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Method Development and Validation of Assay of Docusate Sodium in Docusate Sodium Liquid Filled Capsules by HPLC Method

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Abstract: ***Although the USP monograph has provided the method for the determination of % Assay of Docusate sodium in Docusate sodium capsules, it could not produce precise and accurate results in the existing laboratory environment. Thus, the method for the Determination of Assay for Docusate Sodium in Soft Gelatin Capsules was developed on high-performance liquid Chromatographic (HPLC) using Certified Reference Material Pharmaceutical Secondary Standard. A reversed phase chromatographic method was developed with a reversed-phase column to quantify the potency of docusate sodium from Soft Gelatin liquid filled Capsule 100mg. The method was validated according to ICH Q2R2 guidelines for Specificity, Precision (System precision, Method precision, Intermediate Precision), Linearity and Accuracy.***

Keywords: HPLC, ICH Guidelines, Assay, Docusate Sodium, Soft Gelatin Capsule, Validation.

Abbreviations

PPM: Parts per million
WS: Working standard
RSD: Relative Standard Deviation
COA: Certificate of Analysis
NA: Not Applicable
USP: United States Pharmacopeia
NMT: Not More Than
NLT: Not Less Than
ICH: International Council of Harmonisation
AVG: Average
WT: Weight

I. INTRODUCTION

Docusate is a medication usually used for managing and treating constipation [1]. It is categorized as the class of stool softener drugs. As a stool softener drug, it minimizes the surface tension of the oil and water interface within the stool which facilitates the passage of water and lipids into the stool mass. The goal is for the stool to become softer and move through the intestinal tract more easily. Docusate, also known as dioctyl sulfosuccinate, is of two types that can be administered orally in the form of Tablet or Soft Gelatine Capsule [2]. Docusate comes in the form of either calcium or sodium salts. Docusate Sodium has molecular weight of 444.6 g/mol and molecular formula of $C_{20}H_{37}NaO_7S$ (Fig.-1).

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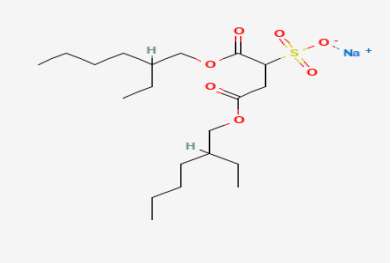


[Fig.1: Structure of Docusate Sodium]

Although the USP monograph has provided the method for the determination of % Assay of Docusate sodium in Docusate sodium capsules [3], it could not produce precise and accurate results in the existing laboratory environment. Hence, the method for determination of % Assay of Docusate sodium in Docusate sodium liquid filled capsules 100 mg has been developed [4] and validated as per ICH guideline for Specificity, Precision (System Precision, Method Precision and Intermediate Precision), Linearity and Accuracy [5].

II. MATERIALS AND METHODS

Various methods and techniques have been developed and researched for its precision, accuracy, linearity [6]. However, none of these methods have been consistently produce precise and accurate results. The research work of executing different procedure using different detectors such UV [7] / PDA (Diode-Array) detector [8], Refractive Index Detection technique [9] and Charged Aerosol Detection [10]. However, due to its complexity and nature of the molecule it did not produce precise results [11]. Thus, HPLC [12] method with UV [13] detection was developed using Docusate Sodium Soft Gel Capsule [14] and Docusate Sodium Certified Secondary standard [15]. The method was developed using different columns and buffer/mobile [16] phase composition to get adequate results without interference of diluent and/or excipient peaks [17].

