

Domperidone EP10.0

Batch no

230516-3

Mf date

May 19 2023

Retest

May 18 2026

Molecular Structure

Molecular Formula

 $C_{22}H_{24}CIN_5O_2$

Molecular Weight

425.9

CAS Registry Number

57808-66-9

Aug 15 2023

Tests	Specifications				Results
Appearance	White or off-white	crysta	Iline powder		Conforms
Solubility	Practically insolu		100 N 100 N		Conforms
	dimethylformamide,			ol (96%)	
	& in methanol		•		
Identification	IR, TLC				Positive
Melting point	244 ~ 248°C				244.7 ~ 247.3°C
Appearance of solution	The solution is cle	ar & co	lorless		Conforms
Loss on drying	≤ 0.5%				0. 17%
Sulfated ash	≤ 0.1%				0. 04%
Related substances	Impurity A	≤	0. 25%		0. 1%
	Impurity B	≤	0. 25%		0. 06%
	Impurity C	<u><</u>	0. 25%		ND
	Impurity D	≤	0. 25%		0. 16%
	Impurity E	≤	0. 25%		0. 04%
	Impurity F	≤	0. 25%		0. 02%
	Total impurities	<	0. 5%		0. 28%
Residue on ignition	≤ 0.10%				0. 05%
Heavy metals	≤ 20 ppm				< 20 ppm
Assay (odb)	99.0 ~ 101.0% of C ₁₀	$H_{20}N_2S_4$			99. 8%

Packaging & storage Protected from light		
Conclusion	Material complies with EP10.0	_

