Annexure I

SPMC	STATE PHARMACEUTICALS MANUFACTURING CORPORATION-SRI LANKA TRAMADOL DF GRANULES 50 mg SPECIFICATIONS	
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Test Parameter & Acceptance Criteria

S. No:	Test Parameter	Acceptance Criteria
1.	Description	White to off white colour granular powder free from extraneous matter.
2.	Identification By HPLC	The principal peak in the chromatogram obtained with the test solution corresponds to the peak peak in the chromatogram obtained with the reference solution.(In the Assay)
3.	Moisture Contemt (105^0C 03 Hours)	Not more than 4.0%
4.	Assay (By HPLC)	95.0% - 105.0% or 47.5mg – 52.5mg
5.	Related Substances (By HPLC)	Tramadol Impurity A NMT 0.3% Individual Unidentified Impurity NMT 0.2% Sum Of Impurities NMT 1.0%
6.	Microbial Limit test	Total Aerobic Viable Count -NMT 10^3cfu/g Total Combined Yeast and Moids Count -NMT 10^2cfu/g E . Coli -Shouldbe absent per g

	Prepared by	Reviewed by
Name	N. P. Kannangara	C. S. Obeysekera.
Signature	NPKannegan	C. Obeys
Date	05. 09. 2023	05. 09. 2023.

SPMC Quality Control Department
State Pharmaceuticals Manufacturing Corporation
No: 11, Sir John Kotelawala Mawatha,
Kandawala Estate, Ratmalana,
Sri Lanka.