



Certificate of Analysis

Product name	Domperidone	Manufacture date	Jun.09.2023
Batch number	SW230609	Analysis date	Jun.10.2023
Batch quantity	500kg	Expiry date	Jun.09.2025

Characteristic/method	Specification	Result
Appearance	White Crystalline powder	Conforms
Solubility	Practically insoluble in water, soluble in dimethylformamide, slightly soluble in ethanol	Conforms
Identification	A. M.P. 244~248℃	244.5~245.5℃
	B. IR should comply	Conforms
	C. TLC should comply	Conforms
	D. It gives the reaction of non-nitrogen substituted barbiturates	Conforms
Clarity of solution	The solution is clear and not more intensely colored than reference solution Y6	Conforms
Related substances	Total impurity $\leq 0.5\%$	$\leq 0.29\%$
	Individual impurity $\leq 0.25\%$	$\leq 0.18\%$
Heavy Metals	$\leq 20\text{ppm}$	Conforms
Loss on drying	$\leq 0.5\%$	0.07%
Sulphated ash	$\leq 0.1\%$	$\leq 0.05\%$
Assay	99.0%-101.0%	99.49%
Conclusion	Conforming to Enterprise Standard	

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place. keep away from strong light and heat
Shelf life:	2 years when properly stored

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