

Domperidone EP10.0

Batch no

241116-4

Mf date Retest Nov 16 2024 Nov 15 2027

Molecular Structure

Molecular Formula

 $C_{22}H_{24}CIN_5O_2$

Molecular Weight

425.9

CAS Registry Number

57808-66-9

Jan 09 2025

Tests	<u>Specifications</u>				Results
Appearance	White or off-white	crystalline powd	er		Conforms
Solubility	Practically insolub				Conforms
82.	dimethylformamide,			(96%)	
	& in methanol	originary conducto	· · · · · · · · · · · · · · · · · · ·	(00/0)	
Identification	IR, TLC				Positive
Melting point	244 ~ 248°C				244.6 ~ 247.1°C
Appearance of solution		ar & colorless			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. 07%
	Impurity C	≤ 0.25%			ND
	Impurity D	≤ 0.25%			0. 17%
	Impurity E	≤ 0.25%			0. 04%
	Impurity F	≤ 0.25%			0. 01%
	Total impurities	≤ 0.5%			0. 28%
Residue on ignition	≤ 0.10%	- E			0. 06%
Heavy metals	≤ 20 ppm	a ·			< 20 ppm
Assay (odb)	99.0 ~ 101.0% of C ₁₀ l	$H_{20}N_2S_4$			99. 8%
	g e a				

Packaging & storage	Protected from light				
Conclusion	Material complies with EP10.0	F. 88	<i>y</i>		