III. EXPERIMENTAL DETAILS

A. Standard/Sample/Reagents/Instruments/Filter

Table 1: Instrument Details

Instrument	Make & Model No.
HPLC	Waters- Alliance - 2695
	Waters- Alliance - 2690
Analytical balance	Mettler Toledo -AT 261
	Sartorius – CP324S
pH meter	Thermo Scientific – Orion versa Star
Sonicator	Fisher Scientific – FS28
	Bransonic – CPX8800
Vacuum pump	GAST

Table 2: Reagents Details

Chemicals	Grade
Triethylamine	ACS
Orthophosphoric acid	ACS
Acetonitrile	HPLC
	HPLC
Water	HPLC (Milli-Q or equivalent)

Table 3: Standards Details

Name of Standards	Potency
Docusate Sodium Working Std	99.4 %
Docusate sodium Capsules, Placebo	NA
Docusate Sodium 50% PEG400 NF	49.8 %
Docusate Sodium Capsules 100 mg	NA

Table 4: Filter Details

0.45 µm Nylon filter	Agilent Maker

IV. ANALYTICAL METHOD

A. Preparation of Solution A (Water: Acetonitrile)

Mix, Water and Acetonitrile in the ratio of 20:80 v/v. Mix well.

B. Preparation of Mobile Phase

Add 2 mL of Triethylamine in 1000 mL of Solution A (Water: Acetonitrile) and mix well. Adjust the pH to 7.0 ± 0.5 using ortho phosphoric acid and degas by sonication (approx. 15 minutes).

C. Preparation of Diluent

Mix, Acetonitrile, and water in ratio of 50:50 v/v. Mix well and degas by sonication.

D. Chromatographic Condition

LC with PDA/UV detector.
Column: Zorbax SB C-8, 250mm x 4.6 mm, 5µ or equivalent
Column Temperature: 30°C
Injection Volume: 50 µL
Detection wavelength: 210 nm
Flow rate: 1.0 mL/min.
Run time: 16 minutes

E. Preparation of Standard Solution

Accurately weigh and transfer 50 mg of Docusate Sodium standard into 50-mL volumetric flask. Add about 25 mL of diluent and sonicate for 10 minutes to dissolve. Dilute up to the mark with diluent and mix well. Accurately transfer 5.0 mL of this solution into 50 mL of volumetric flask and dilute to volume with diluent.

Filter through 0.45 µm filter after discarding the first few mL of the filtrate and collect the remaining filtrate. (Concentration of Docusate Sodium is about 100 ppm)

F. Preparation of Sample Solution

Accurately weigh not less than 20 capsules and determine average weight. Weigh and transfer 5 intact capsules into a 200-mL volumetric flask, add about 50 mL water at about 50°C and sonicate to dissolve completely, (if required sonicate the soft gels for 30 minutes) and add 50-mL of acetonitrile. Allow this solution to cool to room temperature and dilute to volume with diluent.

Accurately transfer 4.0 mL of this solution into a 100 mL volumetric flask, dilute to volume with diluent. Filter through 0.45 µm filter after discarding the first few mL of the filtrate and collect the remaining filtrate. (Concentration of Docusate Sodium is about 100 ppm)

[Note: Take special care to ensure that all of the capsules have ruptured.**]**

G. Procedure

Equilibrate the column with mobile phase for sufficient time, separately inject diluent, standard solution and sample solution as recommended in below sequence and evaluate chromatograms.

Table 5: Injection Sequence

Sr. #	Solution	No. of injections
1	Blank	1 or 2
2	Standard solution	5
3	Each sample solution	1
4	Bracketing Standard (after every 10 injections)	1

H. System Suitability Requirements

Tailing factor for Docusate sodium peak in Standard solution – Not More Than 2.0.

Theoretical plates for docusate sodium peak from first standard injection – Not Less Than 3000.

% RSD for area of Docusate sodium peak from five replicate injections of standard solution – Not More Than 2.0%.

I. Calculation

Calculate% Assay in each of the sample solutions by using following formula,

$$\%Assay(w/w) = \frac{A_u \times W_S \times 5 \times 200 \times 100 \times Avg.Wt \times P}{A_S \times 50 \times 50 \times W_T \times 4 \times LC \times 100}$$

Where,
Au = Area of Docusate sodium peak in sample solution.
As = Average area of Docusate sodium peaks from five replicate injections of standard solution.
W_S = Weight of Docusate Sodium Standard in mg
W_T = Weight of sample in mg
P = Potency of Docusate Sodium standard (% as is)
Avg. Wt = average weight of tablet (mg/capsule)
LC = label claim of Docusate Sodium (mg/capsule)

V. METHOD VERIFICATION PARAMETERS

A. System Suitability

To verify the analytical system is working properly and can give accurate and precise results, the system suitability parameters are to be seated.

