Validation of Dissolution Method of Levofloxacin 750 mg Tablet by High Performance Liquid Chromatography

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ABSTRACT

Dissolution test is needed to investigate the drug release of dosage form and its performance in vivo. The lot-to-lot quality of drug product is estimated by dissolution test. Research and validation of procedures of dissolution is of utmost significance during formation of new formulation and quality control. The process of dissolution should be adequately formulated and justified. This paper aims to summarize the creation and validation of dissolution procedure/s as well as to propose a feasible method of specificity, linearity, range, accuracy, and precision of the methods and limit of detection and limit of quantitation. Validation and development of dissolution test procedures may be an unwieldy process, in several dimensions. Techniques need to be generated and proven not only of the dissolution test technique per se, but also of some assay to determine the test outcomes [1]. This research aims at establishing, testing, and testing a strong dissolution process of Levofloxacin 750 mg tablets, using RP HPLC. The dissolution process will provide a reflection of what happens in vivo when administering the drug and assist in evaluating quality on a lot-to-lot basis and in the comparability of generic and brand-name products [2].

Key Words: Levofloxacin, HPLC, Assay, Method Validation, Dissolution, Chromatography

Levofloxacin:

Levofloxacin is an antimicrobial agent. It is administered in the treatment of several bacterial infections. It may be used as well to treat tuberculosis, meningitis, pelvic inflammatory diseases among some of its other uses

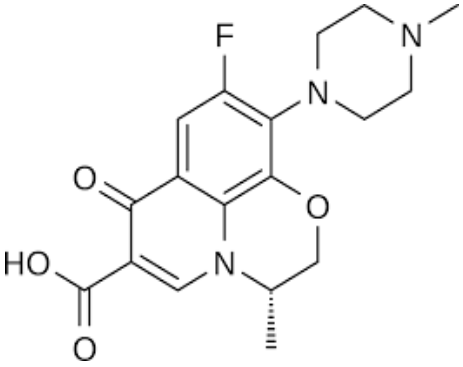

Fig 1: Structure of Levofloxacin

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Its use is not suggested as a rule of thumb under the circumstances when alternative services are available. It is administered through the mouth, intravenously and as eye drops. The side effects are very common, they are nausea, diarrhea, disturbing sleep. Tendon rupture, tendon inflammation, seizure, psychosis and possibly irreversible damage to peripheral nerves are potentially severe side effects. The damage on the tendons can be seen months after the treatment. Individuals can also get sun burned much easier. Myasthenia gravis may further deteriorate in terms of muscle weakness in affected people and difficulty with breathing. Although it was not suggested to be used during pregnancy, there seems to be low risk. Use of other drugs under this group seems to be safe during breast feeding, but the safety of the Levofloxacin is still uncertain. Levofloxacin is a general antibiotic belonging to the group of drugs obtained using the fluroquinolone. It normally leads to death of the bacteria. It is an isomer of the medicine ofloxacin which is left sided.

Levofloxacin was invented in 1985 and licensed to treatment in the US in 1996. It is available as generic drug. In the third world countries, the wholesale treatment costs approximately 0.44- 0.95 a week [3]. Approximately, a week of treatment in the US costs between 50-100. As of 2016 it ranked as the 161 to be prescribed most in the United States with over 3 million prescription numbers.

Aim:

Validation of dissolution procedure aims at proving that it is appropriate to the purpose of its implementation. Dissolution validation is relevantly significant in the role of developing pharmaceutical [4].

The aim and goal included to come up with a dissolution method to be used in the routine analysis of Levofloxacin 750mg tablet with RP-HPLC to analyze it. It is conducted to derive data that have potential in high quality, peak efficacy and safety of drug therapy in addition to peak economy in drug production [5]..

Objectives:

- ✓ To know the validation parameters of Levofloxacin that includes System Precision, Method Precision, Linearity [6].
- ✓ To know about the drug Levofloxacin in shortly.
- ✓ To minimize validation method and instrumental error.
- ✓ Assure consistent production performance.
- ✓ To give reliable and reproducible results in accordance with the given specification of the test method [7].
- ✓ To ensure the quality of test results.
- ✓ To assured of the correctness of results.
- ✓ To minimize rejection loss.
- ✓ Help timely corrective action.
- ✓ Reduce extensive and product testing.

The scope is the application of the validated methods for routine analysis which may be included in the pharmaceutical monograph in future.

