RESEARCH PAPER

# Analytical Method Development And Validation Of Cromolyn Sodium By Rp-Hplc Technique

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## *Abstract*

A simple, précised, accurate method was developed for the estimation of cromolyn sodium by reverse phase high performance liquid chromatography technique. Chromatographic conditions used are stationary phase is, agilent zorbax stable bond aqueous (250 x 4.6mm, 5µ). Diluents are, 50% 0.1% perchloric acid: 50% acetonitrile and detection wave length was 272 nm, column temperature was set to 30°c and diluents were methanol: water (50:50), conditions were finalized as optimized method. System suitability parameters were studied by injecting the standard five times and results were well under the acceptance criteria.

The mean absolute recovery of cromolyn sodium was the recovery of first level was 99.64%, for second level 99.75% and for third level 100.17%. The drug shows linearity in the range of 40 -60 µg/ml for chromatography respectively and r2 value was found to be as 0.9999. Limit of detection is equal to 3.3σ/$ which is found as 2.52 and limit of quantitation is equal to10σ / $ which is found as 7.64. The proposed method offers distinct advantage in simplicity and sensitivity and could be easily used in quality control laboratory for the analysis of cromolyn sodium in its bulk powder.

**Keywords:** Cromolyn Sodium, Rp-Hplc, Ich Guidelines, Method Development.

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## INTRODUCTION

Chromatography is a method of separating a mixture of components into individual components through equilibrium distribution between two phases[1]. The technique of chromatography is based on the differences in the rate at which components of a mixture move through a porous medium (stationary phase) under the influence of some solvent or gas/mobile phase[2].

### High-Performance Liquid Chromatography (HPLC)

High-Performance Liquid Chromatography was created in the late 1960s and early 1970s. Today, it is widely used for separations and

purifications in a number of industries, including pharmaceutical biotechnology, environmental, polymer, and food[3]. Over the last decade, HPLC has emerged as the preferred technology for analyzing a wide range of chemicals. Its key benefit over GC is that analytes do not need to be volatile; hence macromolecules can be analyzed using HPLC. HPLC is achieved by injecting a small amount of liquid sample into a moving stream of liquid (referred to as the mobile phase) that passes through a stationary phase packed column[4]. In high-performance liquid chromatography (HPLC), the analyte is distributed between a stationary phase and a mobile phase (eluent), usually within the column packing material. The chemical structure of the analyte determines its movement rate through the stationary phase, which is the basis for separation. HPLC is a crucial analytical chemistry technology, especially in the pharmaceutical sectors, due to its ability to separate and analyze various substances[5].

**Validation**

Validation is a systematic process that provides objective evidence that a product meets its intended usage requirements. The process comprises analyzing a method's performance and demonstrating its capacity to meet particular requirements. Validation ensures that your analytical method, such as High-Performance Liquid Chromatography, can deliver consistent results even under demanding conditions or with low doses[6]. Validation is necessary for new or updated methods to provide repeatable and trustworthy findings, regardless of whether they are used by many operators using the same equipment in various laboratories. Validation programs are necessary to ensure the analytical process is robust and suitable for varied circumstances, depending on the method and intended usage[7].

Cromolyn sodium (CS) (5, 5′-(2-hydroxypropane-1, 3-diyl) bis (oxy) bis (4-oxo-4H-chromene-2-carboxylic acid), the structure shown in figure 1.

CS therapy for asthma is administered intra nasally or orally, which requires a multiple dose regimen due to its short half-life (~80 minutes) and low bioavailability (~1% orally and ~7% intra nasally), causing inconsistent use among patients. Atopic dermatitis can cause sleeplessness and severe pruritus, and conventional therapies give less than satisfying results in relieving symptoms[8]. Previous clinical studies have demonstrated promising results with CS as a topical agent for treatment, most notably because topical use allows for direct access to mast cells of the skin[9].

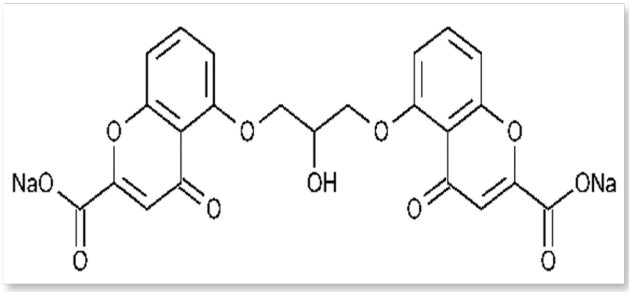


**Figure 1: Chemical structure of Cromolyn sodium**

The development of a gastro-retentive floating microballoon product for CS in asthmatic patients is necessary due to pharmacokinetic features, which enable longer release, reduce the number of doses, and improve patient compliance. The present study was focused on a new simple, sensitive, and selective method for analyzing Cromolyn sodium using Reverse Phase High-Performance Liquid Chromatography[10].