Mobile phase, diluent/blank solution, and standard solution were prepared as below and analyzed as per methodology. Injected Blank and Standard solution (5 replicates). Evaluated system suitability.

- *Experimental Condition*

LC with PDA
Column : Zorbax SB C-8, 250mm x 4.6 mm, 5µ or equivalent
Column Temperatures: 30°C
Injection Volume : 50 µL
Detection wavelength : 210 nm

Flow rate : 1.0 mL/min.
Run time : 16 minutes

- *Preparation of Solution A*

Mixed, 800 mL of Water and 3200 mL of Acetonitrile in the ratio of 20:80 v/v. Mixed well.

- *Preparation of Mobile Phase*

Added 8 mL of Triethylamine in 4000 mL of Solution A (Water: Acetonitrile) and mixed well. Adjusted the pH to 7.03 using ortho phosphoric acid and degassed for 15 minutes by sonication.

- *Preparation of Diluent*

Mixed, 2000 mL of Acetonitrile and 2000 mL of Water in ratio of 50:50 v/v. Mixed well and degassed by sonication.

- *Preparation of Standard Solution*

Accurately weighed and transferred 50.49 mg of Docusate Sodium standard into 50-mLvolumetric flask. Added about 25 mL of diluent and sonicated for 5 minutes to dissolve. Diluted up to the mark with diluent and mixed well. Accurately transferred 5.0 mL of this solution into 50 mL of volumetric flask and dilute to volume with diluent.

Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate. (Concentration of Docusate Sodium is about 100 ppm)

- *Procedure*

Injected the solutions into the chromatographic system as per the methodology and evaluated chromatograms.

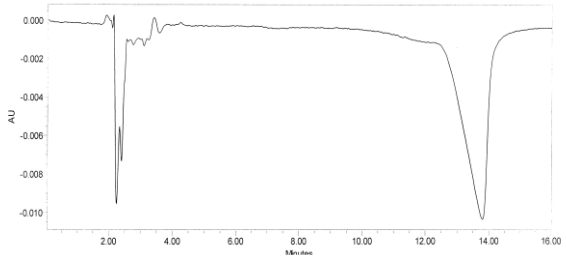
- *System Suitability Results*

Tailing factor for Docusate sodium peak in Standard solution – 1.2 (Not more than 2.0).

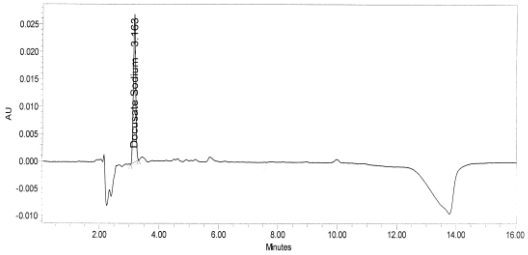
Theoretical plates for docusate sodium peak from first standard injection – 7763 (Not less than 3000).

Table 6: Area of Standard Solution

Standard Injection #	Area
1	144959
2	144276
3	144730
4	144360
5	144720
Average	**144609**
%RSD	**0.2**



[Fig.2: Typical Chromatogram of Blank]



[Fig.3: Typical Chromatogram of Standard]

B. Specificity

- *Blank Interference and Placebo Interference*

Specificity includes selectivity. The study demonstrates that the method is specific for determination of % Assay of Docusate sodium in Docusate sodium capsules 100 mg. Specificity was evaluated to ensure that no other compound interferes with the analytes.

- *Preparation of Placebo Solution*

Weighed and transferred placebo 955.80 mg & 928.90 mg into an individual 200-mL volumetric flask, added about 50 mL water at about 50°C and allowed it to dissolve completely, sonicated for about 7 minutes and added 50-mL of acetonitrile, sonicated for 1 minute. Allowed this solution to cool to room temperature and diluted to volume with diluent.