LITERATURE REVIEW

Journal Name	International Journal of Advances in Pharmacy, Biology and Chemistry
Author Name	K. Srinivas
Method Name	RP-HPLC Method
Column Name	Phenomenex column 250 x 4.6 mm, 5µm
Mobile Phase	Orthophosphoric acid: Methanol (70:30)
Wave Length	230 nm
Run Time	30 min

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Flow Rate	1 ml /min
Journal Name	International Journal of Pharmaceutical and Clinical Research
Author Name	Shafrose Syed, Haritha Pavani
Method Name	Validated Simultaneous Estimation and Development of Levofloxacin.
Column Name	Hypersil BDS C18 Column
Mobile Phase	Acetonitrile (75:25)
Wave Length	315 nm
Run Time	8 min
Flow Rate	1 ml /min
Journal Name	International Journal of Pharmacy and Pharmaceutical analysis
Author Name	Vaddeswarapu Madhavi and Mandalapu Neehanika
Method Name	RP-HPLC Method
Column Name	Intersil ODS C18 column
Mobile Phase	Methanol
Wave Length	223 nm
Run Time	6 min
Flow Rate	1 ml /min
Journal Name	International Journal of Chemical Science
Author Name	CH. Narasimha Raju Bh,
Method Name	RP-HPLC Method
Column Name	Phenomenex column 250 x 4.6 mm, 5µm
Mobile Phase	Methanol
Wave Length	295 nm
Run Time	110 min
Flow Rate	1 ml /min
Journal Name	Research Gate Journal
Author Name	E Reddy, Raghuram Reddy
Method Name	Development and Validation of Levofloxacin
Column Name	Hypersil BDS C18 Column 120 A (250 x 4.6mm), 5µm
Mobile Phase	Acetonitrile and Methanol (60:40)
Wave Length	285 nm
Run Time	5 min and 3 min
Flow Rate	1 ml /min

Materials and Reagents:

The reference standard of Levofloxacin Hemihydrate (Potency 98.0%) was obtained from Eskayef Pharmaceutical Limited, Tongi, Gazipur 1711, Bangladesh and Levofloxacin (Trevox 750 mg and Levox 750 mg) tablets manufactured by Square Pharmaceuticals Limited and Opsonin Pharmaceutical Limited

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respectably were purchased from local pharmaceutical market (Table 1). HPLC grade acetonitrile from Korea, HPLC grade water from Thiland and Trifluoroacetic acid was obtained from Korea.

Table1. Lists of Materials

Material	**Manufacturer**
Levofloxacin Hemihydrate (Standard)	Eskayef Pharmaceutical Limited
Levofloxacin (Trevox)	Square Pharmaceutical Limited
Levofloxacin (Levox)	Opsonin Pharmaceutical Limited

Table 2. Lists of Reagents

Reagents	**Purity**	**Manufacturer**
Acetonitrile	HPLC grade	Daejung Chemical Co., Korea
Water	HPLC grade	RCI Labscan Ltd., Thailand
Trifluoroacetic acid	Reagent grade	Samchun Pure Chemical Co., Korea

Instrumentation:

Chromatographic analysis was performed on Adept series CECIL [8] (Cecil Instruments Ltd., Cambridge, UK) with power Stream Software in RP-HPLC (Fig-2). Adept CECIL system CE 4900 was equipped with 4102 gradient pump, CE 4300 UV detector and CE 4020 degasser. AGE injector from Australia was used for manual injection (Fig-3), Dissolution Tester RC-6 (Fig-4) from Korea was used.

Table 3. Lists of Instruments

Instruments	**Source**
HPLC	Cecil Instruments Ltd., Cambridge, UK
Dissolution Tester	Humanlab Instrument Co. Korea
Ultrasonic Cleaner	Spectrolab (England)
Electronic Balance	Thomas Scientific

Fig. 2: HPLC

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Fig.3 - Microinjection

Fig. 4 - Dissolution Tester

Fig.5 - Ultrasonic

Fig.6 - Electronic Balance

Chromatographic Condition:

Column: An analytical reversed phase column C8 was used for analysis. Chromatographic was performed in ambient temperature.

Flow Rate: 0.3 ml/min

Detection: 295 nm

Runtime: 25 min

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Mobile Phase: Acetonitrile and Water with 0.15% Trifluoroacetic Acid (buffer). Mobile phase used in the following ratio (Table 4)

Table 4: Gradient Condition in Mobile Phase

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0	10	90
5	20	80
8	30	70
10	40	60
12	50	50
15	40	60
20	30	70
22	20	80
25	10	90

Preparation of mobile phase:

Mobile Phase- A:

Mobile phase A was prepared by adding 0.15% of Trifluoroacetic acid in 1L Acetonitrile.

Mobile Phase- B:

Mobile phase B was prepared by adding 0.15% of Trifluoroacetic acid in 1L Water.

Preparation of Blank:

86.9 ml conc. HCl is added in 10L water and 0.1N HCl was prepared.

Preparation of Standard:

The reference standard of Levofloxacin Hemihydrate 100 mg was weighted and taken in 100ml flask. After 10ml take from solution into another volumetric flask and make it 100ml. Therefore, per ml solution contains 100µg/ml [9].

Preparation of Sample:

Take 900 ml 0.1N HCl in dissolution tester 6 vessels [10]. Levofloxacin 750 mg 6 tablets (Trevox) and Levofloxacin 750 mg 6 tablets (Levox) were given to 6 vessels. So, conc. will be 1.16 mg/ml. After 30 min and 45 min 10 ml sample is collected from each vessel. After filtration 10 ml is taken and volume up to 50 ml with 0.1N HCl. So, conc. will be now 116 µg/ml [10].