## MATERIALS AND METHODS

### 2.1. Chemicals and Reagents

Cromolyn sodium was kindly supplied by Sigma Pharmaceutical Industries (Egypt) and certified to contain 99.61%. Acetonitrile served as solvent mixture was also obtained from CDH Lab, New Delhi. All other chemicals/reagents were of analytical grade and were used without further purification.

**2.3. Preparation of Calibrants and Samples**

CS calibrants were separately prepared in 1X PBS (10 mM, pH 7.4) and methanol. A solution of 1 mg/mL CS was initially prepared in these solvents and further diluted to prepare stock solutions of 100 $\mu$g/mL. (e following concentrations were then prepared from the stock solutions by dilution with the respective solvents: 0.1, 0.25, 0.5, 0.75, 1, and 2.5 $\mu$g/mL. All calibrants were filtered through a 0.22-$\mu$m nylon syringe filter membrane (New Oxford, PA, USA) before analysis[11].

**Preparation of buffer (0.1% OPA):** 1 ml of ortho phosphoric acid solution in a 1000 ml of volumetric flask is taken and adds about 100 ml of milli-Q water and final volume make up to 1000 ml with milli-Q water[12].

**Optimized chromatographic conditions**

Column : BDS (250 × 4.6 µm)

Mobile Phase : OPA buffer: Acetonitrile (60:40)

Flow rate : 1.0 ml/min

Detector : PDA 267 nm

Temperature : 30°C Injection

Volume: 10 µL.

**Method of validation**

The proposed method was validated for various parameters such as linearity and range, accuracy, precision, robustness, ruggedness, sensitivity and specificity according to ICH Q2 (R1) guideline and USP guidelines[13].

**Method of linearity and range**

The linearity of an analytical procedure is its ability (within a given range) to obtain test result which are directly proportional to the concentration of an analyte in the sample. The range of an analytical procedure is the interval between the upper and lower concentration of an analyte in the sample for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity. The linearity of the analytical method was demonstrated over the concentration range investigated by triplicate analysis (n=3) at a concentration range of 2-20 µg/ ml. The absorbance obtained at respective concentration was recorded, and the graph is plotted as concentration (µg/ml) versus absorbance. The linear regression equation and the coefficient correlation were obtained from the UV probe software.

**Method of accuracy**

The accuracy of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found. This is sometimes termed trueness. The final concentration of Cromolyn sodium was determined at each levels of the amount; three determinations were performed. The percentage recovery was calculated as mean ± standard deviation[14].

**Method of precision**

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the homogeneous sample under the prescribed conditions. The precision of the method was demonstrated by intra-day and inter-day variation studies. In the intra-day precision study, three different solutions of same concentration were prepared and analyzed in the same day (morning, noon and evening), whereas in the inter-day precision study, the solutions of same concentration were prepared and analyzed, for three consecutive days, and the absorbance were recorded. All study was performed in triplicates. The result was indicated by calculating percentage relative standard deviation[15].

**Method of Robustness**

The robustness of an analytical procedure is a measure of its capacity remains unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage[16].

**Method of Ruggedness**

The ruggedness is a degree of reproducibility of test result under verification of condition

like a different analyst, different instruments and different days[17].

**Limit of Detection (LOD)**

Each analyte technique has a detection limit, which is the smallest quantity of analyte in a sample that can be detected but is not necessarily regarded as a precise measurement. Limit of detection based on the response and slope standard derivation. Detection limit (or) limit of detection may be expressed as,

**LOD= (3.3σ/ S)**

Were, σ =standard deviation of the response S =slope of the calibration curve (of the analyte)

**Limit of Quantitation (LOQ)**

The quantitation of an analytical procedure is the lowest amount of analyte in a sample, which can be quantitatively determined with suitable precision and accuracy. Quantitation limit based on the standard deviation of the response and the slope[18]. It can be expressed as

**LOQ= (10 σ /S)**

Were, σ =standard deviation of the response S =slope of the calibration curve (of the analyte).

