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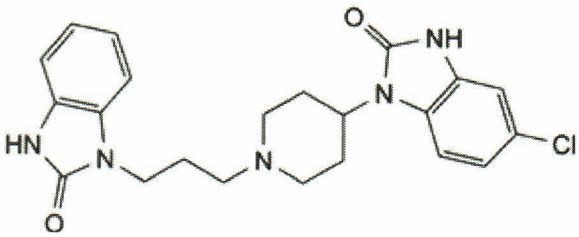
Domperidone EP10.0

Batch no	230516-3
Mf date	May 19 2023
Retest	May 18 2027

Molecular Structure



Molecular Formula	$C_{22}H_{24}ClN_5O_2$
Molecular Weight	425.9
CAS Registry Number	57808-66-9

May 08 2026

Tests	Specifications		Results
Appearance	White or off-white crystalline powder		Conforms
Solubility	Practically insoluble in water, soluble in dimethylformamide, slightly soluble in ethanol (96%) & in methanol		Conforms
Identification	IR, TLC		Positive
Melting point	244 ~ 248℃		244.7 ~ 247.3℃
Appearance of solution	The solution is clear & 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%	0.06%
	Impurity C	≤ 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