Accurately transferred 4.0 mL of this solution into an individual 100 mL volumetric flask, diluted to volume with diluent and filtered discarding the first few mL of the filtrate and collected the remaining filtrate.

- *Sample Solution Preparation (As Such)*

Accurately weighed not less than 20 capsules and determined average weight (376.385mg). Weighed (1889.1mg) and transferred 5 intact capsules into a 200-mL volumetric flask, added 50 mL water at about 50°C and sonicated for 15 minutes. Added 50-mL of acetonitrile and sonicated for 5 minutes. Allowed this solution to cool to room temperature and diluted to volume with diluent.

Accurately transferred 4.0 mL of this solution into a 100 mL volumetric flask, diluted to volume with diluent. Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate.

- *Procedure*

Equilibrated the column with mobile phase as per the chromatographic condition. The solutions were injected into a chromatograph. Evaluated the chromatograms.

- *System Suitability Results*

Tailing factor for Docusate sodium peak in Standard solution – 1.2 (Not more than 2.0).

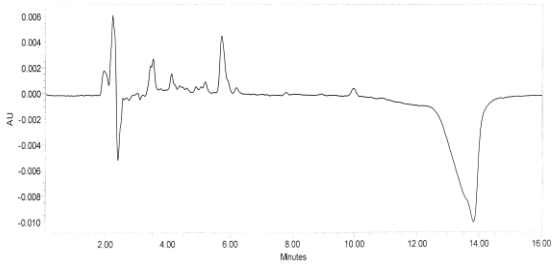
Theoretical plates for docusate sodium peak from first standard injection – 7763 (Not less than 3000).

Table 7: Area of Standard Solution

Standard Injection #	Area
1	144959
2	144276
3	144730
4	144360
5	144720
Average	144609
%RSD	0.2

Table 8: Specificity Results

Name of Solution	Area of Docusate Sodium	RT of Docusate Sodium
Blank	NA	NA
Placebo solution 1	Not Detected	NA
Placebo solution 2	Not Detected	NA
Standard solution	144959	3.16
100 mg Sample Solution	147007	3.16



[Fig.4: Typical Chromatogram of Placebo]

- *Acceptance Criteria*
  - The system suitability should comply as per methodology.
  - The retention time of Docusate sodium peak in standard solution and sample solution should match.
  - There should not be any interference from diluent and placebo at RT of Docusate sodium peak.
- *Observation*

The system suitability criteria are well within the limit. There is no interference found at the retention time of Docusate sodium from diluent and Placebo. Retention time of docusate sodium in standard and sample solutions were the same. Hence, the method is specific for estimation of Assay.

C. Linearity

Linearity of the detector response was assessed for Docusate Sodium from 50% to 150% of sample concentration.

Plot the linearity graph for the response versus concentration. Determine slope, correlation coefficient and Y intercept bias at 100% level.

- *Preparation of Standard Solution*

Accurately weighed and transferred 49.14 mg of Docusate Sodium standard into 50-mLvolumetric flask. Added about 25 mL of diluent and sonicated for 5 minutes to dissolve. Diluted up to the mark with diluent and mixed well (Concentration of Docusate Sodium is about 1000ppm). Accurately transferred 5.0 mL of this solution into 50 mL of volumetric flask and diluted to volume with diluent.

Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate. (Concentration of Docusate Sodium is about 100 ppm)

- *Preparation of Linearity Stock Solution*

Refer to stock standard preparation of 1000 ppm.

- *Preparation of Linearity Solutions*

The linearity stock solution was diluted as mentioned in the table below with diluent and mix well.

