INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Research Article

Development and Validation of UV Spectrophotometric and RP-HPLC Methods for Quantitative Estimation of Levosalbutamol Sulphate in Pharmaceutical Dosage Forms

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ARTICLE INFO

Published: 14 July 2026
Keywords:
Levosalbutamol Sulphate, RP-HPLC, UV Spectrophotometry, Method Validation, ICH Guidelines.
DOI:
10.5281/zenodo.21363263

ABSTRACT

Levosalbutamol sulphate is a selective β2-adrenergic agonist widely used in the treatment of asthma and chronic obstructive pulmonary disease. The present study aimed to develop and validate simple, accurate, precise, and economical UV spectrophotometric and RP-HPLC methods for the quantitative estimation of Levosalbutamol sulphate in pharmaceutical dosage forms. The UV method was developed using methanol as solvent with a maximum absorption wavelength of 226 nm, while the RP-HPLC method employed a Phenomenex Kinetex XB-C18 column using 0.1% orthophosphoric acid and acetonitrile (30:70 v/v) as the mobile phase. The developed methods were validated according to ICH Q2(R2) guidelines for specificity, linearity, accuracy, precision, robustness, limit of detection, and limit of quantification. Both methods showed excellent linearity (R^2 >0.999), satisfactory recovery, and low relative standard deviation. The validated analytical methods are suitable for routine quality control analysis of Levosalbutamol sulphate in pharmaceutical formulations.

INTRODUCTION

Levosalbutamol sulphate is the pharmacologically active R-enantiomer of salbutamol and is widely used as a selective β2-adrenergic receptor agonist for the treatment of bronchial asthma and chronic obstructive pulmonary disease (COPD). It produces bronchodilation by relaxing bronchial smooth muscles and provides rapid relief from airway obstruction. Compared with racemic salbutamol, levosalbutamol exhibits improved therapeutic efficacy and fewer cardiovascular adverse effects because it lacks the inactive S-enantiomer, which has been associated with undesirable pharmacological responses.[1-2]

Analytical quality control plays an essential role in ensuring the safety, efficacy, and consistency of pharmaceutical products. Reliable analytical methods are required for routine assay, dissolution

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

testing, stability studies, and quality assurance during manufacturing. The selected analytical method should provide high accuracy, precision, specificity, sensitivity, and reproducibility while remaining economical and simple to perform.[3] Among the available analytical techniques, UV-visible spectrophotometry is one of the most commonly employed methods because of its simplicity, rapid analysis, and cost-effectiveness. It is extensively used for routine quantitative estimation of pharmaceutical compounds. However, UV spectroscopy has limitations in selectivity when formulation excipients or degradation products interfere with drug estimation. Therefore, chromatographic techniques such as Reverse Phase High Performance Liquid Chromatography (RP-HPLC) are preferred for pharmaceutical analysis requiring higher sensitivity and specificity.[4]

RP-HPLC has become the analytical technique of choice in pharmaceutical industries because of its excellent resolution, reproducibility, short analysis time, and capability to separate analytes from impurities and degradation products. Method optimization involves selecting an appropriate stationary phase, mobile phase composition, flow rate, detection wavelength, and sample preparation conditions to achieve efficient chromatographic separation.[5] Before an analytical method can be routinely applied, it must undergo systematic validation to demonstrate its suitability for the intended purpose. According to the International Council for Harmonisation (ICH) guideline Q2(R2), analytical methods should be validated for specificity, linearity, accuracy, precision, robustness, limit of detection (LOD), limit of quantification (LOQ), and range. Proper validation ensures that the developed method consistently produces reliable and reproducible analytical results.[6] Several analytical methods have been reported for the estimation of bronchodilator drugs; however, there remains a need for a simple, rapid, economical, and fully validated method suitable for routine quality control laboratories.

The present investigation aimed to develop and validate both UV spectrophotometric and RP-HPLC methods for the quantitative estimation of Levosalbutamol sulphate in pharmaceutical dosage forms according to current ICH guidelines. The developed methods are expected to provide reliable analytical performance for routine pharmaceutical quality control and regulatory applications.

MATERIALS AND METHODS

Materials

Levosalbutamol sulphate reference standard (purity ≥99.0%) was obtained from a certified pharmaceutical manufacturer. Commercial tablet formulations containing Levosalbutamol sulphate were procured from the local market. HPLC-grade acetonitrile, methanol, orthophosphoric acid, HPLC-grade water, and analytical-grade chemicals were used throughout the study. All reagents complied with the specifications of the Indian Pharmacopoeia (IP) and were used without further purification. Glassware and volumetric apparatus were calibrated before use.[8]

Instrumentation

UV spectrophotometric analysis was carried out using a double-beam UV–Visible spectrophotometer equipped with 1 cm quartz cells. RP-HPLC analysis was performed using a high-performance liquid chromatographic system equipped with a quaternary pump, autosampler, PDA detector, and chromatography software. Separation was achieved using a Phenomenex Kinetex XB-C18 column (150 × 4.6 mm, 5 µm).[9]

UV Spectrophotometric Method

A standard stock solution of Levosalbutamol sulphate was prepared in methanol. The solution was scanned between 190–400 nm, and the maximum absorbance (λmax) was found at 226 nm. Working standard solutions were prepared in the concentration range of 40–60 µg/mL. The absorbance of each solution was measured at 226 nm, and a calibration curve was constructed by plotting absorbance against concentration. The developed method was validated for linearity, accuracy, precision, repeatability, LOD, and LOQ according to ICH Q2(R2) recommendations.[10]

RP-HPLC Method Development

Chromatographic separation was achieved using a Phenomenex Kinetex XB-C18 column (150 × 4.6 mm, 5 µm). The optimized mobile phase consisted of 0.1% orthophosphoric acid and acetonitrile (30:70, v/v), delivered at a flow rate of 1.0 mL/min. The injection volume was 10 µL, the detection wavelength was 226 nm, and the total run time was 10 min. Before use, the mobile phase was filtered through a 0.45 µm membrane filter and degassed by ultrasonication. Standard and sample solutions were prepared using the optimized diluent and filtered before injection into the HPLC system.[11]

Method Validation

The developed UV spectrophotometric and RP-HPLC methods were validated in accordance with ICH Q2(R2) guidelines. Validation parameters included specificity, linearity, accuracy, precision, repeatability, robustness, limit of detection (LOD), and limit of quantification (LOQ). Linearity was evaluated over the concentration range of 80–120% of the working concentration. Accuracy was determined by recovery studies at 80%, 100%, and 120% concentration levels. Precision was assessed by intraday and interday studies, while robustness was evaluated by small deliberate variations in wavelength and column temperature.[12]

Statistical Analysis

Experimental results were expressed as mean ± standard deviation. Calibration curves were generated by linear regression analysis, and the correlation coefficient (R^2) was calculated to evaluate linearity. Statistical parameters including regression equation, standard deviation, relative standard deviation (%RSD), LOD, and LOQ were calculated using Microsoft Excel and chromatography software. Acceptance criteria were evaluated according to ICH validation requirements.[13]

RESULTS AND DISCUSSION

Organoleptic attributes:

- **Color:** White to almost white crystalline powder
- **Smell (Odor):** Odorless
- **Taste:** Slightly bitter

Physical parameters:

Melting point of Levosalbutamol sulphate: 187–190°C

Solubility:

The solubility of levosalbutamol sulphatewas determined in various solvents as shownin Table 1.