Method Validation:

Method validation is the "process of establishing documented evidence" which provides a high degree of assurance [11]. The method was validated as per ICS guidelines. The method was validated by performing:

Parameters	**Dissolution**
System Precision	+

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Method Precision	+
Linearity	+

System Precision:

The system precision is checked by using standard chemical substance to ensure that the analytical system is working properly. [12].

Method Precision:

In method Precision, a homogenous sample of single batch should be analyzed 6 times. [13].

Linearity:

Linearity is the property of a mathematical relationship or function which means that it can be graphically represented as a straight line [14]. In analytically it directly proportional to the concentration of the analyte and sample. [15]

From stock solution 1, pipette out 6ml, 8ml, 10ml, 12ml, 14ml into 100 ml volumetric flask to get 60% 80% 100% 120% 140% of standard solution [16].

System Precision:

System Precision was determined by repeatability of the Levofloxacin hemihydrate standard solution [17]. The system precision of the method was evaluated by carrying out six determinations [18]. The areas of all injections were taken from Power Stream (Table-5); mean, standard deviation and % relative standard deviation was calculated. The calculation formula:

Standard deviation

$$\% \text{ RSD} = \frac{\text{Standard deviation}}{\text{Mean}} \times 100$$

Table 5: System Precision Data

Parameters	Data
Number of determinations(n)	6
Individual results (areas)	9373.3, 9355.2, 9386.7, 9402.3, 9397.2, 9483.5
Mean (area)	9399.7
Standard deviation (SD)	47.55
%RSD	0.51
Acceptance Criteria	Co-efficient of variation NMT 2.0%

*NMT = Not More Than

Result and Evaluation:

The system was precise, as the co-efficient of variation was less than 2.0%.

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Method Precision:

Dissolution sample Preparation:

10 ml Dissolution media containing drug was withdrawn from dissolution vessel after 30 minutes [19]. Then from this 7 ml was diluted to 50 ml. Then it was filtered and injected.

Table 6: Method Precision Data

Parameters	Data
Number of determinations(n)	6
Individual dissolution results (%)	92.18, 93.40, 96.03, 93.92, 91.60, 92.69
Mean	93.30
Standard deviation (SD)	1.57
Relative Standard Deviation (%RSD)	1.68
Acceptance Criteria	Co-efficient of variation NMT 2.0%

Result and Evaluation:

The method was precise, as the co-efficient of variation was less than 2.0%.

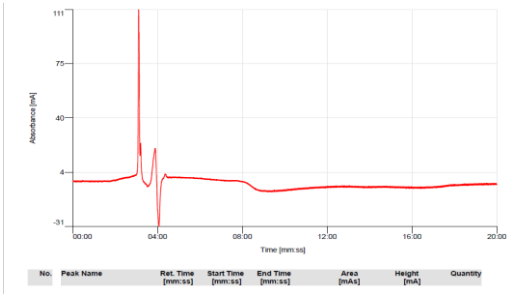

Figure 7: Blank chromatogram of Levofloxacin Dissolution

Naturally, the Figure 7 shows the blank chromatogram of the Levofloxacin dissolution by the HPLC, there is only one major peak, with large absorbance at the 4-minute mark and then with stable position at the end of 6 minutes without any notable peaks. This shows little interference or impurities in the blank sample.

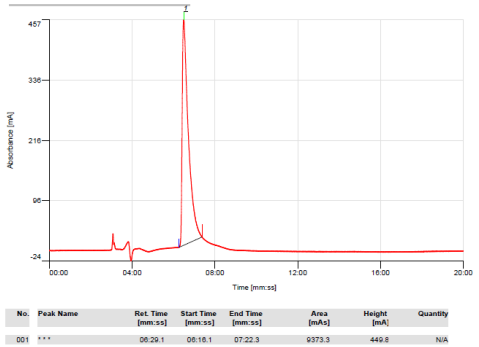

Figure 8: Standard chromatogram of Levofloxacin Dissolution

The standard chromatogram of the dissolution of Levofloxacin presented in Figure 8 indicates that there was a prominent peak at about 6.3 minutes whose absorbance was high to a level of about 450 mAU. This significant peak indicates Levofloxacin and the height should be constant and clear after this peak which proves the successful separation and purity of the standard solution.

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Linearity:

The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration of analyte in the sample.

Linearity with Standard Solution:

The linearity of peak area (y)/ concentration (x) of a dilution series was determined for standard solution in the range 60% - 140% (e.g. 60,80,100,120,140) % of the nominal concentration.