Table 9: Linearity Solutions

Level (%)	mL of stock Solution	Diluted to (mL)	Concentration (PPM)
50	2.5	50	48.8452
80	4.0	50	78.1523
100	5.0	50	97.6903
130	6.5	50	126.9974
150	7.5	50	146.5355

Table 10: Area of Standard Solution

Standard Injection #	Area
1	145361
2	145181
3	145378
4	145954
5	145389
Average	145453
%RSD	0.2

- *System Suitability Results*

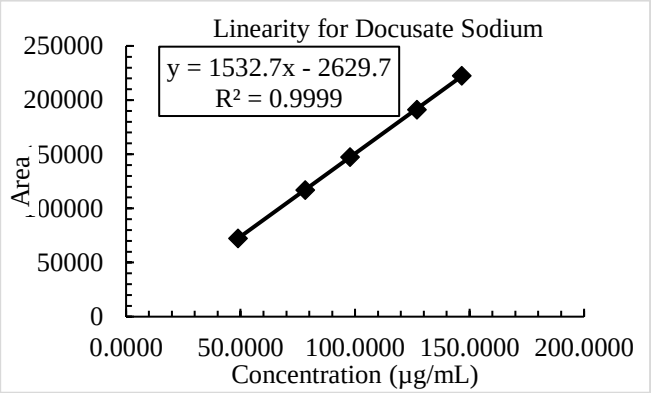
Tailing factor for Docusate sodium peak in Standard solution – 1.2 (Not more than 2.0).

Theoretical plates for docusate sodium peak from first standard injection – 7803 (Not less than 3000).

- *Linearity Results*

Table 11: Linearity Results

Level (%)	Concentration (µg/mL)	Area-1	Area-2	Avg. Area
50	48.8452	72510	72238	72374
80	78.1523	116876	117026	116951
100	97.6903	147152	147765	147459
130	126.9974	191024	191323	191174
150	146.5355	222409	222660	222535
Slope		1532.7370		
Correlation Coefficient (R)		1.0000		
Y-Intercept		-2629.6565		
Y-Int Bias at 100%		-1.7833		



[Fig.5: Linearity Curve]

- *Acceptance Criteria*
  - The system suitability should comply as per methodology.
  - The correlation coefficient (R) should not be less than 0.99.
  - Intercept (Y-Intercept bias) should be within ± 3.0% of response at 100%.
  - Report the value of slope and intercept.
- *Observation*

The results are well within acceptance criteria. The correlation coefficient is 1.00. The Y-intercept bias is less than 3.0%. Hence it has been concluded that the method shows linear response for working range of concentration. Slope and intercept found to be 1532.7370 & -2629.6565 respectively.

D. Precision

The precision of an analytical method is the degree of agreement among

individual test results when the method is applied repeatedly to multiple portions of a homogeneous sample. The system precision expresses the instrument precision over a short period of time.

- *System Precision*

Evaluate the Area of Docusate sodium peak and calculate %RSD from standard solution injection.

- *System Suitability*

Tailing factor for Docusate sodium peak in Standard solution – 1.2 (Not more than 2.0).

Theoretical plates for docusate sodium peak from first standard injection – 7763 (Not less than 3000).

Table 12: Area of Standard Solution

Standard Injection #	Area
1	144959
2	144276
3	144730
4	144360
5	144720
Average	144609
%RSD	0.2

- *Acceptance Criteria*

The system suitability should comply as per methodology.

%RSD of Docusate sodium peak area should not be more than 2.0.

- *Observation*

The system suitability and %RSD of the main peak area are well within acceptance criteria. The system is precise for determination of assay of Docusate Sodium in Docusate Sodium capsules.

Method Precision

- *Preparation of Sample Solution (Prepared in Six Replicates)*

Accurately weighed not less than 20 capsules and determined average wight. Weighed and transferred 5 intact capsules into a 200-mL volumetric flask, added 50 mL water at about 50°C and sonicated for 15 minutes. Added 50-mL of acetonitrile and sonicated for 5 minutes. Allowed this solution to cool to room temperature and diluted to volume with diluent.

Accurately transferred 4.0 mL of this solution into a 100 mL volumetric flask, diluted to volume with diluent. Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate.