Table No.1 Solubility Chart

Solvent	Solubility Description
Water	Freely soluble
Methanol	Soluble
Ethanol	Slightly soluble
Chloroform	Practically insoluble
Acetone	Slightly soluble
Ether	Practically insoluble

Dilute Hydrochloric Acid	Soluble
Phosphate Buffer (pH 6.8)	Soluble

UV

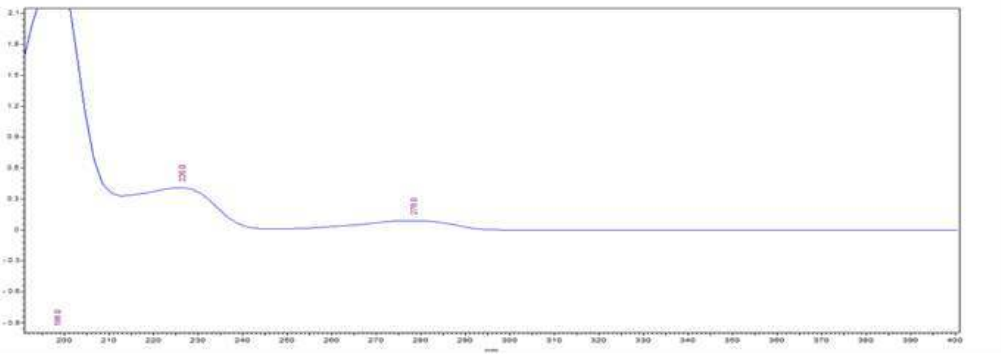


Figure 1 UV-Visible absorption spectrum of levosalbutamol sulphate in the selected solvent.

Table: 2 Absorbance Data and % Assay Results of Levosalbutamol Sulphate by UV Spectrophotometric Method

Sample	LSB	
	Absorbance	% Assay
1	0.489	98.99
2	0.491	99.39
3	0.490	99.19
4	0.492	99.60
5	0.491	99.39
6	0.492	99.60
AVG		99.36
STDEV		0.24
RSD		0.24

Table: 3 UV Spectrophotometric Repeatability Data of Sample (100% Concentration)

Sample ID	Absorbance
100% Rep 1	0.493
100% Rep 2	0.494
100% Rep 3	0.495
100% Rep 4	0.494
100% Rep 5	0.491
100% Rep 6	0.494
AVG	0.494
STDEV	0.001
RSD	0.28

UV Repeatability

UV repeatability refers to the ability of a UV spectrophotometric method to produce consistent and similar absorbance values when the same sample is measured multiple times under identical conditions. It is an important parameter in method validation that ensures the precision and reliability of the analytical method. In the given data, the sample at 100% concentration was analyzed six times (Replicates 1–6). The absorbance values are very close to each other, showing minimal variation. The mean absorbance was 0.494 with SD0.001 and relative standard deviation (RSD) of **0.28%**.

UV Linearity

Table: 4 Linearity data of the UV spectrophotometric method at five concentration levels.

% Level	Concentration (ug/ml)	Absorbance
80	40	0.394
90	45	0.441
100	50	0.493
110	55	0.544
120	60	0.593

The calibration curve exhibited an excellent linear relationship over the studied concentration range.

LOD and LOQ of levosalbutamol

Table:5 Regression Statistics of UV Spectrophotometric Method for Linearity Study

Regression Statistics	
Multiple R	0.999882491
R Square	0.999765
Adjusted R Square	0.999686662

Standard Error	0.001402379
Observations	5

ANOVA

Table: 6 ANOVA, Regression Analysis, and LOD & LOQ Determination of UV Spectrophotometric Method for Levosalbutamol

	df	**SS**	**MS**	**F**	**Significance F**
Regression	1	0	0	12763	1.52908
Residual	3	0	0		
Total	4	0			
	Coefficients	***Standard Error***	***t Stat***	***P-value***	
Intercept	0	0	-2	0	
X Variable 1	0	0	113	0	
LOD & LOQ of Levosalbutamol			**LOD**	1.48	ug/ml
			LOQ	4.47	ug/ml

% Level	**Reps**	**Spiked Conc (ug/ml)**	**Abs**	**Amount Recovered (ug/ml)**	**% Recovery**	**AVG**	**STD EV**	**RSD**
80	Rep 1	40.00	0.393	39.78	99.44	99.44	0.25	0.25
	Rep 2	40.00	0.394	39.88	99.70			
	Rep 3	40.00	0.392	39.68	99.19			
100	Rep 1	50.00	0.493	49.90	99.80	100.00	0.20	0.20
	Rep 2	50.00	0.494	50.00	100.00			
	Rep 3	50.00	0.495	50.10	100.20			
120	Rep 1	60.00	0.593	60.02	100.03	100.03	0.17	0.17
	Rep 2	60.00	0.594	60.12	100.20			
	Rep 3	60.00	0.592	59.92	99.87			

Intra & Interday

Table: 7 Intraday and Interday Precision Data of UV Spectrophotometric Method

Condition	**Interval**	**Absorbance**	**% Assay**
Intraday	**Mrng WS**	0.494	-
	Mrng DP	0.489	98.99
	Evng WS	0.491	-
	Evng DP	0.486	98.98
Interday	**Day 2 WS**	0.475	-
	Day 2 DP	0.468	98.53
			0.27

The intraday and interday studies show consistent absorbance and % assay values, indicating good precision of the method within the same day and across different days.

The low variation (RSD ≈ 0.27%) confirms that the UV method is reliable and reproducible for routine analysis.

UV investigation

UV absorbance scanning should beperformed before HPLC method developmentto identify an appropriate detectionwavelength.

A. Choice of normal solvents

Solubility studies were done so as to locate an appropriate dissolvable in which tablet of Levosalbutamol are totally dissolvable and stable. Solvents like Water, Methanol, Ethanol, Chloroform, Acetone, Ether were pursued for checking solubility. Subsequent to surveying the dissolvability of medication in various dissolvable has been chosen and settled as regular dissolvable to watch other worldly qualities.

B. Study of spectra and selection of wavelength:

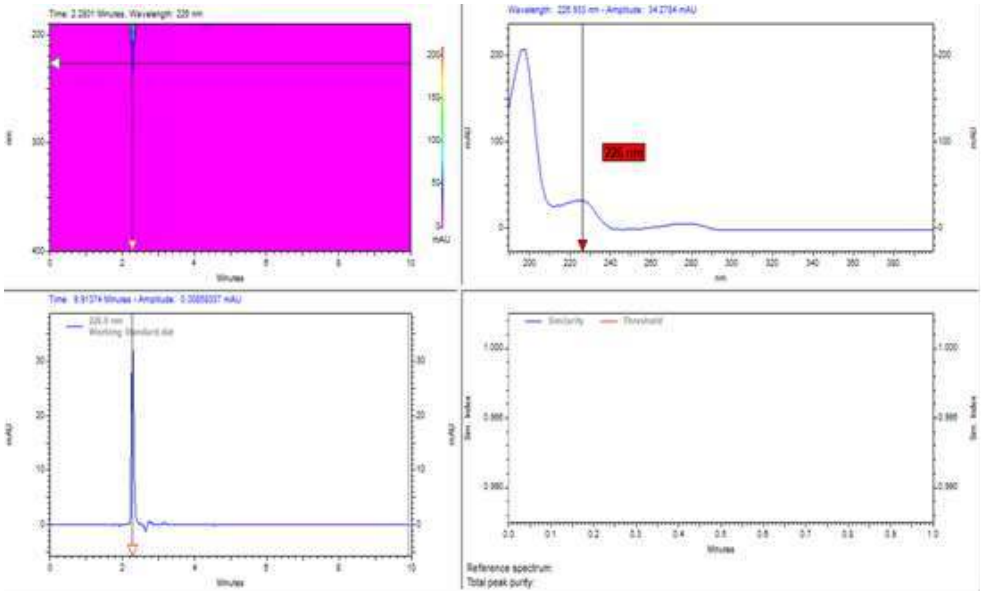


Figure No. 2 UV Spectrum of Levosalbutamol Sulphate showing λmax of 226 nm

HPLC Method Development:

Preparation of 0.1% O-phosphoric acid: In 1000 ml HPLC water, 1 ml of orthophosphoric acid was added and mixed well.