Table 7: Linearity Data

Concentration (µg/ml)	Area (mAs)
60	5553.8
80	7514.4
100	9373.3
120	11347.6
140	13310.7

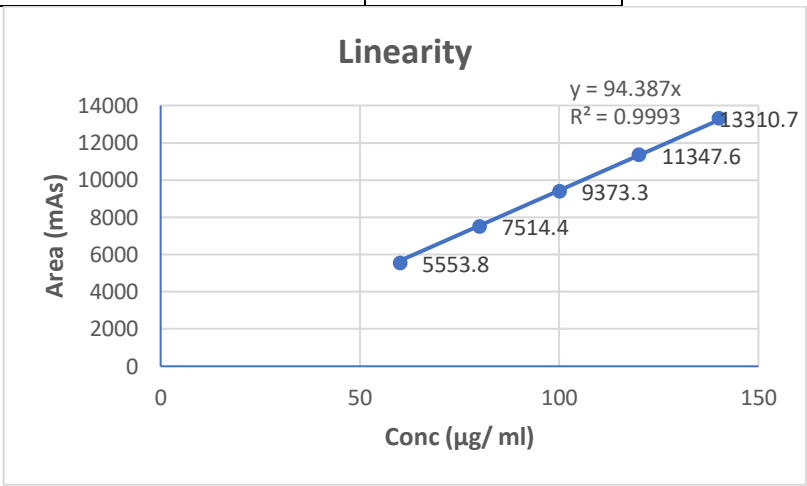

Figure 9: Levofloxacin Dissolution Linearity curve (60% -140%)

In Figure 9 it can be observed the Levofloxacin Dissolution Linearity at the concentration level of 60 percent to 140 percent. In the graph the regression equation was y = 94.387x and the correlation coefficient (R2) = 0.9999 showing that there was high linearity between concentration (ug/ml) and peak area (mAs). The findings affirm that the procedure is accurate and gives reliable consistent quantification over the concentration range that was tested.

Acceptance Criteria:

Correlation Coefficient, r2 is ≥ 0.999

Result and Evaluation:

The Correlation Coefficient, r2 was found 0.9993. This method is sufficient linear as the Correlation Coefficient, r2 is ≥ 0.999.

Range:

To determine the range of the method, 60% solution for 6 replicas and 140% solution for 6 replicas were injected and %RSD was calculated.

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Table 8: Data of Range

Ranges	Areas (mAs)	Average	Standard Deviation (SD)	% RSD	Remarks
60%	5553.8, 5592.3, 5409.5, 5529.7, 5486.0, 5543.4	5519.12	63.83	1.16	Complies
140%	13310.7, 13555.2, 13375.4, 13597.3, 13611.4, 13768.7	13536.45	167.64	1.24	Complies

Acceptance Criteria:

Method is suitable if co-efficient of variation is less than 2.0% for each level.

Result and Evaluation:

The method is suitable as %RSD is within limits.

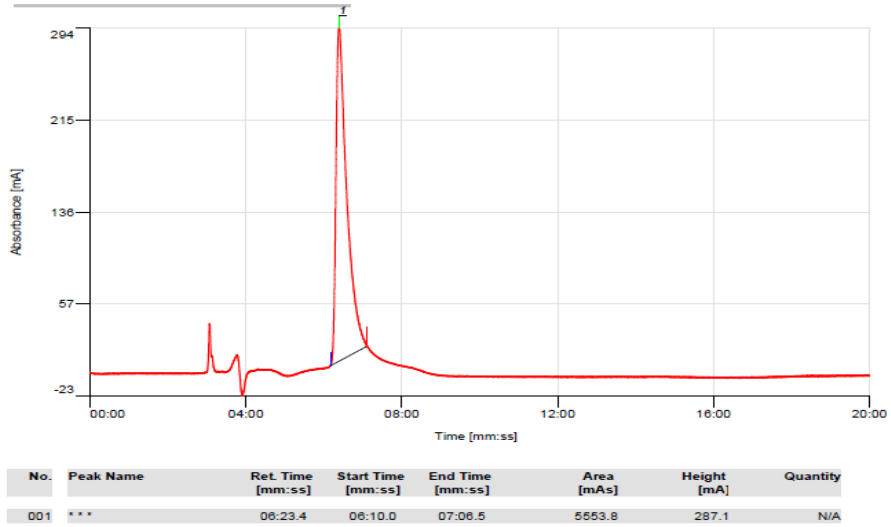

Figure 10: Chromatogram of Levofloxacin at Range 60%

The chromatogram shown in Figure 10 is that of Levofloxacin at 60% concentration. The retention time of 6.23 is a sharp, symmetrical peak which shows good separation and detection. It has a peak area of 5553.8 mAs and a height of 287.1 mA which indicates the correct quantification of the analysis at this concentration level.