Table 13: Weight of Samples

Sample #	Sample weight (mg)
1	1889.1
2	1885.5
3	1877.8
4	1874.7
5	1845.7
6	1867.7

Table 14: Results of Method Precision

Sample #	% Assay
1	101.7
2	102.0
3	100.9
4	101.0
5	99.8
6	100.7
Average	101.0
%RSD	0.8

- *Acceptance Criteria*

The system suitability should comply as per methodology. % RSD for results of six samples should not be more than 2.0.

- *Observation*

The system suitability and %RSD of results for both strengths are well within acceptance criteria. Hence, the method produces precise results.

- *Intermediate Precision*

Analysis was performed by a second analyst on different instruments on different days using new mobile phase, diluent, and standard solution as per methodology.

- *Preparation of Standard Solution*

Accurately weighed and transferred 50.24 mg of Docusate Sodium standard into 50-mLvolumetric flask. Added about 25 mL of diluent and sonicated for 10 minutes to dissolve. Diluted up to the mark with diluent and mixed well. Accurately transferred 5.0 mL of this solution into 50 mL of volumetric flask and diluted to volume with diluent.

Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate. (Concentration of Docusate Sodium is about 100 ppm).

- *Preparation of Sample Solution*

Accurately weighed not less than 20 capsules and determined average wight. Weighed and transferred 5 intact capsules into a 200-mL volumetric flask, added 50 mL water at about 50°C and sonicated for 30 minutes. Added 50-mL of acetonitrile and sonicated for 5 minutes. Allowed this solution to cool to room temperature and diluted to volume with diluent. Accurately transferred 4.0 mL of this solution into a 100 mL volumetric flask, diluted to volume with diluent. Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate.

Table 15: Weight of Samples of Intermediate Precision

Sample #	Sample weight (mg)
1	1868.16
2	1822.49
3	1881.96
4	1871.38
5	1846.83
6	1890.48

Table 16: Results of Intermediate Precision

Sample #	% Assay
1	100.0
2	97.0
3	99.5
4	99.3
5	98.8
6	100.5
Average	99.2
%RSD	1.2

Table 17: Overall Results of Intermediate Precision

Set	% Assay
Aanlyst-1	101.7
	102.0
	100.9
	101.0
	99.8
	100.7
Analyst-2	100.0
	97.0
	99.5
	99.3
	98.8
	100.5
Average	100.1
%RSD	1.4

- *Acceptance Criteria*

The system suitability should comply as per methodology. % RSD for results of six samples should not be more than 2.0.

- *Observation*

The system suitability and %RSD of results of 12 samples for both strengths are well within acceptance criteria. Hence, method produces precise results.

E. Accuracy

The accuracy of an analytical method is the closeness of the test results obtained by that method to the theoretical value. Accuracy has been performed for 50% and 100% level of target concentration. For diluent preparation, standard solution and chromatographic condition refer to linearity parameter.

- *Preparation of Recovery Stock Solution for 50% and 100%*

Accurately weighed and transferred Docusate Sodium API and placebo into 200-mL volumetric flask for each level as mentioned in the Table-18 below. Added 50 mL water at about 50°C and sonicated for 15 minutes. Added 50-mL of acetonitrile and sonicated for 10 minutes, allowed it to dissolve completely. Allowed this solution to cool to room temperature and diluted to volume with diluent. Mixed well.

Accurately transferred 4.0 mL of this solution into a 100 mL volumetric flask, diluted to volume with diluent. Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate.

- *Preparation of Recovery Stock Solution for 150%*

Accurately weighed and transferred Docusate Sodium API and placebo into 200-mL volumetric flask for each level as mentioned in Table-18 below. Added 50 mL water at about 50°C and sonicated for 15 minutes. Added 50-mL of acetonitrile and sonicated for 10 minutes, allowed it to dissolve completely. Allowed this solution to cool to room temperature and diluted to volume with diluent. Mixed well.

Accurately transferred 3.0 mL of this solution into a 100 mL volumetric flask, diluted to volume with diluent. Filtered through 0.45 µm filter after discarding first few mL of the filtrate and collected the remaining filtrate.