- Runtime: 10 minutes
- Injection Volume: 10 µl
- Wavelength: 226 nm
- Diluent: 0.1% O-phosphoric acid: Acetonitrile (50: 50, % v/v)
- Column: Phenomenex Kinetex XB-C18 (150 x 4.6 mm, 5µ)

Table: 8 Chromatographic Condition for optimization Method

Trial No.	Mobile Phase	Ratio	Diluent	Column	Wavelength	Flow rate (ml/min)	Runtime (minutes)
1	0.1% O-phosphoric Acid : Acetonitrile	50-50	50-50	Kinetex XB C18 (4.6 x 150mm 5-Micron	250 nm	1.00	10.00
2	0.1% O-phosphoric Acid : Acetonitrile	40-60	50-50	Kinetex XB C18 (4.6 x 150mm 5-Micron	226 nm	1.00	10.00
3	0.1% O-phosphoric Acid : Acetonitrile	35-65	50-50	Kinetex XB C18 (4.6 x 150mm 5-Micron	226 nm	1.00	10.00
4	**0.1% O-phosphoric Acid : Acetonitrile**	**30-70**	**50-50**	**Kinetex XB C18 (4.6 x 150mm 5-Micron**	**226 nm**	**1.00**	**10.00**
Levosalbutamol						**Observation**	
RT	**TP**	**Aysmmetry**	**Peak Purity**				
1.11	2734	1.13	1.00			The peak eluted too early and The theoretical plate count was low.	

1.36	4018	1.31	1.00	Retention time increased slightly and theoretical plates improved.
1.81	5453	1.31	1.00	Retention time increased by 0.5 minutes and theoretical plates also increased by 1400.
2.29	**6364**	**1.27**	**1.00**	**Retention time was 2.29 minutes which is acceptable and theoretical plates were around 6300. Final Method**

Standard Preparation:

Levosalbutamol Standard Stock Solution-I (LSSS-I):

Initially Prepare a Standard Stock Solution (LSSS-I) of by adding5 mg of Levosalbutamolin 100 ml volumetric flask & add 50 ml diluent, mix for 2 minutes and make the volume to 10 ml with diluent.

Further 1 ml of this solution was diluted to 10 ml using diluent. (Conc. Of Levosalbutamol= 5 µg/ml).

Drug Product Preparation:

Powder equivalent to 5 mg of drug was weighed in 100 ml volumetric flask and diluent was added upto the mark and sonicated for 5 minutes and further 1 ml of this solution was diluted to 10 ml using diluent.

Selection of Wavelength:

The sample was scanned from 190-400 nm with PDA detector. The Wavelength selected for analysis chosen was 226 nm basis of appropriate intensity of Levosalbutamol.

Method Validation:

a. Specificity and Assay:

Individual solution of Levosalbutamol working standard and Drug product was prepared of 5 µg/ml, respectively and peak was for identified from Retention Time. Blank was injected to ensure there is no blank peak interfering with the main analyte peaks.

Table: 9 Results for Assay

Sample ID	Levosalbutamol		
	RT	Area	Assay (%)
Blank	-	-	-
Working STD	2.28	315951	-
Drug Product	2.28	314754	99.62

b. Instrument Precision and System Suitability:

A single sample was prepared as described and 6 injections were made from same sample and checked for system suitability.

System suitability parameters are as below:

1. Retention Time,

2. Theoretical plates,

3. Asymmetry (Tailing factor),

4. Peak Purity.

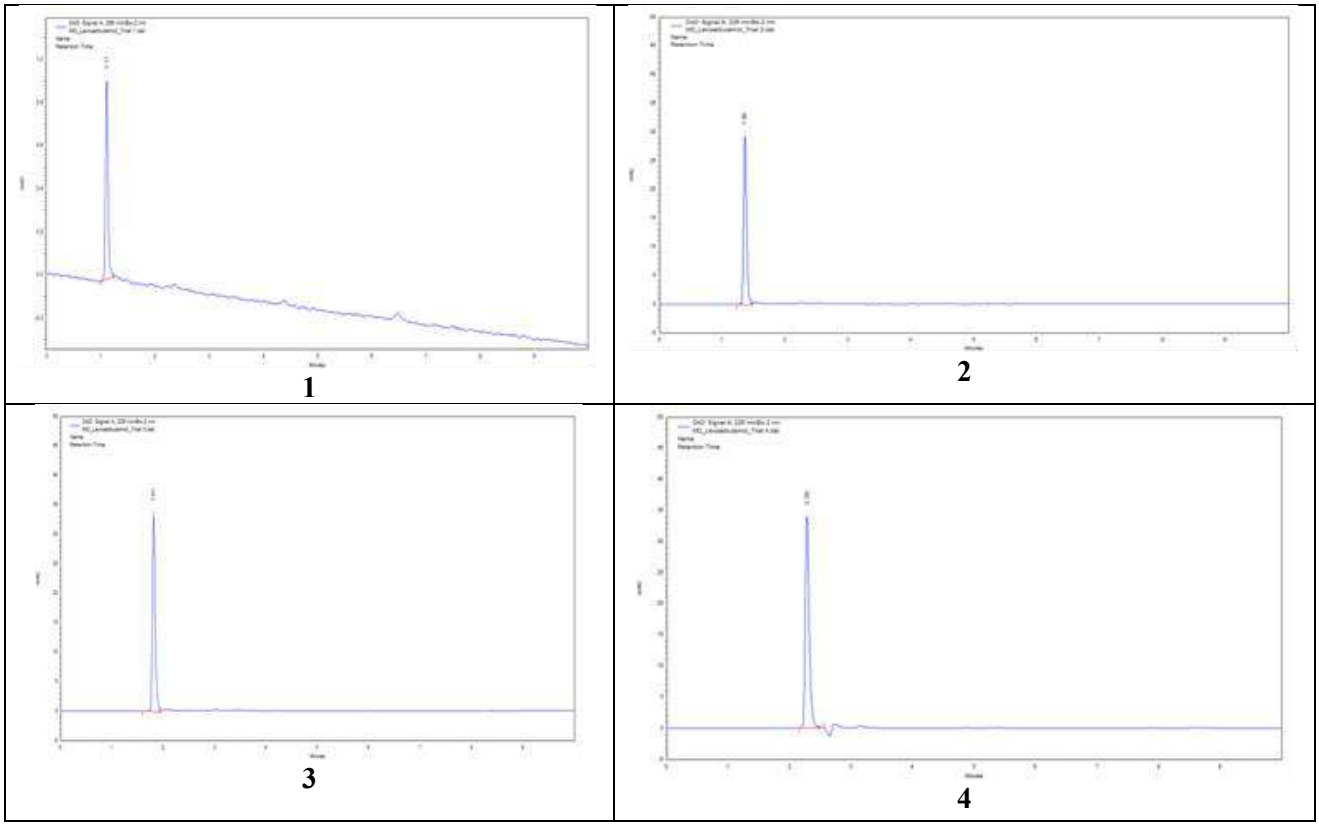


Fig No 3 Chromatogram of Chromatographic Condition 1,2,3 and 4

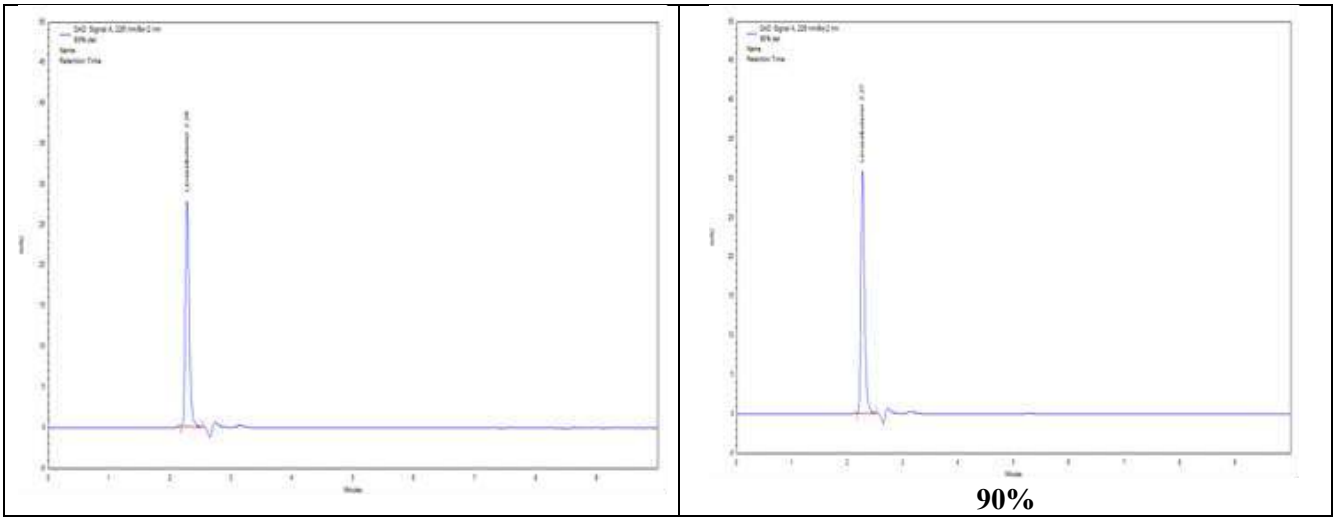
Linearity and Range:

Samples of varying concentrations ranging from 80%-120% were made.

The sample preparations and concentrations are given as below;

X ml of Levosalbutamol was added to 10 ml diluent to make up the concentrations given above:

% Level	X ml of LSSS-I	Levosalbutamol Conc. (µg/ml)
80	0.8	4.0
90	0.9	4.5
100	1.0	5.0
110	1.1	5.5
120	1.2	6.0



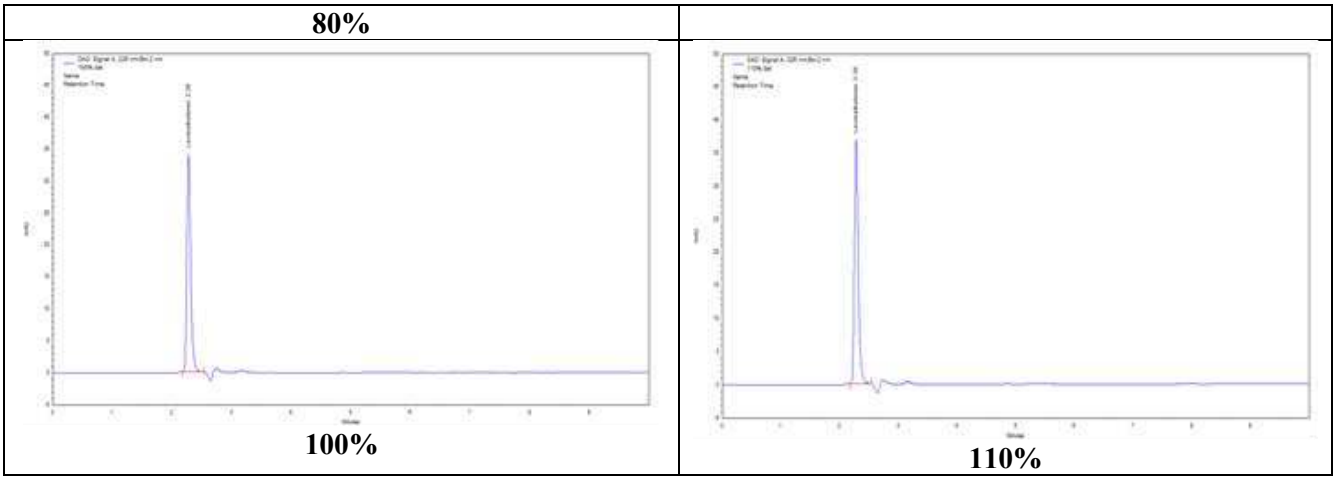


Figure No. 4 Chromatograms for Linearity at 80%, 90%, 100%, 110%

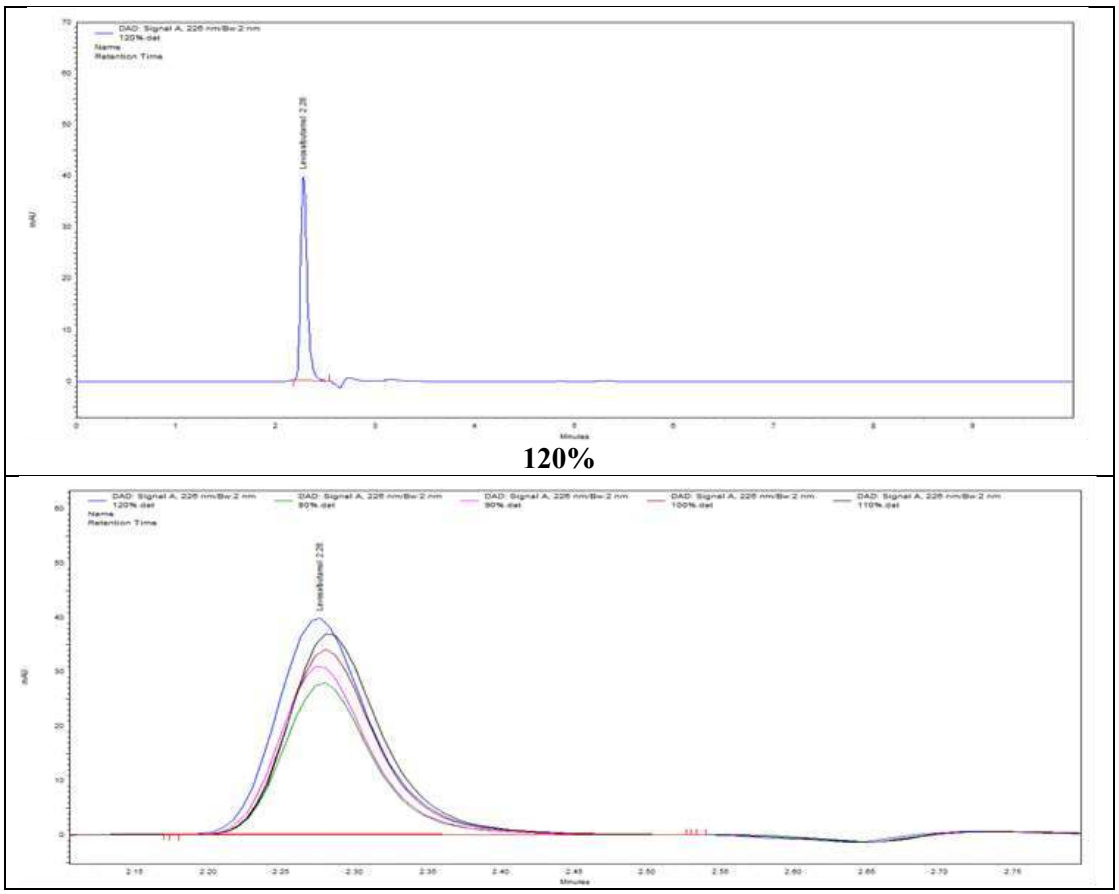


Figure No. 5 Chromatograms of Overlay Linearity at 80%, 90%,100%,110%,120%

Table No. 10 Calculation for Linearity of Levosalbutamol

Levosalbutamol		
% Level	**Conc (ug/ml)**	**Area**
80	4	252765
90	4.5	285443
100	5	315951
110	5.5	348110
120	6	379894

Data Integration:

The Correlation coefficient for Levosalbutamol was found to be 0.999 respectively, which indicates that the peak responses are linear. This concluded that the method was linear throughout the range selected.