**Specificity**

Specificity is the capacity to access the analyte in the presence of the components that may be anticipated to be present. It is important for chromatographic procedures to demonstrate specificity, which is the capacity to precisely detect the analyte response in the presence of all possible sample components. All possible sample components (placebo formulation, process contaminants, etc.) are compared to the analyte's reaction in a test mixture including the analyte and the analyte alone. The analyte peak must have a baseline chromatographic resolution of at least 1.5 from all other sample components to be considered specific. If this isn't possible, the final test result will be affected by no more than 5% by the unresolved components at their highest predicted level[19].

**System suitability testing**

Analytical processes often include system suitability assessment as a component of the process. All aspects of testing are examined as a single integrated system that can be evaluated as a whole. This is how the tests are conducted. Typically, five injections of a standard solution are made and chromatographic characteristics such as resolution, area percent repeatability, the number of theoretical plates, and the tailing factor are evaluated[20].

## RESULTS

**RP-HPLC Method Development and Validation**

Depending on the wavelength, theoretical plate and asymmetry factor fourth no. of method was optimized because of higher TP, lower retention time, less than 2 asymmetry factor.

**Chromatographic Conditions**:

Column Oven Temp - 30° C
Flow Rate - 1 ml/min
Mobile Phase - 0.1% Perchloric acid: Acetonitrile (80: 20, % V/V)
Run time - 10 minutes
Injection Volume - 10µl
Wavelength - 272 nm
Diluent - Acetonitrile: 0.1% Perchloric acid (50 : 50, % v/v)
Column (stationary phase) - Agilent Zorbax SB-Aq (250 x 4.6 mm, 5µ)

The results were shown in table 1 and figure 2.

**Range:** Range of an analytical procedure for RP-HPLC is 40 to 60 µg/ml.

**Selection of wavelength** The 10 µg/ml standard solution was scanned in UV Spectrophotometer from a range of 200 -400 nm against Acetonitrile as blank & maximum absorption was found at 272 nm.

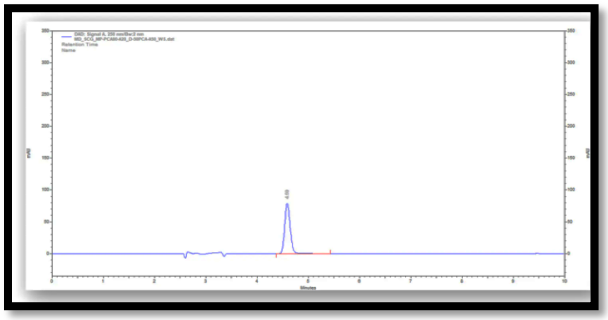

**Figure 2: Optimized chromatogram of Cromolyn sodium**

**Table 1: Chromatographic Trials for obtaining optimized methods**

| Sl. No. | Mobile phase | RT | TP | $\lambda_{Max}$ | Asymmetry |
|---|---|---|---|---|---|
| 1 | 0.1% Perchloric acid Acetonitrile =50:50 | 2.92 | 554 | 250 | 0.73 |
| 2 | 0.1% Perchloric acid Acetonitrile =60:40 | 2.95 | 1576 | 250 | 0.83 |
| 3 | 0.1% Perchloric acid Acetonitrile =70:30 | 3.27 | 3469 | 250 | 0.77 |
| 4 | 0.1% Perchloric acid Acetonitrile =80:20 | 4.59 | 8876 | 272 | 1.11 |
| 5 | 0.1% Perchloric acid Acetonitrile =90:10 | 12.43 | 8992 | 272 | 1.10 |

**Linearity** The drug shows linearity in the range of 40 -60 µg/ml for Chromatography respectively. The results were shown in table 2 and figure 3.

**Table 2: Linearity data for RP-HPLC**

| Sl. No | Concentration (µg/ml) | Concentration (%) | Area |
|---|---|---|---|
| 1 | 40 | 80 | 2808897 |
| 2 | 45 | 90 | 3186270 |
| 3 | 50 | 100 | 3512722 |
| 4 | 55 | 110 | 3848126 |
| 5 | 60 | 120 | 4223381 |

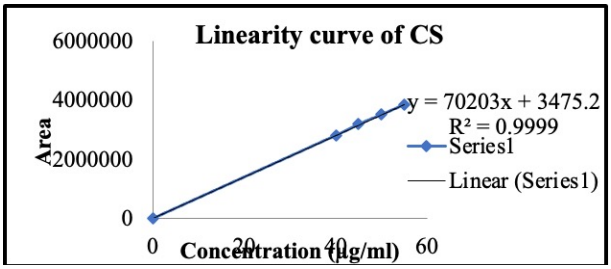


**Figure 3: Linearity curve of Cromolyn sodium**

**Limit of detection and Limit of quantitation** (LOD, LOQ)
LOD = 3.3σ/$ Which is found as 2.52
LOQ = 10σ / $ Which is found as 7.64
Where, σ = standard deviation of the response
$ = slope of the calibration curve.
The results were shown in table 3.

