

26/10/2023

METAPHARMACEUTICAL

N DE LOTE:

0171023



WISDOM PHARMACEUTICAL CO., LTD.

江苏慧聚药业有限公司

No.18, Qinghua Road, Sanchang, Haimen, Jiangsu, China 江苏省南通市海门区三厂街道青化路 18 号
TEL.: +86-513-8129-2202, FAX.: +86-513-8129-2226, 邮编: 226123

CERTIFICATE OF ANALYSIS

Batch No.: PPMBD201003S

kg/Batch Size: kg

Date: 2021/01/30

Pimobendan 匹莫苯丹	(5RS)-6-[2-(4-methoxyphenyl)-1H-benzimidazol-5-yl]-5-methyl-4,5-Dihydropyridazin-3(2H)-one (5RS)-6-[2-(4-甲氧基苯基)-1H-苯并咪唑-5-基]-5-甲基-4,5-二氢吡嗪-3(2H)-酮	
CAS No.	74150-27-9	
Molecular Formula(分子式)	C ₁₉ H ₁₈ N ₄ O ₂	
Molecular Weight(分子量)	334.37	
Manufacture Date(生产日期)	2020 年 12 月 08 日 Dec. 08, 2020	
Retest Date(复检期)	2024 年 11 月 Nov., 2024	
Manufacture Address(生产地址)	No.18, Qinghua Road, Sanchang, Haimen, Jiangsu, China 江苏省南通市海门区三厂街道青化路 18 号	
According to(检验依据)	欧洲药典 EP9.5 PhEur.9.5 & No.R0-CEP 2013-329-Rev 02	
Items (检测项目)	Specifications (质量标准)	Results (检测结果)
Appearance(外观)	White or slightly yellowish powder 白色或微黄色粉末	White powder 白色粉末
Solubility(溶解度)	Practically insoluble in water, freely soluble in dimethylformamide, slightly soluble in acetone and in methanol 几乎不溶于水, 易溶于 DMF, 微溶于丙酮和甲醇	Practically insoluble in water, freely soluble in dimethylformamide, slightly soluble in acetone and in methanol 几乎不溶于水, 易溶于 DMF, 微溶于丙酮和甲醇
Melting Point(熔点)	about 242°C	242°C
Infrared Spectroscopy(红外)	Complies with reference standard spectrum 与对照品图谱一致	Conformed 符合
Water(水分)	≤ 1.0%	0.09%
Sulphated ash(灰分)	≤ 0.1%	0.04%
Heavy Metals(重金属)	≤ 10ppm	<10ppm

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Items (检测项目)	Specifications (质量标准)	Results (检测结果)
Pd residue(钯残留)	$\leq 10\text{ppm}$	$< \text{LOD}(\text{LOD: } 0.5\text{ppm})$ (Testing result: 0.15ppm)
Assay(含量)	98.0 - 101.0% (Anhydrous substance, 以无水物计)	100.4%
Hydrazine hydrate(水合肼)	$\leq 300\text{ppm}$	ND
Related substances(相关物质)		
Impurity A (杂质 A)	$\leq 0.1\%$	ND
Impurity B (杂质 B)	$\leq 0.1\%$	ND
Any other unknown impurity (其他未知杂质)	$\leq 0.10\%$	0.04%
Total impurities (总杂质)	$\leq 0.2\%$	0.12%
WI-0110	$\leq 300\text{ppm}$	ND
Residual Solvent(溶剂残留)		
Ethanol(乙醇)	$\leq 3000\text{ppm}$	1162ppm
Ethyl acetate(乙酸乙酯)	$\leq 5000\text{ppm}$	659ppm
DMF(N,N-二甲基甲酰胺)	$\leq 660\text{ppm}$	ND
Conclusion (结论)	Test results conform to the specifications (合格)	

WI-0110 : 6-(3,4-diaminophenyl)-5-methyl-4,5-dihydropyridazin-3(2H)-one



批准(Approval):

阿、修
2021/01/30

审核(Review):

陈
2021/01/30

检测(Testing):

张、林
2021/01/30



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ADDITIONAL TESTING

Batch No.: PPMBD201003S

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附加项目(Additional Items)	规格(Specifications)	检测结果(Results)
1.检测(Tests)		
Particle size (粒径)	报告结果 Report Result	D50:7 μ m D90:21 μ m