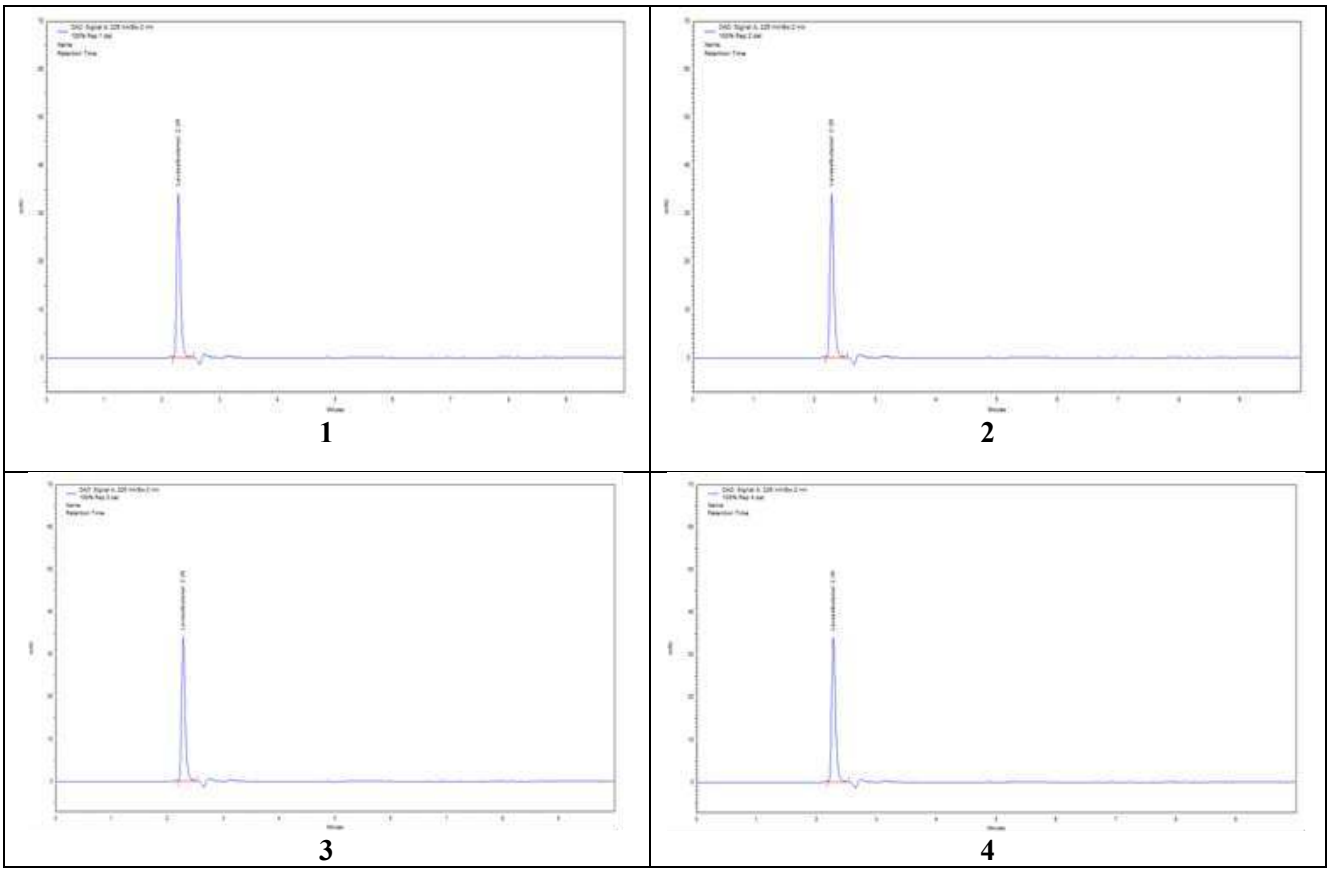
Precision:

Intra-day and inter-day precision exactness is done in the same day on various days as communicated as % R.S.D. The estimations of % R.S.D. for inter-day variation, which proposed a phenomenal exactness of technique.

Levosalbutamol				
Condition	**Sample ID**	**RT**	**Peak Area**	**% Assay**
Morning	WS	2.28	315951	-
	DP	2.28	314754	99.62
Evening	WS	2.28	312014	-
	DP	2.28	310312	99.45
% RSD			**0.82**	**0.12**
Day 2	WS	2.28	305685	-
	DP	2.28	303114	99.16
% RSD			**1.63**	**0.24**

Repeatability:

A minimum 6 determinations at 100% of the test concentration.



1 **2**

3 **4**

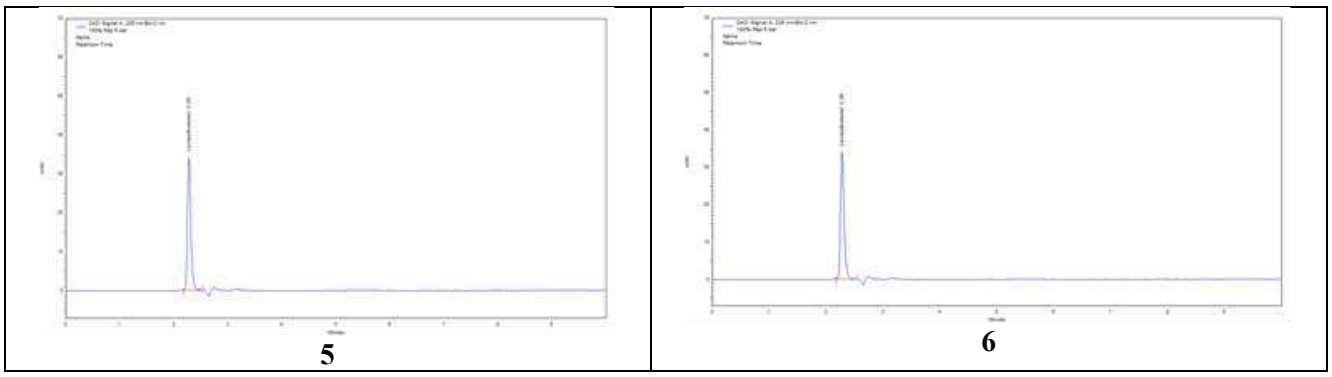


Figure No. 6 Chromatograms for system suitability of Levosalbutamol

System suitability results for Levosalbutamol

Table No.11 Replicate of 100% Test Concentrations for Levosalbutamol

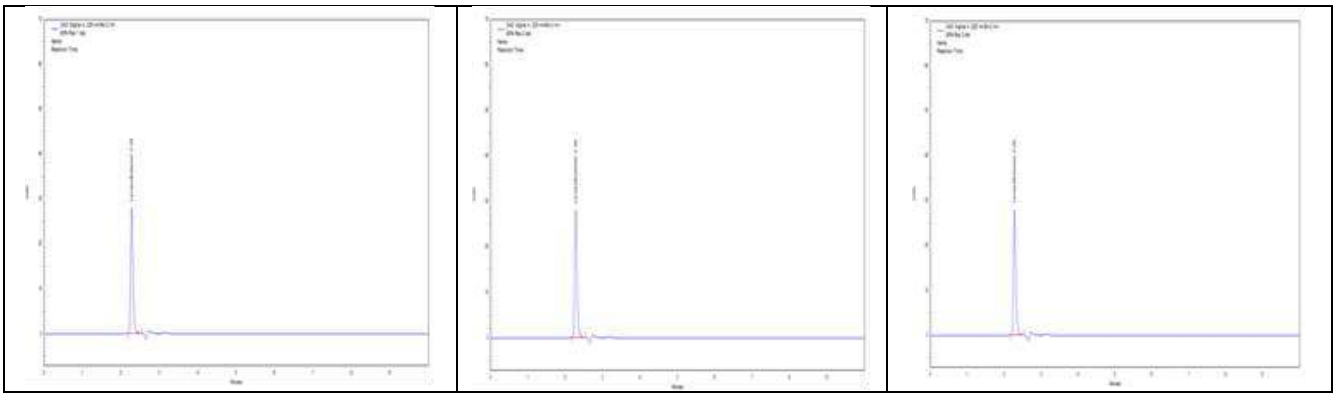
Levosalbutamol					
Sample ID	**Area**	**RT**	**TP**	**Asymmetry**	**Peak Purity**
100% Rep 1	315951	2.28	6439	1.32	1.00
100% Rep 2	315125	2.28	6571	1.28	1.00
100% Rep 3	315334	2.28	6234	1.27	1.00
100% Rep 4	315585	2.28	6374	1.31	1.00
100% Rep 5	315858	2.28	6621	1.29	1.00
100% Rep 6	315642	2.28	6175	1.33	1.00
AVG	315583	2.28			
STDEV	311.8646	0			
% RSD	0.10	0.00			

Data Interpretation:

The results of Repeatability were found within acceptance criteria. From the above results, it was concluded that the method is precise.