**Table 3: LOD, LOQ data for RP-HPLC**

| Sl. No. | Parameters | HPLC Observation |
|---|---|---|
| 1 | Range (µg/ml) | 40 -60 |
| 2 | Slope | 69816.48 |
| 3 | Correlation coefficient ($R^2$) | 0.9993 |
| 4 | LOD | 2.52 |
| 5 | LOQ | 7.64 |
| 6 | Intercept | 25055 |

**Accuracy:** The accuracy of an analytical procedure expresses the closeness of agreement between the value which is

accepted either as a conventional true value or an accepted reference value and the value found. The mean absolute recovery of Cromolyn sodium was the recovery of first level was 99.64%, for second level 99.75% and for third level 100.17%. The results were shown in table 4 and figure 4.

**Table 4: Accuracy data for RP-HPLC**

| Sample (%) | Amount spiked (µg/ml) | Amount recovered | % recovery | Average | % RSD |
|---|---|---|---|---|---|
| 80 | 39.88 | 39.63 | 99.37 | 99.64 | 0.34 |
| | 39.88 | 39.69 | 99.52 | | |
| | 39.88 | 39.89 | 100.03 | | |
| 100 | 49.85 | 49.56 | 99.42 | 99.75 | 0.32 |
| | 49.85 | 49.88 | 100.05 | | |
| | 49.85 | 49.74 | 99.79 | | |
| 120 | 59.82 | 59.59 | 99.61 | 100.1 | 0.49 |
| | 59.82 | 60.10 | 100.04 | | |
| | 59.82 | 60.09 | 100.05 | | |

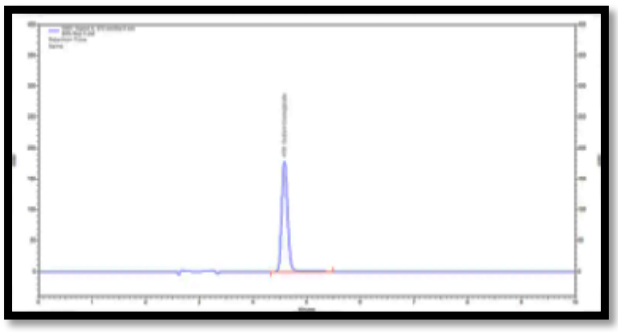

**Figure 4: RP-HPLC chromatogram of Cromolyn sodium (80%)**

**Table 5: Precision data for Cromolyn sodium**

| Sl. No. | Concentration (µg/ml) | Area |
|---|---|---|
| 1 | 40 | 3512722 |
| 2 | 40 | 3535254 |
| 3 | 40 | 3525785 |
| 4 | 40 | 3508674 |
| 5 | 40 | 3518977 |
| 6 | 40 | 3598741 |
| Avg. | | 3533358.833 |
| SD | | 33400.11779 |
| % RSD | | 0.95 |

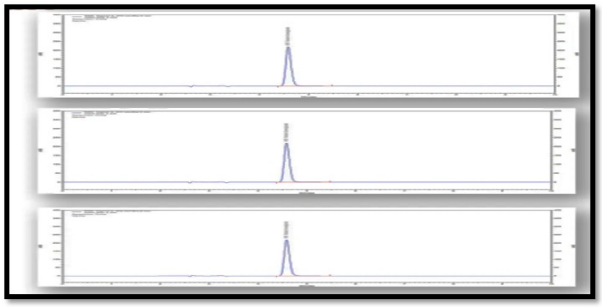

**Figure 5: Repeatability chromatogram of Cromolyn sodium**

**Table 7: Robustness data of Cromolyn sodium for different mobile phases**

| Conditions (%) | Sample ID | % Assay | Area | RT | TP | Asymmetry |
|---|---|---|---|---|---|---|
| MP A=78 MP B=22 | WSDP | -99.23 | 3529587 3502585 | 4.55 4.55 | 8345 8296 | 1.16 1.09 |
| MP A=80 MP B=20 | WSDP | -98.85 | 3533359 3492674 | 4.58 4.58 | 8287 8178 | 1.19 1.15 |
| MP A=82 MP B=18 | WSDP | -99.40 | 3578452 3556857 | 4.63 4.63 | 8421 8524 | 1.08 1.03 |