Table 18: Linearity Solutions

Recovery level	Stock Solution			Final Solution	
	Weight of Placebo (mg)	Wt. of API	Diluted to (mL)	mL of Stock Solution	Diluted to (mL)
50%	901.9	508.6	200	4	100
	905.4	515.5	200	4	100
	902.0	515.4	200	4	100
100%	905.0	1009.1	200	4	100
	900.4	1029.5	200	4	100
	903.5	1014.2	200	4	100
150%	903.2	2003.2	200	3	100
	905.5	2003.5	200	3	100
	902.8	2002.7	200	3	100

- *Procedure*

Equilibrated the column with mobile phase as per the chromatographic condition for sufficient time. Injected solutions into chromatography and evaluated the chromatograms. Calculated recovery for each sample. Calculated %RSD for each level and overall % RSD.

- *System Suitability*

Tailing factor for Docusate sodium peak in Standard solution – 1.2 (Not more than 2.0).

Theoretical plates for docusate sodium peak from first standard injection – 7803 (Not less than 3000).

Table 19: Area of Standard Solution

Standard Injection #	Area
1	145361
2	145181
3	145378
4	145954
5	145389
Average	**145453**
%RSD	**0.2**

Table 20: Recovery Results

% Level	Area	'mg' added	'mg' found	% Recovery	Avg. Recovery (%)	% RSD
50%	75520	5.066	5.072	100.1	100.6	0.4
	77171	5.134	5.183	101.0		
	76925	5.133	5.166	100.6		
100%	151106	10.051	10.149	101.0	101.4	0.4
	155168	10.254	10.422	101.6		
	152974	10.101	10.274	101.7		
150%	226639	14.964	15.037	100.5	100.7	0.2
	221720	14.966	15.069	100.7		
	227237	14.960	15.076	100.8		
Overall					100.9	0.4

- *Acceptance Criteria*

The system suitability should comply as per methodology. % Recovery for each level shall be between 98.0% to 102.0%. % RSD for results of triplicate preparation of each level and overall %RSD for entire results shall not be more than more than 2.0%.

- *Observation*

The system suitability, % recovery of each level, % RSD of each level and all levels found well within the acceptance criteria. Hence the method produces accurate results.

VI. RESULTS AND DISCUSSION

The analytical method obtained the specific, precise results with % RSD for results of six samples was

1.2% and for twelve samples was 1.4% against the specification of NMT 2.0%. Additionally, the correlation coefficient for linearity samples was obtained 1.00 against NLT 0.99. Furthermore, the recovery from accuracy study was obtained for % RSD of each level (50%, 100%, 150%) and overall, as 0.4%, 0.4%, 0.2% and 0.4%. Hence, the method was determined as Specific, Linear, Precise and Accurate for Finished product and Stability analysis.

VII. CONCLUSION

The analytical method is quite simple and suitable for finished product analysis. The method was verified according to ICH guidelines for (Q2) Analytical Method Validation and produces precise, linear and accurate results. Although USP monograph has provided the analytical method, the method was not suitable for the Assay analysis of docusate sodium soft gelatine capsules considering the existing in-house laboratory environment. Hence, the new method was developed and successfully validated. Thus, it is suitable for finished product analysis and stability indicating analysis in Quality Control.

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DECLARATION STATEMENT

After aggregating input from all authors, I must verify the accuracy of the following information as the article's author.

- **Conflicts of Interest/ Competing Interests:** Based on my understanding, this article has no conflicts of interest.
- **Funding Support:** This article has not been sponsored or funded by any organization or agency. The independence of this research is a crucial factor in affirming its impartiality, as it has been conducted without any external sway.
- **Ethical Approval and Consent to Participate:** The data provided in this article is exempt from the requirement for ethical approval or participant consent.
- **Data Access Statement and Material Availability:** The adequate resources of this article are publicly accessible.
- **Authors Contributions:** The authorship of this article is contributed equally to all participating individuals.

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