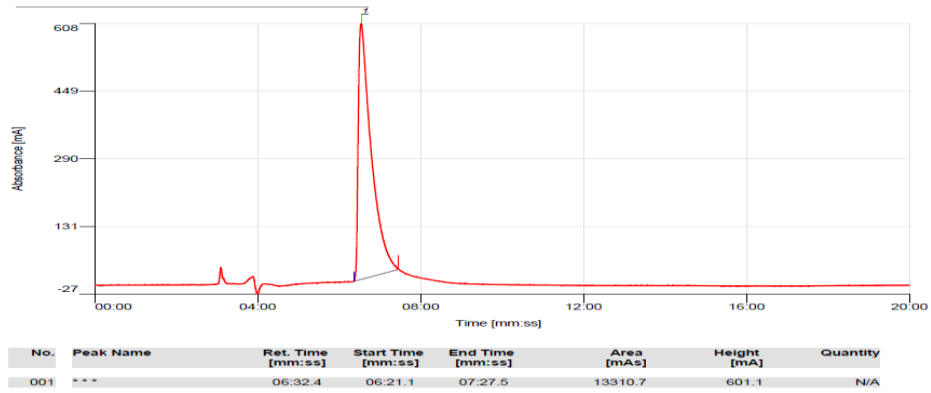

Figure 11: Chromatogram of Levofloxacin at Range 140%

It is yet easy to understand through the presentation of Figure 11 that the chromatogram of the Levofloxacin at concentration of 140 percent. At 6.32 minutes, there is a sharp and well-defined peak which has an excellent resolution. its highest area is 13310.7 mAs and a height is 601.1 mA meaning omnipotent detector reaction and excellent linearity at this degree of concentration.

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Percentage of Dissolution of Levofloxacin (Trevox) 750 mg Tablet After 30 minutes:

Standard Solution				**Sample Solution**		**After 30 minutes**
Replica	**Area of Std (mAs)**		Replica	Area (mAs)	Average Area (mAs)	% of Dissolution
1	9373.3	Tab1	1	9967.0	10050.85	92.18
2	9355.2		2	10134.7		
3	9386.7	Tab2	1	10234.2	10184.45	93.40
4	9402.3		2	10134.7		
5	9397.2	1	10452.3		10470.45	96.03
6	9483.5	2	10488.6			
Average	**9399.7**	1	10192.8		10240.75	93.92
		2	10288.7			
		1	9953.2		9987.75	91.60
		2	10022.3			
		1	10024.4		10106.35	92.69
		2	10188.3			
					Average	**93.30**

Acceptance Criteria:

After 30 minutes dissolution should be ≥70%

Result and evaluation:

From the above table all tablets (6 tablets) comply the acceptance criteria.

Percentage of Dissolution of Levofloxacin (Trevox) 750 mg Tablet After 45 minutes:

Standard Solution				**Sample Solution**		**After 45 minutes**
Replica	**Area of Std (mAs)**		Replica	Area (mAs)	Average Area (mAs)	% of Dissolution
1	9373.3	Tab1	1	10220.9	10328.2	94.72
2	9355.2		2	10435.4		
3	9386.7	Tab2	1	11044.3	11000.3	100.89
4	9402.3		2	10956.3		
5	9397.2	Tab3	1	10753.7	10594.25	97.16
6	9483.5		2	10434.8		
Average	**9399.7**	Tab4	1	10356.8	10472.65	96.05
			2	10588.5		
		Tab5	1	10972.5	10917.4	100.13
			2	10862.3		
		Tab6	1	11054.1	11064.75	101.48
			2	11075.4		
					Average	**98.40**

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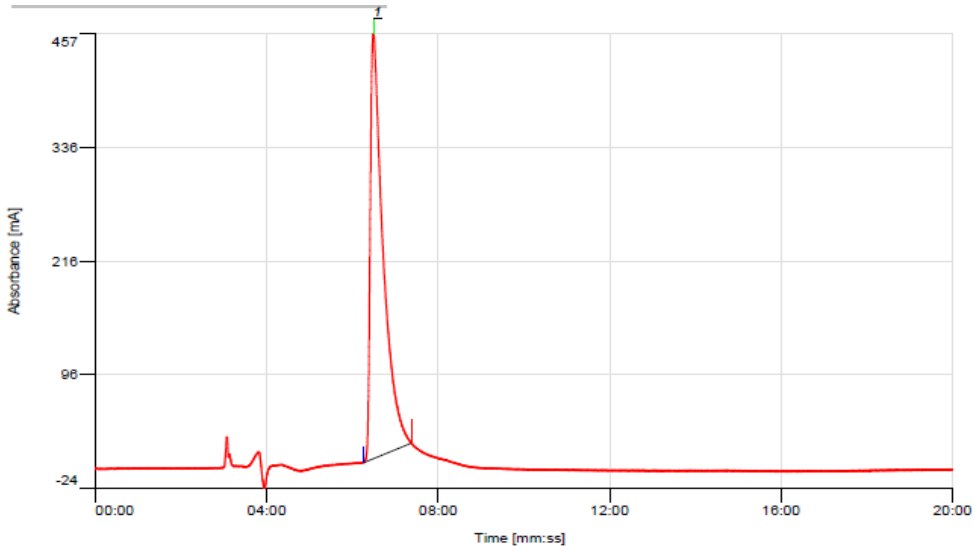
Acceptance Criteria:

After 45 minutes dissolution should be ≥75%

Result and evaluation:

