International Journal of Advanced Pharmaceutical Sciences and Research (IJAPSR)
ISSN: 2582-7618 (Online), Volume-5 Issue-3, April 2025

# Method Development and Verification of Assay of Simethicone in Simethicone Soft Gel Capsule in the Form of Polydimethylsiloxane by FT-IR

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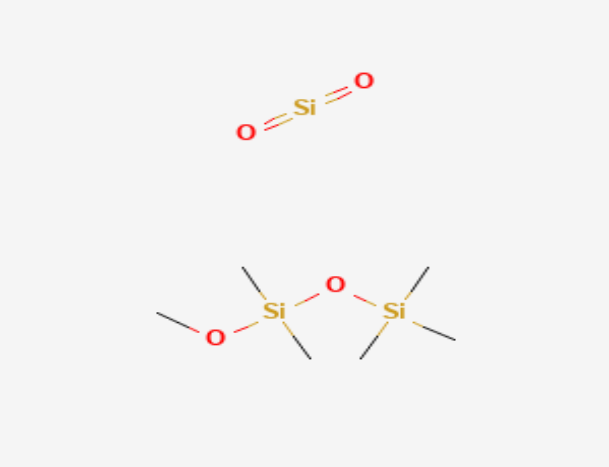
***Abstract:*** ***In this research article, Fourier Transform Infrared (FT-IR) Spectroscopy method was developed for the determination of Assay of Simethicone in Simethicone Soft Gel Capsule. The method has been adopted from United States Pharmacopeia (USP). However, it could not produce precise results since different instruments and data acquisition software have wide range of instrumental/software parameters. Thus, the FT-IR method was developed using Shimadzu IR affinity instrument with Lab solution data acquisition software and verified according to ICH guideline Q2R(2) Validation of Analytical Procedure. The acceptance criteria for the determination of Assay of Simethicone in Simethicone Capsule liquid filled in the form of Polydimethylsiloxane is 85.0% to 115.0%.***

***Keywords: FT-IR, ICH Guidelines, Assay, Simethicone, Soft Gelatin Capsule, Validation, Lab Solution Data Acquisition***

***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

Simethicone is a silicone-based polymer compound used for the treatment and management of gas and bloating [1]. It relieves the excess gas present in the gastrointestinal tract. Simethicone is also known as dioxosilane; methoxy-dimethyl-trimethylsilyloxysilane and it's a mixture of polydimethylsiloxanes. Simethicone has an antifoaming and anti-bloating effect due to which it decreases the surface tension of gastrointestinal gas bubbles to facilitate their elimination. Simethicone has a molecular weight of 238.46 g/mol and formula of $C_6H_{18}O_4Si_3$. Simethicone Drug Substance is widely used in different forms such as Tablets, Liquid filled Capsules (Soft Gel), Suspensions, Drops etc. Furthermore, it is widely formulated as single drug as well as with combination of other drugs to deliver its anti-bloating property in various dosage forms [2].




**[Fig.1: Structure of Simethicone [2]]**

Since Simethicone is a silicon based organic polymer and it does not contain UV chromophore in its structure, Quantification of polydimethylsiloxane is difficult through UV detector [3]. The analytical method for determination of % Assay of Simethicone in Simethicone Soft Gel Capsule developed and executed with various analytical techniques including HPLC. Feasibility & development methods were performed using various detectors such as UV detectors [4], PDA detectors [5], RI detectors with HPLC. However, it did not obtain precision and accuracy in the results [6]. Thus, it is difficult to develop a High-Performance Liquid Chromatography (HPLC) method for the determination of Simethicone in Simethicone Soft Gel Capsule in the form of Polydimethylsiloxane (-(CH3)2 SiO-]n) [7].

Moreover, Pharmacopeial methods for Simethicone Drug Product such as USP and British Pharmacopoeia have adopted the Assay determination by FT-IR method due to its complex nature [8]. Though the analytical method has been adopted from USP [9], there were few challenges in the preparation of standard-sample solution and to set up the instrument considering the nature of molecules and absence of UV chromophore [10]. Moreover, different makers of instrument and data acquisition software have their own challenges to execute the method. Thus, to obtain accurate and precise results, the analytical method has been developed and verified according to ICH Q2R(2) guidelines for the development and verification of analytical procedure. The method was verified with Precision study (System Precision, Method Precision and Intermediate Precision) [11].

