Hangzhou Huarong Pharm Co.,Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.
TEL: 0086-571-86758373 FAX: 0086-571-81131109

产品检验证书
CERTIFICATE OF ANALYSIS

产品名称: Product Name:	奥沙利铂 Oxaliplatin		
报告日期: Report Date:	15/12/2023 D/M/Y	生产日期: Manuf. Date:	02/03/2023 D/M/Y
生产批号: Batch No.:	3B004GA4	有效期至: Expiry Date:	N/A D/M/Y
数量: Quantity:	5822g	复验日期: Retest Date:	01/03/2026 D/M/Y
标准依据: Specification Basis:	USP-NF USP - NF	包装规格: Package size:	3000g/桶 3000g/drum

检验结果 Analytical Results

项目 Item	分项 Component	标准 Specification	结果 Result
性状 Description	性状 Description	白色或类白色结晶性粉末 White or off-white , crystalline powder	白色结晶性粉末 White crystalline powder
鉴别 Identification	鉴别A IdentificationA	本品的红外光吸收图谱应与奥沙利铂对照品的图谱一致 IR spectrum of the sample corresponds to the spectrum of oxaliplatin reference substance	符合规定 Conforms
	鉴别B IdentificationB	在含量测定项下记录的色谱图中，供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 The retention time of the major peak in the Sample solution corresponds to that in the Standard solution, as obtained in the Assay	符合规定 Conforms
比旋度 Specific rotation	比旋度 Specific rotation	+74.5°至+78.0° Between +74.5° and +78.0°	+74.9 °
酸度 Acidity	酸度（1） Acidity（1）	溶液应无色 The solution is colorless	无色 Colourless
	酸度（2） Acidity（2）	使溶液变为粉红色所用的氢氧化钠滴定液(0.01mol/L)不得过0.6ml NMT 0.6 ml of 0.01 M sodium hydroxide is required to change the color to pink	0.4 ml
干燥失重 Loss on drying	干燥失重 Loss on drying	不得过0.5% Not more than 0.5%	0.04 %

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银的限度 Limit of silver	银的限度 Limit of silver	不得过5 ppm Not more than 5 ppm	2.1 ppm
铂含量 Content of platinum	铂含量 Content of platinum	按干燥品计算，应为48.1% ~50.1 % Between 48.1% and 50.1%, on the dried basis	48.7 %
含量测定 Assay (HPLC)	含量测定 Assay (HPLC)	按干燥品计算，应为98.0% ~ 102 .0% Not less than 98.0 percent and not more than 102.0 percent, calculated on the dried basis	100.0 %
有机杂质 Organic impurities (HPLC)	草酸的限度 Limit of oxalic acid	不得过0.1% Not more than 0.1%	0.002 %
	环己二胺二水合铂的限度 Limit of(SP-4-2)-diaqua[(1 R, 2R)-cyclohexane-1, 2-diamine-N, N]platinum	不得过0.1% Not more than 0.1%	0.01 %
	双水二氨环己烷铂二聚物 Diaquodiaminocyclohexaneplatinum dimer	不得过0.1% Not more than 0.1%	未检测到 ND
	奥沙利铂有关化合物C Oxaliplatin related compound C	不得过0.1% Not more than 0.1%	未检测到 ND
	单一非指定杂质 Any individual unspecified impurity	不得过0.10% Not more than 0.10%	低于忽略阈值 LTDL

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检验结果 Analytical Results

项目 Item	分项 Component	标准 Specification	结果 Result
	总杂质：草酸，环己二胺二水合铂，奥沙利铂有关化合物C，双水二氨环己烷铂二聚物及所有非指定杂质的总和	不得过0.30%	0.01 %
	Total impurities:the sum of oxalic acid , (SP-4-2) -diaqua[(1R, 2R)-cyclohexane-1, 2-diamine-N, N]platinum, oxaliplatin related compound C, diaquodiaminocyclohexaneplatinum dimer and all unspecified impurities	Not more than 0.30%	
	奥沙利铂有关化合物D的限度	不得过0.1%	未检测到
	Limit of oxaliplatin related compound D	Not more than 0.1%	ND
细菌内毒素	细菌内毒素	每1mg奥沙利铂不得过1.0 EU	符合规定
Bacterial endotoxins	Bacterial endotoxins	Not more than 1.0 USP Endotoxin Unit per mg of Oxaliplatin	Conforms
微生物限度	需氧菌总数	每1g不得过20 cfu	<1 cfu/g
Microbiological examination	Total aerobic microbial count	Not exceed 20 cfu per g	
	霉菌和酵母菌总数	每1g不得过5 cfu	<1 cfu/g
	Total combined molds and yeast count	Not exceed 5 cfu per g	

结论(Conclusion)： 按USP-NF检验，以上检验项目符合规定
Above items Conform to USP - NF

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