Annexure I

SPMC	**STATE PHARMACEUTICALS MANUFACTURING CORPORATION-SRI LANKA** **THYROXINE SODIUM DC GRANULES 50 mcg SPECIFICATIONS**	
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Test Parameter & Acceptance Criteria

S. No:	Test Parameter	Acceptance Criteria
1.	Description	White to off white granular powder.
2.	Identification By HPLC	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.(In the Assay)
3.	Moisture Contemt (105^0C 03 Hours)	Not more than 7.0% w/w
4.	Assay (By HPLC)	90.0% - 110.0% or 45.0mg – 55.0mg (Label amount of Levothyroxine Sodium)
5.	Bulk Density	0.4 to 0.7 gm / ml
6.	Tapped Density	0.5 to 0.8 gm / ml
7	Liothyronine Sodium	The area of any peak corresponding to Liothyronine is NMT the area of the principal peak in the chromatogram obtained with reference solution (d)
8.	Microbial Limit test	Total Aerobic Viable Count - NMT 10^3cfu/g Total Fungal Count - NMT 10^2cfu/g E . Coli - Should be absent per g

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