Title	Analytical Method Validation Report for Assay of Levothyroxine sodium	
Product Name	Levothyroxine sodium	
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EVALUATION OF SYSTEM SUITABILITY:

Inject blank solution (solvent mixture) into the chromatograph and record the chromatogram.

Inject reference solution-a into the chromatograph and record the chromatograms.

Resolution between between peaks due to Liothyronine (Impurity-A) and Levothyroxine is not less than 5.0

Inject reference solution-(c) in replicate (Five) into the chromatograph and record the chromatograms.

% RSD of Levothyroxine peak in reference solution- (c) is not more than 1.0.

PROCEDURE:

Inject sample solution in (Duplicate) into the chromatograph and record the chromatogram.

Examine the blank chromatogram for any peak due to diluents and disregard corresponding peaks observed in the chromatogram of sample solution.

Retention time of Levothyroxine is about 12 min.

CALCULATION:

$$\% \text{ w/w Assay (OAB)} = \frac{As}{At} \times \frac{Ds}{Dt} \times \frac{100}{(100-M)} \times P$$

Where,

As= Average area due to of Levothyroxine peak in sample solution.
At= Average area due to of Levothyroxine peak in reference solution-c.
Ds= Dilution of Levothyroxine reference solution-c. (Weight ÷ Volume)
Dt= Dilution of sample (Weight ÷ Volume)
P= potency of Levothyroxine standard (% As such)
M=Moisture content (%w/w)

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Date	10/12/16	12/12/16	13/12/16