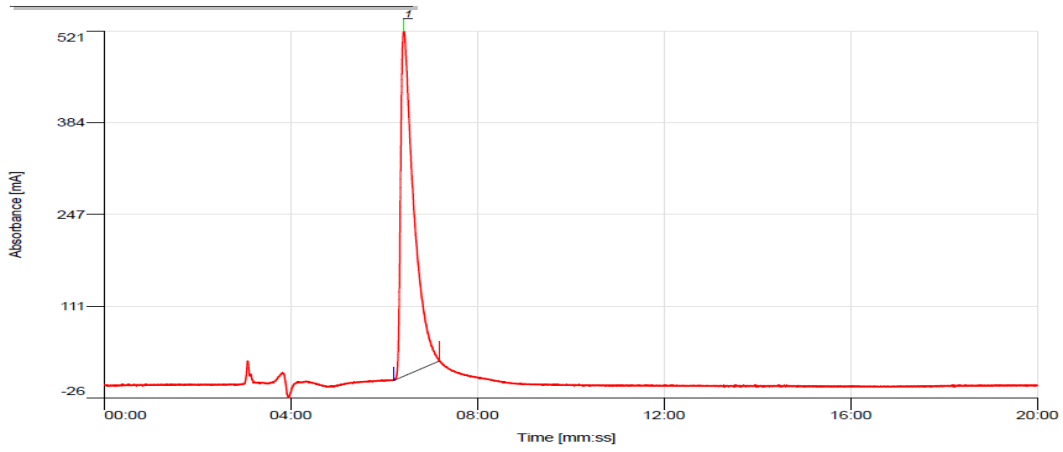
From the above table all tablets (6 tablets) comply the acceptance criteria.



No.	Peak Name	Ret. Time [mm:ss]	Start Time [mm:ss]	End Time [mm:ss]	Area [mAs]	Height [mA]	Quantity
001	* * *	06:29.1	06:16.1	07:22.3	9373.3	449.8	N/A

Figure 12: Standard chromatogram of Levofloxacin

The normal chromatogram of levofloxacin can be seen in figure 12 and indicates that there was sharp and prominent peak at 6.29 minutes of retention time. High purity and correct resolution are also denoted by the peak. Proper detection and quantification is attested by the area under the curve of 9373.3 mAs and a height of 440.8 mA.



No.	Peak Name	Ret. Time [mm:ss]	Start Time [mm:ss]	End Time [mm:ss]	Area [mAs]	Height [mA]	Quantity
001	* * *	06:25.4	06:12.8	07:11.3	9967.0	515.0	N/A

Figure 13: Dissolution Chromatogram of Levofloxacin (Trevox) 750 mg Tablet after 30 minutes

Understandably, in the Figure 13, the dissolution chromatogram of the Levofloxacin (Trevox) 750 mg tablet 30 minutes later with a clear peak at a retention strength of 6.25 minutes. The sharp peak that has an area of 9967.0 mAs and the height of 515.0 mA allows attaining efficient drug release and a good chromatographic resolution.

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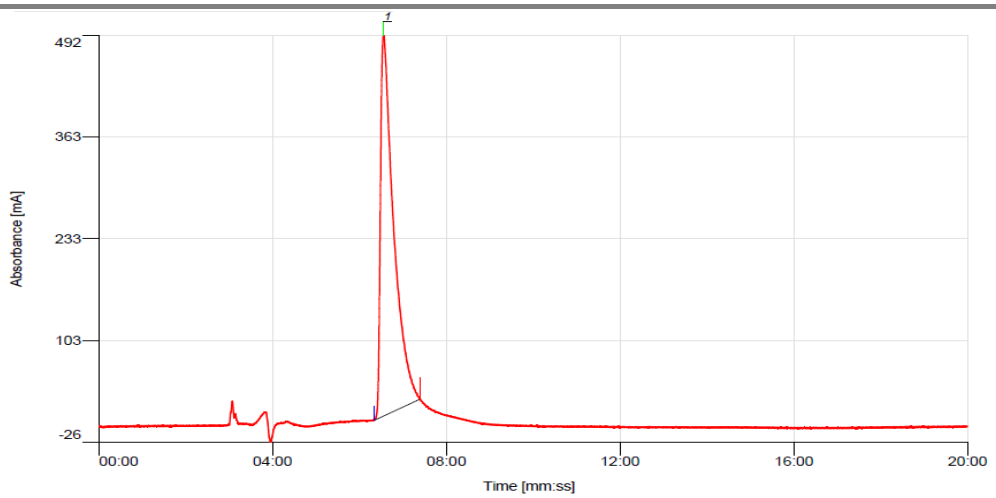

No.	Peak Name	Ret. Time [mm:ss]	Start Time [mm:ss]	End Time [mm:ss]	Area [mAs]	Height [mA]	Quantity
001	* * *	06:33.4	06:20.0	07:23.4	10220.9	485.2	N/A

Figure 14: Dissolution Chromatogram of Levofloxacin (Trevox) 750 mg Tablet after 45 minutes

Figure 14 depicts the dissolution chromatogram of Levofloxacin (Trevox) 750 mg tablet 45 minutes later and a sharp and well-defined peak is observed in 6.33 minutes. An area of 10220.9 mAs and a height of 485.2 mA appear in the chromatogram and it is a marker of successful dissolution and that the drug is released in a stable way.