**Manuscript received on 23 January 2025 | First Revised Manuscript received on 27 January 2025 | Second Revised Manuscript received on 16 March 2025 | Manuscript Accepted on 15 April 2025 | Manuscript published on 30 April 2025.**
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## II. EXPERIMENTAL DETAILS

### A. Standard/Sample/Reagents/Instruments

**Table 1: Instrument Details**

| Instrument | Make & Model No. |
|---|---|
| FT-IR | Shimadzu IR affinity |
| Analytical balance | Mettler Toledo -AT 261 |
| | Sartorius – CP324S |
| Sonicator | Fisher Scientific – FS28 |
| | Bransonic – CPX8800 |
| Centrifuge | CGOLDEBWALL - 80-2 |

**Table 2: Reagents Details**

| Chemicals | Grade |
|---|---|
| Toluene | ACS |
| Hydrochloric Acid | ACS |
| Sodium Sulphate Anhydrous | ACS |

**Table 3: Standards Details**

| Name of Standards | Potency |
|---|---|
| Polydimethylsiloxane Working Standard | 99.98% |
| Simethicone Capsules liquid filled 180 mg | N/A |

## III. ANALYTICAL METHOD

### A. Precautions

Carefully handle the liquid cell. After completion of analysis clean the liquid cell with Toluene followed by IPA twice.

### B. Instrumental Condition

Instrument: IR Spectrophotometer
Method Type: Data collect only
Background valid time limit: 2.0 Hours
Y-Axis units: Absorbance
Scan range: 1100 cm-1 to 1300 cm-1
Background Scans: 32
Sample Scans: 32
Resolution: 8
IR Range: MID
Apodization: HappGenzel
Beam: Internal
Sampling Technology: Transmission cell
Pathlength(mm): 0.50 mm
Gain: Auto
Measurement Mode: Absorbance
Detector Type: Standard

Analytical Wavelength: Wavelength of Maximum absorbance at about 1260 $cm^{-1}$ (About 7.9 µm)

### C. Preparation of 6N Hydrochloric Acid

Transfer 70 mL of water into a 200-mL volumetric flask. Add 102 mL of concentrated Hydrochloric acid to make up the flask up to the mark with water and mix well.

### D. Preparation of Blank Solution

Transfer 10.0 mL toluene into a 100-mL volumetric flask. Add 20 mL of 6 N Hydrochloric acid. Vortex the solution for 10 minutes at high speed. Transfer the solution into a separating funnel and gently shake. Allow to separate two layers and discard the lower aqueous layer and collect the upper layer (toluene layer).

Transfer 10.0 mL upper layer (toluene layer) into centrifuge tube and add about 0.5 g of sodium sulphate anhydrous. Mix well and allow to settle down the sodium sulphate anhydrous, Centrifuge the solution at 2000 rpm for 2 minutes.

### E. Preparation of Standard Solution

Accurately weigh and transfer about 50 mg of Polydimethylsiloxane into a 20-mL volumetric flask. Add about 15 mL toluene and sonicate the solution for 20 minutes. Dilute up to the mark with Toluene and mix well. Transfer 20.0 mL standard stock in 100-mL volumetric flask. Add 20 mL of 6 N Hydrochloric acid and mix well. Vortex the solution for 20 minutes at high speed.

Transfer the solution into a separating funnel and gently shake. Allow to separate two layers and discard the lower aqueous layer and collect the upper layer (toluene layer).

Transfer the 20.0 mL upper layer (toluene layer) into a centrifuge tube and add about 0.5 g of sodium sulphate anhydrous. Mix well and allow to settle down the sodium sulphate anhydrous, Centrifuge the solution at 2000 rpm for 2 minutes.

### F. Preparation of Sample Solution

Accurately weigh and transfer 1 capsule of Simethicone 180 mg into a 200-mL volumetric flask, add 20 mL of 6 N hydrochloric acid and swirl it occasionally until dispersing the capsule. Add 72 mL of toluene, mix vigorously and vortex it at high speed for 20 minutes.

Transfer the solution into a separating funnel and gently shake. Allow to separate two layers and discard the lower aqueous layer and collect the upper layer (toluene layer).

Transfer the upper layer (toluene layer) to a centrifuge tube and add about 0.5 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuge the solution at 2000 rpm for 2 minutes.

*[**Note**: Perform this procedure on at least 3 individual Capsules and report the mean of the assay value]*

### G. Procedure

Fill up the liquid cell for IR spectrophotometer (path length 0.5 mm) by using syringe with solutions as mentioned in below Table- 4 individually. Scan the solutions range of 1100 $cm^{-1}$ to 1300 $cm^{-1}$ for absorbance. Determine the absorbance at about (7.9 µm) 1260 $cm^{-1}$.

**Table 4: Injection Sequence**

| