

LUPIN LIMITED

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July 25, 2025

Lupin Limited, Nagpur

TO WHOMSOEVER IT MAY CONCERN

This letter is with regards to product Sertraline Hydrochloride Tablets USP (25mg, 50mg and 100mg) supplied to the USA Market.

Sertraline Hydrochloride Tablets USP (25mg, 50mg & 100mg) is being manufactured by Lupin Limited, Nagpur and supplied to the USA market. Recently, as part of continuous product development, Lupin reformulated the subject drug product by reducing the weight of the tablets for each strength. In addition to this formulation change, the inclusion of an oxygen absorber in the final bottle pack.

Due to reduction in the weight of the tablets, dimensions of the tablets also changed; however, there is no change in the description of tablets and details are as follows:

Strength	25mg		50mg		100mg	
	Previous formulation	Current formulation	Previous formulation	Current formulation	Previous formulation	Current formulation
Dimension	7.0 × 4.0mm	6.9 X 4.0mm	10.3 × 4.2mm	10.1 X 4.2mm	13.1 × 5.2mm	12.1 X 5.2mm
Thickness	2.6 - 3.0mm	2.0–2.6mm	3.1 - 3.5mm	2.5-3.1mm	3.9 - 4.5mm	3.5-4.1mm
Theoretical weight of tablet	309.000mg	247.200mg	154.500mg	123.600mg	77.250mg	61.800mg
Description	Green colored, capsule shaped, biconvex, film coated tablets debossed with 'L' and 'U' on either side of the break line on one side and 'D01' on the other side.		Blue colored, capsule shaped, biconvex, film coated tablets, debossed with 'L' and 'U' on either side of the break line on one side and 'D02' on the other side.		Yellow coloured capsules shaped, biconvex tablets, debossed with 'L' and 'U' on either side of the break line on one side and 'D03' on the other side.	

The subject changes have been implemented with prior approval of the FDA (United States Food and Drug Administration). Revised formulation batches are supplied to the market with revised label stating "New Formulation".

The above implemented changes may contribute to the difference in size of the tablets as compared with the previous formulation tablets, as previous formulation batches are also available in the market.

It is our goal to continuously deliver our best service and highest quality of products to our customers.

Regards,

Mr. R Saravanan

General Manager – Quality Assurance

Lupin Ltd, Nagpur – India.