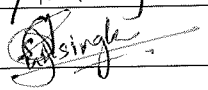
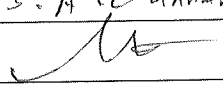


	STATE PHARMACEUTICALS MANUFACTURING CORPORATION			
	No.11, Sir John Kotelawala Mw., Kandawala Estate, Ratmalana, Sri Lanka.			
RAW MATERIAL STANDARD TEST SPECIFICATION				
OMEPRAZOLE DF PELLETS 8.5 %				
STS No.	FP/STS/085/00	Department	Quality Control	
Reference	IP 2022	Revision No	R-00	
Review Date	01 AUG 2025	Effective Date	01 AUG 2025	Page No. Page 1 of 1

Test Parameter & Acceptance Criteria

Sr. No:	Test Parameter	Acceptance Criteria
1.	Description	White spherical pellets
2.	Identification	In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak due to omeprazole in the chromatogram obtained with the reference solution.
3.	Bulk density	0.70 – 0.90 g/ml
4.	Assay	95.0% - 105.0%
5.	Loss on Drying	Not more than 3.0%
6.	Pellet size	NLT 95% pellets should pass through 12 mesh NMT 5% pellets should pass through 16 mesh
7.	Microbial Limit test	Bacteria : 1000 CFU/g Fungi : 100 CFU/g

	Prepared by	Checked by	Approved by
Name	S. N. Gunasinghe	S. A. Desma Medusmita	S. A. Chandrasiri
Signature			
Date	01.08.2025	01.08.2025	01.08.2025