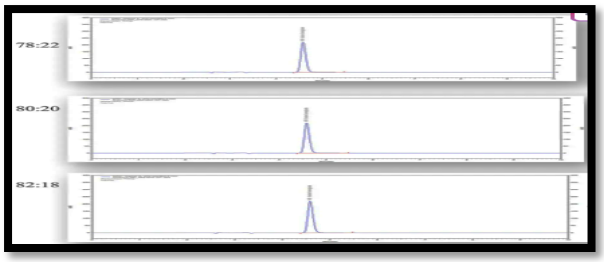


**Figure 7: Chromatogram for different mobile phases**

**Precision**: The precision of an analytical procedure expresses the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision is divided into two class i.e. Intra-day precision and Inter-day precision which was part of precision i. e repeatability. A single sample was prepared as described and 6 injections were made from same sample and checked for system suitability. Its limit of % RSD is <2% as per ICH guidelines. The RP-HPLC (Repeatability) is 0.95%. The results were shown in table 5 and figure 5.

**Robustness**: Robustness of the method was studied by injecting the standard solutions with slight variations in the optimized conditions namely, ± 2% in the ratio of Acetonitrile in the mobile phase, varying flow rate ± 2ml. WS-working standard, DP- drug product. The results were shown in table 6 and figure 6 and figure 6, 7.

**Table 6: Robustness data of Cromolyn sodium for different flow rates**

| Conditions | Sample ID | % Assay | Area | RT | TP | Asymmetry |
|---|---|---|---|---|---|---|
| 0.8ml | WS | - | 3687814 | 4.62 | 8324 | 1.08 |
| | DP | 99.03 | 3652145 | 4.62 | 8317 | 1.11 |
| 1.0ml | WS | - | 3533358 | 4.58 | 8287 | 1.9 |
| | DP | 98.85 | 3492674 | 4.58 | 8178 | 1.15 |
| 1.2ml | WS | - | 3692545 | 4.52 | 8237 | 1.12 |
| | DP | 99.12 | 3658874 | 4.52 | 8211 | 1.15 |

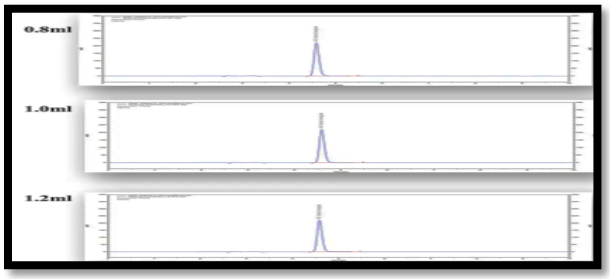


**Figure 6: Chromatogram for different flow rates**

**Specificity:** Specificity is the ability to assess unequivocally the analyte in the presence of components which may be expected to be present. There is no interference of the blank solution in region of the main peak of Cromolyn sodium. Hence the solvent system & chromatographic conditions are specific for the method. The results were shown in table 7 and figure 8.

**Table 8: Retention time, Theoretical plates, Asymmetry (Tailing factor)**

| Sample | RT | TP | Asymmetry |
|---|---|---|---|
| Rep 1 | 4.58 | 8287 | 1.19 |
| Rep 2 | 4.58 | 8365 | 1.10 |
| Rep 3 | 4.58 | 8214 | 1.12 |
| Rep 4 | 4.58 | 8202 | 1.09 |
| Rep 5 | 4.58 | 8352 | 1.08 |
| Rep 6 | 4.58 | 8288 | 1.15 |
| Average | 4.58 | | |
| SD | 9.72951E-16 | | |
| % RSD | 0.00 | | |

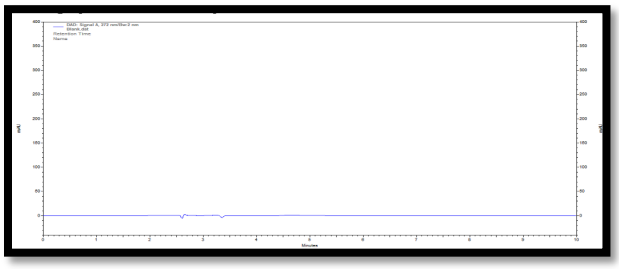

**Figure 8: Chromatogram of blank solution**

**System suitability**: The test is based on the concept that the equipment, electronics analytical operation and sample to be analyzed constitute an integral system that can be evaluated as such. The results were shown in table 8 and figure 9.

