.2% 杂质 B ≤0.2%	未检出
	Impurity C ≤0.2% 杂质 C ≤0.2%	0.04%
	Impurity D ≤0.2% 杂质 D ≤0.2%	No Detectable 未检出
	Unspecified impurities ≤0.10% 非特定杂质 ≤0.10%	No Detectable 未检出
	Total impurities ≤0.5% 杂质总量 ≤0.5%	0.15%
Loss on drying 干燥失重	≤0.5%	0.05%
Residue on ignition 炽灼残渣	≤0.1%	0.03%
Purity by HPLC 含量	98.0%~102.0%	100.3%
Residual solvents 溶剂残留	N-hexane ≤290ppm 正己烷 ≤290ppm	No-detectable 未检出
	Ethyl acetate ≤5000ppm 醋酸乙酯 ≤5000ppm	No-detectable 未检出
	Tetrahydrofuran ≤720ppm 四氢呋喃 ≤720ppm	No-detectable 未检出
	N-heptane ≤5000ppm 正庚烷 ≤5000ppm	121ppm
	Ethlenediamine should not be detected	No-detectable

Conclusion: It Complies with EP7.0.