Accuracy:

Accuracy of a scientific strategy is the vicinity of the sample outcomes acquired by the technique to the genuine worth. To check the accuracy of proposed technique, exactness was completed 80, 100, and 120 % of test fixation according to ICH rules. Known measure of standard medications were added to dissected example and exposed to the created UV strategy. At that point the absorbance was taken and further count was completed. The Accuracy study was performed multiple times at each level.



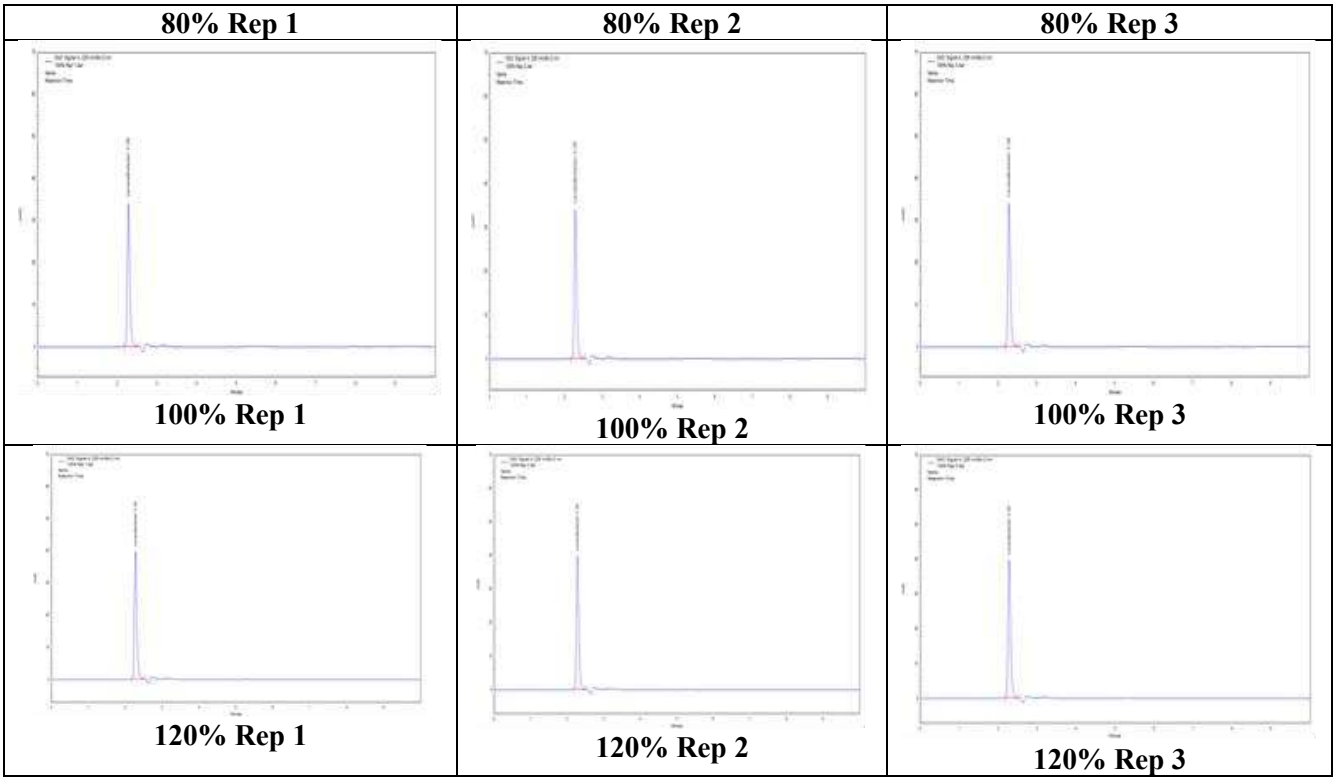


Figure No. 7 Chromatograms for Accuracy at 80%, 100% and 120% level

Table No. 12 Peak Results for Accuracy of Levosalbutamol

Levosalbutamol			
Std wt. (mg)	**% Purity**	**Std Stock Conc. (ug/ml)**	**Working Std Area**
5	99.9	49.95	315583

Sample ID	Reps	Spiked Conc. (ug/ml)	Area	Amount Recovered (ug/ml)	% Recovery	AVG	STD EV	% RSD
80%	Rep 1	4.00	252765	4.00	100.12	**100.02**	0.09705	**0.10**
	Rep 2	4.00	252275	3.99	99.92			
	Rep 3	4.00	252515	4.00	100.02			
100%	Rep 1	5.00	315951	5.00	100.12	**99.96**	0.136087	**0.14**
	Rep 2	5.00	315125	4.99	99.86			
	Rep 3	5.00	315334	4.99	99.92			
120%	Rep 1	5.99	379894	6.01	100.32	**100.21**	0.111154	**0.11**
	Rep 2	5.99	379562	6.01	100.23			
	Rep 3	5.99	379058	6.00	100.09			

Data Interpretation:

The results met the acceptance criteria;however, this conclusion relates to filter compatibility and should not be discussedunder LOD/LOQ."

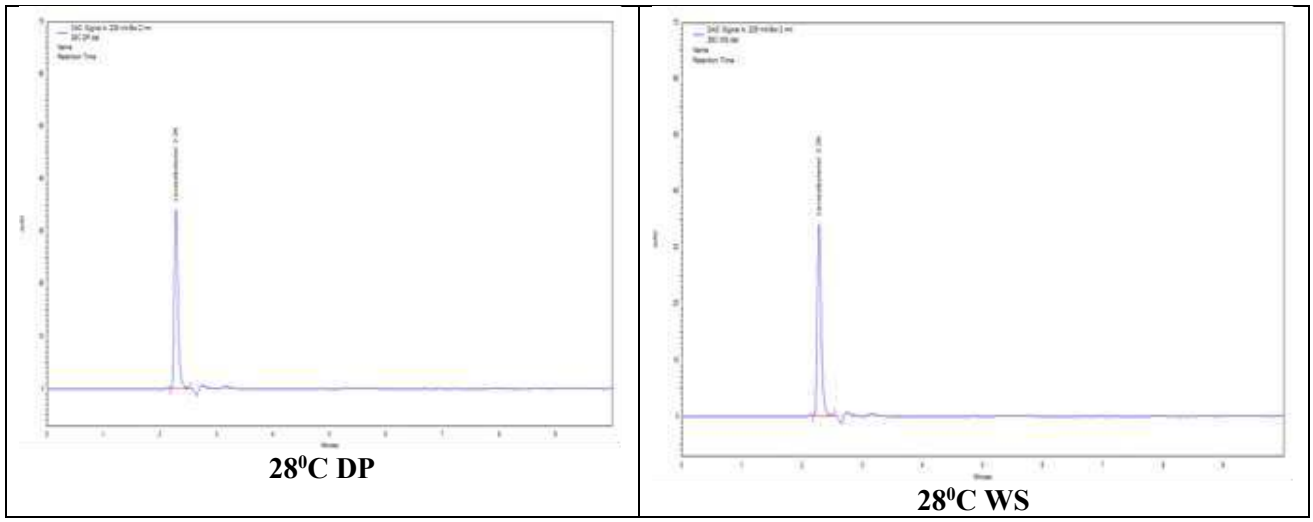
Robustness:

The Robustness was performed by changing the column temperature by ± 2 ℃.