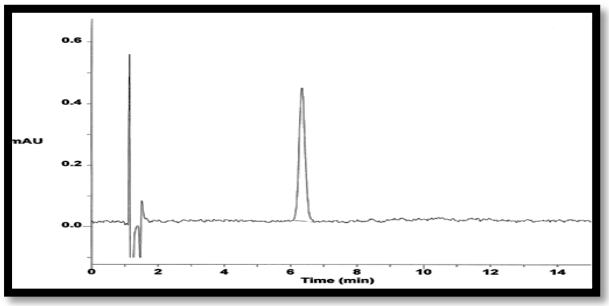


**Figure 9: Chromatogram of standard solution of Cromolyn sodium**

## DISCUSSION

Method validation was done by using Validation parameters i.e. Linearity, Range, Accuracy, Precision, Specificity, System suitability, Robustness, Repeatability, Ruggedness etc. with the help Chromatographic methods as per ICH guidelines. Stationary phase is, Agilent Zorbax SB-Aq (250 x 4.6mm, 5µ). Diluents are, 50% 0.1% PCA: 50% ACN. LOD = 3.3σ/$ which is found as 2.52, LOQ = 10σ / $ which is found as 7.64. The mean absolute recovery of Cromolyn sodium was the recovery of first level was 99.64%, for second level 99.75% and for third level 100.17%. A single sample was prepared as described and 6 injections were made from same sample and checked for system suitability. Its limit of % RSD is <2 % as per ICH guidelines. The RP-HPLC (Repeatability) is 0.95%.

## CONCLUSION

Chromatographic conditions used are stationary phase is, Agilent Zorbax SB-Aq (250 x 4.6mm, 5µ). Diluents are, 50% 0.1% PCA: 50% CAN and detection wave length was 272 nm, column temperature was set to 30°C and diluents was methanol: Water (50:50), The mean absolute recovery of Cromolyn sodium was the recovery of first level was 99.64%, for second level 99.75% and for third level 100.17%. The drug shows linearity in the range of 40 -60 µg/ml for chromatography respectively and $r^2$ value was found to be as 0.9999. Limit of Detection is equal to 3.3σ/$ which is found as 2.52 and Limit of Quantitation is equal to10σ / $ which is found as 7.64.The proposed method offers distinct advantage in simplicity and sensitivity and could be easily used in quality control laboratory for the analysis of Cromolyn sodium in its bulk powder.

## SUMMARY

A simple, précised, accurate method was developed for the estimation of Cromolyn sodium by Reverse phase High Performance Liquid Chromatography technique. Chromatographic conditions used are stationary phase is, Agilent Zorbax Stable bond aqueous (250 x 4.6mm, 5µ). Diluents are, 50% 0.1% Perchloric acid: 50% Acetonitrile and detection wave length was 272 nm, column temperature was set to 30°C and diluents were methanol: Water (50:50), The mean absolute recovery of Cromolyn sodium was the recovery of first level was 99.64%, for second level 99.75% and for third level 100.17%. The drug shows linearity in the range of 40 -60 µg/ml for chromatography respectively and $r^2$ value was found to be as 0.9999. Limit of Detection is equal to 3.3σ/$ which is found as 2.52 and Limit of Quantitation is equal to10σ / $ which is found as 7.64.The proposed method offers distinct advantage in simplicity and sensitivity and could be easily used in quality control laboratory for the analysis of Cromolyn sodium in its bulk powder.

## ABBREVIATIONS

**RP-HPLC:** Reverse phase High Performance Liquid Chromatography; **CS:** Cromolyn sodium; **GC:** Gas Chromatography; **ICH:** International Council for Harmonization;

**PDA:** Photodiode array; **BDS:** Base-deactivated silica; **PBS:** Phosphate buffer solution; **S:** Slope; **OPA:** Ortho phosphoric acid; **PCA:** Perchloric acid; **CAN:** Acetonitrile; **SB-Aq:** Stable bond aqueous; **RT:** Retention time; **TP:** Theoretical Plates; **MP:** Mobile phase; **SD:** Standard Deviation; **RSD:** Relative Standard Deviation; **UV:** Ultra Violet; **LOD:** Limit of detection; **LOQ:** Limit of quantitation; **USP:** United States Pharmacopeia.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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