



Certificate of Analysis

Product name	Nitazoxanide	Manufacture date	Jun.25.2023
Batch number	FQ230625	Analysis date	Jun.26.2023
Batch quantity	500kg	Expiry date	Jun.25.2025

Tests	Standards	Results
Appearance	White or almost white crystalline powder	White crystalline powder
Identification	A:IR absorption	Complies
	B:UV absorption	Complies
	C:TLC	Complies
Melting point	168~172 °C	169.0~170.9 °C
Water	Not more than 0.5%	0.08%
Related substance	Impurity J not more than 10 ppm	2ppm
	Impurity K not more than 50 ppm	15 ppm
	Impurity F not more than 0.05%	Not detected
	Any other impurity not more than 0.05%	0.01%
	Total of other impurities not more than 0.1%	0.02%
Residue on ignition	Not more than 0.1%	0.05%
Chloride	Not more than 0.014%	Less than 0.014%
Sulfate	Not more than 0.02%	Less than 0.02%
Sulfide	Conforms	Conforms
Heavy metals	Not more than 0.001%	Less than 0.001%
Free p-aminophenol	Not more than 0.005%	Less than 0.005%
Limit of P-chloroacetanilide	Not more than 0.001%	Less than 0.001%
Readily carbonizable substances	Conforms	Conforms
Residual solvents	Residual content of acetic acid is limited by the test of loss on drying not more than 0.5%	0.08%
Assay(anhydrous basis)	99.0~101.0%	99.6%

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place not freeze., keep away from strong light and heat
Shelf life:	2 years when properly stored

Quality Assurance Officer: 李强

Corrector: 佟丽华

Analyst: 方琼