Each Sample was injected % Assay was calculated at each condition was calculated.

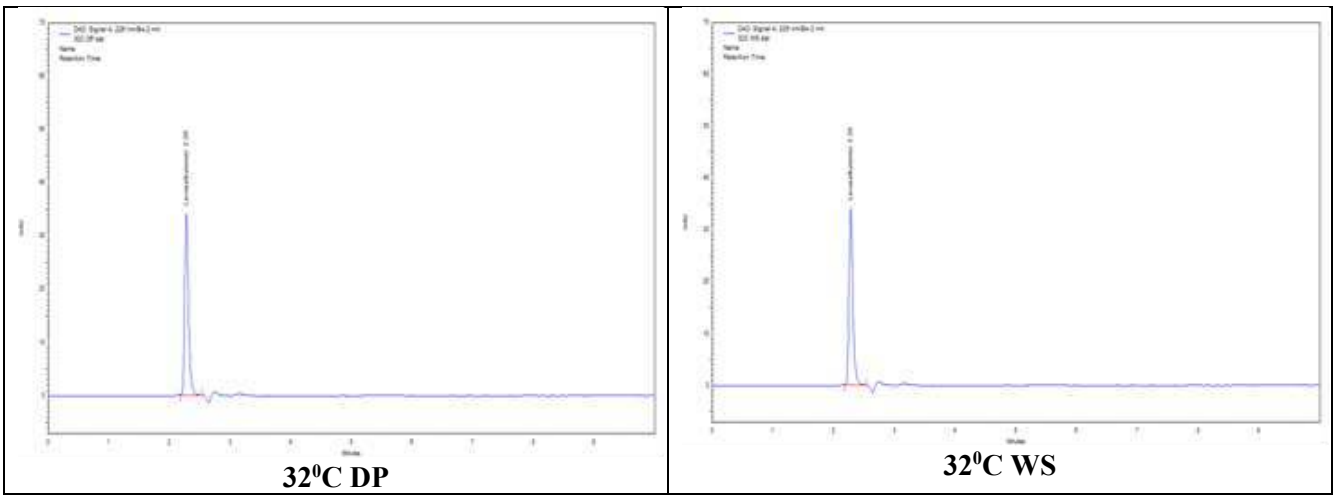
Table No. 13 Robustness Column Temperature 28°C, 30°C, 32°C

Variation in Column temperature				
Condition	**Sample ID**	**RT**	**Area**	**% Assay**
28C	WS	2.28	312467	-
	DP	2.28	311559	99.71
30C	WS	2.28	315951	-
	DP	2.28	314754	99.62
32C	WS	2.28	313254	-
	DP	2.28	312415	99.73
AVG		2.28	313400	99.69
SD		0.00	1648.77	0.06
% RSD		**0.00**	**0.53**	**0.06**



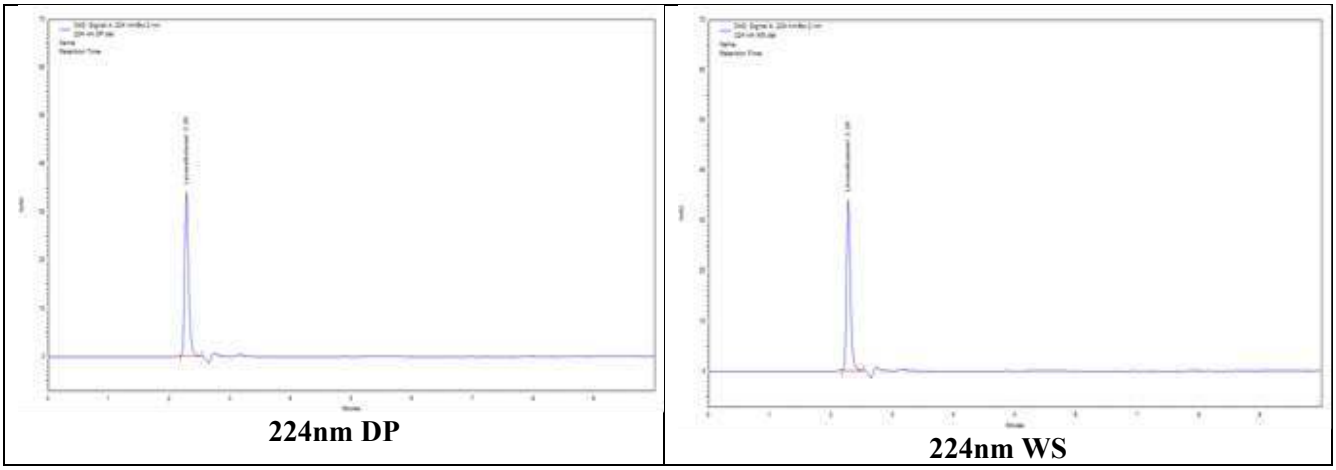
28^0C DP **28^0C WS**

Figure No. 8 Chromatograms for Column temp at 28°C



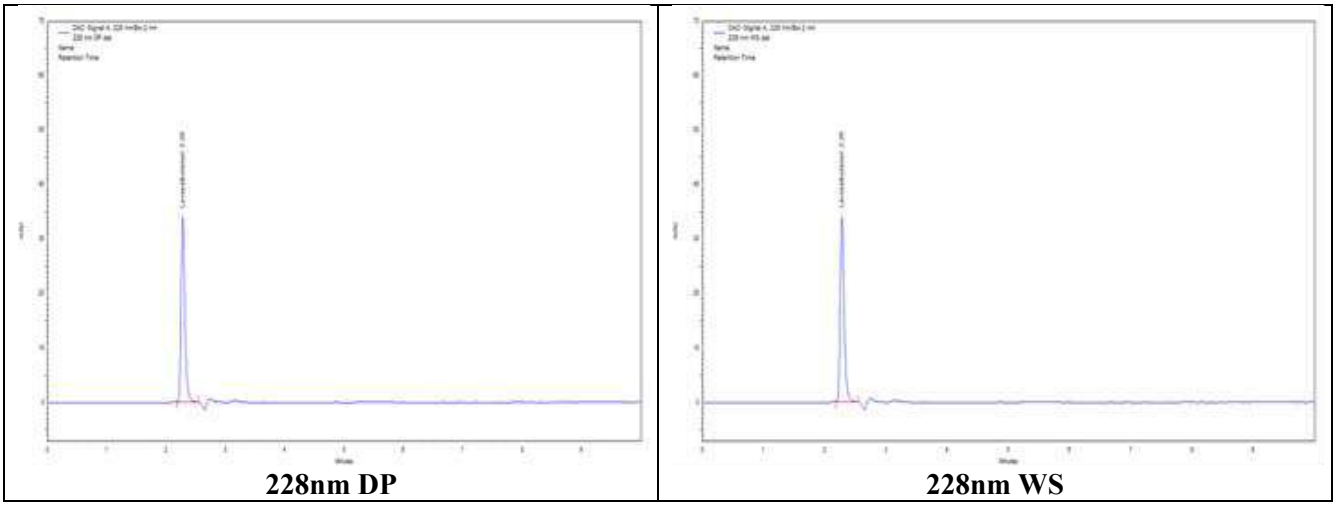
32^0C DP **32^0C WS**

Figure No. 9 Chromatograms for Column temp at 32°C



224nm DP | 224nm WS

Figure No. 10 Chromatograms for Column Variation in wavelength 224nm



228nm DP | 228nm WS

Figure No. 11 Chromatograms for Column Variation in wavelength 228nm

Table No. 14 Robustness Column Variation in wavelength 224nm, 226nm and 228nm

Variation in wavelength				
Condition	**Sample ID**	**RT**	**Area**	**% Assay**
224 nm	WS	2.28	310254	-
	DP	2.28	309112	99.63
226 nm	WS	2.28	315951	-
	DP	2.28	314754	99.62
228 nm	WS	2.28	312121	-
	DP	2.28	311034	99.65
AVG		2.28	312204	99.63
SD		0.00	2656.36	0.02
% RSD		**0.00**	**0.85**	**0.02**

Data Interpretation:

The results were found within acceptance criteria. Hence the method is robust throughout the selected specification criteria.

