

Certificate of Analysis

Product Name: Esomeprazole Magnesium D.R. Pellets 22.5%				CAS. No. : ---	
Batch No. : P/EOM 0020304		QC No. : QC-022822		Total Weight: 50.0 Kg	
Date of Analysis: 1404/03/18		Mfg. Date: 1404/03		Exp. Date: 1406/02	
Test		Specification		Reference	Result
Description		White to off white pellets.		In House	Complies
Identification		0.98 -1.02		USP46	1.00
Water, percent		NMT 5.0		USP46	3.65
Dissolution (Test 1), percent	Buffer Stage	After 30 min	Minimum	USP46	96.2
			Maximum		99.0
		NLT 75 (Q)	Average		97.2
Assay, percent		90 to 110		USP46	99.5
Organic Impurities, percent	Omeprazole sulfone	NMT 0.5		USP46	0.06
	Any other individual imp.	NMT 0.2			0.13
	Total imp.	NMT 2			0.39
Residual solvents, ppm	Ethanol	NMT 5000		USP46	517
	Isopropyl alcohol	NMT 5000			ND
Particle Size, percent		NLT 95 Retain on #18 ASTM		In House	99.0
		NMT 5 Retain on #12 ASTM			0.0
Bulk Density , g/ml.		Between 0.7 – 1.0		In House	0.87
Microbial limit test	TAMC , CFU/g	NMT 10 ¹		USP46	<10
	TYMC , CFU/g	NMT 10 ²			<10
	Salmonella	Absent			Absent
	Escherichia Coli	Absent			Absent
	Staphylococcus aureus	Absent			Absent
	Pseudomonas aeruginosa	Absent			Absent
	Candida albicans	Absent			Absent