

Certificate of Analysis

Product name	Domperidone		
CAS No.	57808-66-9	Manu.Date	2016.10.03
Batch No.	151201M	Anal.Date	2016.10.09
Quality standard	EP7.0	Exp. Date	2018.10.02

Test items	Standards	Results
Appearance	White or off-white powder	White powder
	Practically insoluble in water, soluble in dimethylformamide, slightly soluble in ethanol (96 percent) and in methanol.	Complies
Identification	A.Melting poing: 244~248°C B.IR: Should comply C.TLC: Should comply D.	245.6~246.2°C Complies Complies Complies
	It gives the reaction of non-nitrogen substituted barbiturates.	
Appearance	The solution is clear and not more intensely coloured than reference solution Y ₆ .	Complies
Related substance	Total impurities ≤0.5%	0.28%
	Individual impurity ≤0.25%	0.18%
Loss on drying	≤0.5%	0.17%
Sulphaed ash	≤0.1%	0.06%
Heavy metals	≤20ppm	<20ppm
Assay	99.0~101.0%	99.85%
Conclusion: Complies to the EP7.0 Standards.		