Percentage of Dissolution of Levofloxacin (Levox) 750 mg Tablet After 30 minutes:

Standard Solution				**Sample Solution**		**After 30 minutes**
Replica	**Area of Std (mAs)**		Replica	Area (mAs)	Average Area (mAs)	% of Dissolution
1	9373.3	Tab1	1	10291.2	10211.15	93.65
2	9355.2		2	10131.1		
3	9386.7	Tab2	1	9978.5	9917.4	90.95
4	9402.3		2	9856.3		
5	9397.2	Tab3	1	10176.5	10215.9	93.69
6	9483.5		2	10255.3		
Average	**9399.7**	Tab4	1	9839.4	9858.45	90.41
			2	9877.5		
		Tab5	1	10038.4	10071.25	92.37
			2	10104.1		
		Tab6	1	9956.3	9971.9	91.45
			2	9987.5		
					Average	**92.09**

Acceptance Criteria:

After 30 minutes dissolution should be ≥70%

Result and evaluation:

From the above table all tablets (6 tablets) comply the acceptance criteria.

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Percentage of Dissolution of Levofloxacin (Levox) 750 mg Tablet After 45 minutes:

Standard Solution				**Sample Solution**		**After 45 minutes**
Replica	**Area of Std (mAs)**		Replica	Area (mAs)	Average Area (mAs)	% of Dissolution
1	9373.3	Tab1	1	11198.9	11122.1	102.00
2	9355.2		2	11045.2		
3	9386.7	Tab2	1	10737.3	10720.1	98.32
4	9402.3		2	10702.9		
5	9397.2	Tab3	1	10978.2	10926.85	100.21
6	9483.5		2	10875.5		
Average	**9399.7**	Tab4	1	10522.7	10531.05	96.58
			2	10539.4		
		Tab5	1	10645.3	10577.35	97.01
			2	10509.4		
		Tab6	1	10976.2	10922.35	100.17
			2	10868.5		
					Average	**99.05**

Acceptance Criteria:

After 45 minutes dissolution should be ≥75%

Result and evaluation:

From the above table all tablets (6 tablets) comply the acceptance criteria.

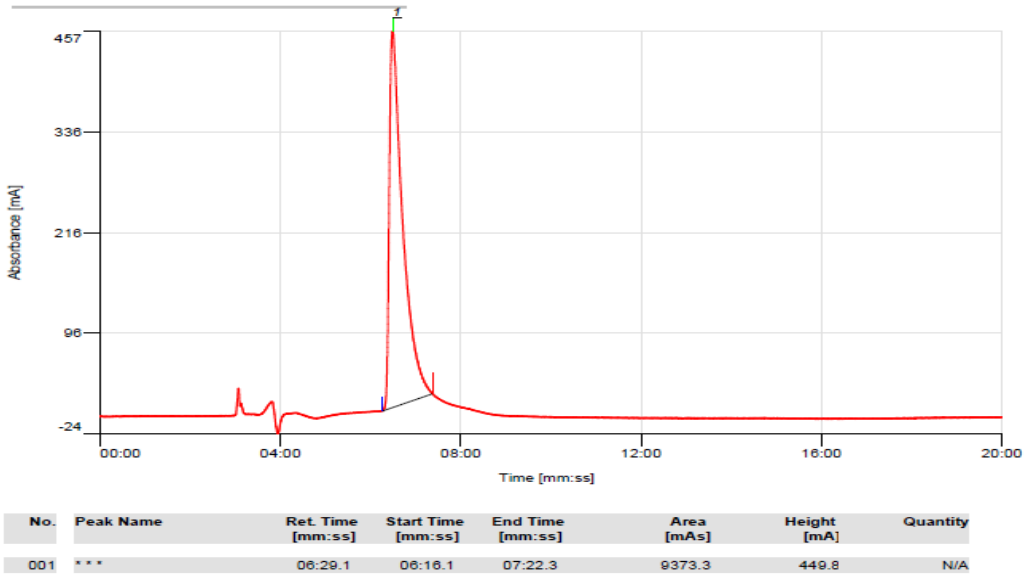

Figure 15: Standard chromatogram of Levofloxacin

The Figured 15 indicate the standard chromatogram of Levofloxacin showing a sharp and high peak with a retention of 6.29 minutes. The maximum value shows the presence, and purity of Levofloxacin, with an area of 9373.3 mAU*s and a height of 449.8 mAU, which proves correct separation of chromatography.

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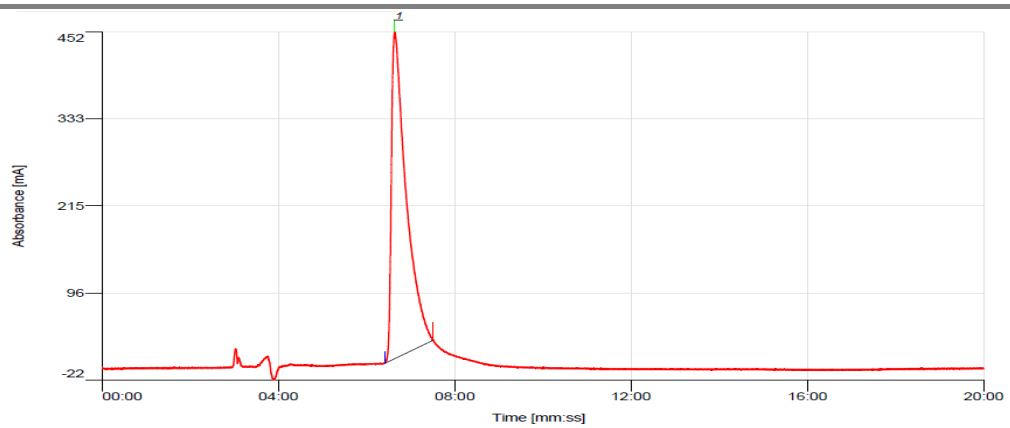
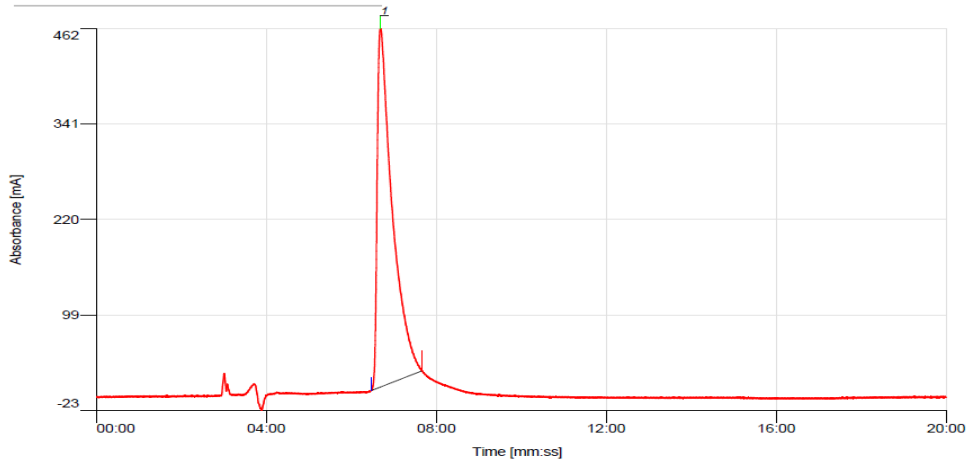


No.	Peak Name	Ret. Time [mm:ss]	Start Time [mm:ss]	End Time [mm:ss]	Area [mAs]	Height [mA]	Quantity
001	* * *	06:38.5	06:24.4	07:30.4	10291.2	445.1	N/A

Figure 16: Dissolution Chromatogram of Levofloxacin (Levox) 750 mg Tablet after 30 minutes

It can be well understood based on the figure 16 that the dissolution chromatogram of the Levofloxacin (Levox) 750 mg tablet after 30 minutes which shows a sharp peak with a retention time of 6.38 minutes. The chromatogram shows efficient drug release with the area of 10291.2 mAU+s and with the height of 445.1 mAU, which points to the coherent dissolution and performance of assays.



No.	Peak Name	Ret. Time [mm:ss]	Start Time [mm:ss]	End Time [mm:ss]	Area [mAs]	Height [mA]	Quantity
001	* * *	06:41.1	06:28.4	07:39.6	11198.9	455.7	N/A

Figure 17: Dissolution Chromatogram of Levofloxacin (Levox) 750 mg Tablet after 45 minutes

The figure 17 is the dissolution chromatogram of Levofloxacin (Levox) 750 mg tablet at the end of 45 minutes and it shows a sharp peak at 6.41 minutes. This chromatogram shows drug release was efficient with an area of 11198.9 mAU+s, height of 455.7 mAU, and indicates that the drug dissented well, and the assay was reliable.

CONCLUSION

The dissolution method for Levofloxacin 750 mg tablets, developed and validated in this study, demonstrated rapid, sensitive, precise, and accurate performance [20]. These met the predefined acceptance criteria with low variability (RSD well below 2%), and linearity showed excellent correlation ($r^2 \geq 0.999$) over the tested range [21]. The method produced consistent dissolution results at 30 and 45 minutes, with all tablets meeting the specified dissolution criteria (≥70% at 30 minutes and ≥75% at 45 minutes). The range and robustness assessments indicated suitability for routine quality control and comparability across brands. While stability testing could not be completed due to time constraints, the current data support the method's reliability for routine analyses and potential inclusion in pharmaceutical monographs after additional stability evaluation. Overall, the validated RP-HPLC dissolution procedure provides a practical, transferable approach for quality assurance of Levofloxacin 750 mg tablets in Bangladesh and similar settings.

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