Specificity:

Blank & Placebo Interference: Placebo was injected in triplicate by weighing the equivalent amount present in the finished drug product and

analyzed for interference due to placebo. The blank and placebo chromatograms showed no interfering peaks at the retention time of Levosalbutamol sulphate (RT ≈ 2.28 min). The drug product chromatogram exhibited a sharp and well-resolved peak corresponding to the analyte. Therefore, the developed RP-HPLC method was found to be specific and free from interference by diluent or formulation excipients.

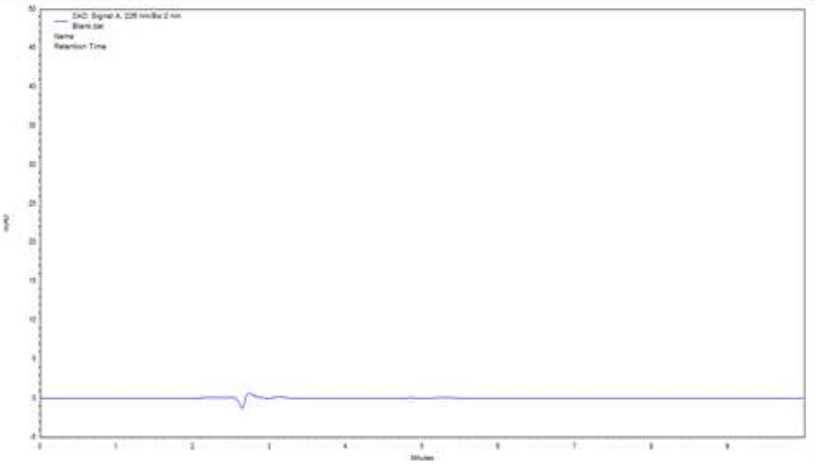


Figure No. 12 Chromatogram of Blank

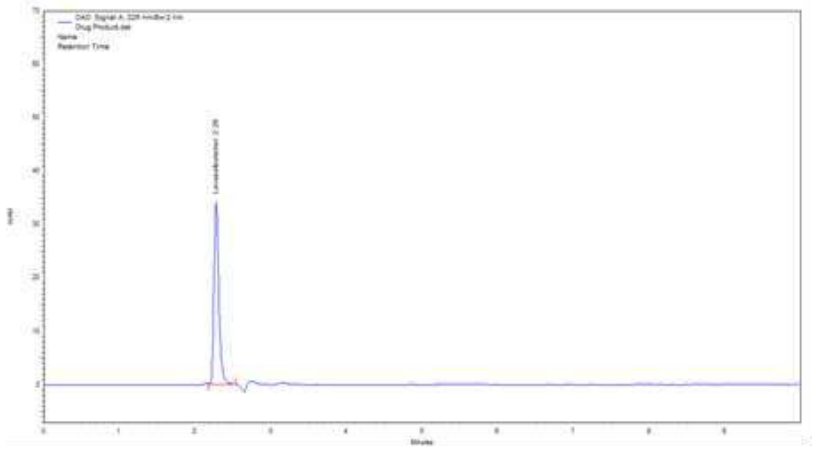


Figure No. 13 Chromatogram of Levosalbutamol

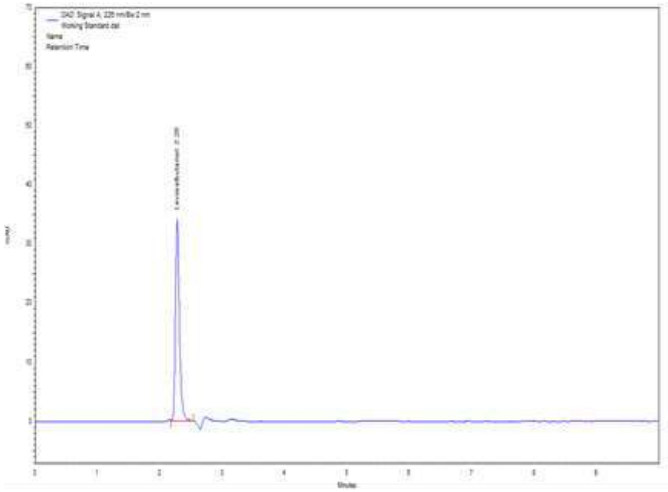


Figure No.14 Chromatogram of Standard

Data Interpretation

On the basis of these chromatograms, we can say that there is no interference of blank and placebo at the retention time of Levosalbutamol., No interference of Levosalbutamol in Levosalbutamol placebo at the retention time of Levosalbutamol. Hence the method is specific.

LOD and LOQ

Was calculated for both drugs by using ANOVA technique.

Formula:

Table No. 15 LOD and LOQ of Levosalbutamol

SUMMARY OUTPUT	
Regression Statistics	
Multiple R	0.999959584
R Square	0.99991917
Adjusted R Square	0.999892227
Standard Error	520.2354275
Observations	5

ANOVA					
	df	**SS**	**MS**	**F**	**Significance F**
Regression	1	10044145563	10044145563	37111.89667	3.08432E-07
Residual	3	811934.7	270644.9		
Total	4	10044957497			
	Coefficients	***Standard Error***	***t Stat***	***P-value***	
Intercept	-492.4	1661.498715	-0.296358941	0.786287985	
X Variable 1	63385	329.0257741	192.6444826	3.08432E-07	
LOD & LOQ of Levosalbutamol			**LOD**	0.09	ug/ml
			LOQ	0.26	ug/ml

The developed RP-HPLC method exhibited excellent sensitivity, with LOD and LOQ values of 0.09 µg/mL and 0.26 µg/mL, respectively, confirming its suitability for the detection and quantification of Levosalbutamol sulphate at low concentration levels. LOD and LOQ are indicators of method sensitivity and should not be interpreted as proof of method accuracy, precision, or overall reliability.

CONCLUSION

The present investigation successfully developed and validated UV spectrophotometric and RP-HPLC methods for the quantitative estimation of Levosalbutamol sulphate in pharmaceutical dosage forms. Both analytical methods exhibited excellent linearity, accuracy, precision, specificity, robustness, and sensitivity in accordance with ICH Q2(R2) guidelines. The RP-HPLC method provided efficient chromatographic separation with acceptable retention time and high theoretical plate count, while the UV spectrophotometric method proved to be simple, rapid, and economical for routine laboratory analysis. The low values of LOD and LOQ demonstrated the high sensitivity of the developed methods for detecting and quantifying small amounts of the drug. Overall, the validated analytical methods are reliable, reproducible, and suitable for routine

quality control testing, assay determination, and regulatory analysis of Levosalbutamol sulphate in pharmaceutical formulations, thereby ensuring product quality, safety, and therapeutic efficacy.

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HOW TO CITE: Rutuja Gangthade, Sagar Kale, Formulation, Development and Validation of UV Spectrophotometric and RP-HPLC Methods for Quantitative Estimation of Levosalbutamol Sulphate in Pharmaceutical Dosage Forms, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 7, 2889-2905. https://doi.org/10.5281/zenodo.21363263