



成品检验报告
CERTIFICATE OF ANALYSIS

品名 Product Name: 替莫唑胺
Temozolomide

生产日期 Man. Date: 2023-09-25

批号 Batch No: 230905

有效日期 Expiry Date: 2025-09-24

批量 Batch Size: 31kg

报告日期 Report Date: 2023-09-28

检测项目 Tests	标准规定 Specifications	检测结果 Results
性状 Appearance	White to light pink powder	White powder
有关物质 Related substances	2-Azahypoxanthine $\leq 0.2\%$	ND
	Dacarbazine Impurity A	ND
	Single unidentified impurity $< 0.1\%$	0.01%
	Total substances $\leq 0.8\%$	0.01%
干燥失重 Loss on drying	$\leq 0.4\%$	0.19%
炽灼残渣 Sulphated ash	$\leq 0.1\%$	$< 0.03\%$
重金属 Heavy metals	$\leq 20\text{ppm}$	$< 20\text{ppm}$
溶剂残留 Residual organic solvents	Acetone $\leq 5000\text{ ppm}$;	ND
	Ethyl acetate $\leq 5000\text{ ppm}$;	ND
	N,N-dimethylformamide $\leq 880\text{ ppm}$	ND
	Acetic acid $\leq 0.5\%$.	ND
含量 Assaying	$\geq 99.2\%$	99.90%

结论 Conclusion:

符合企业标准 Conforms to the requirements of Enterprise Specification

签发人:
Director:

复核人:
Checked by:

检验人:
Tested by: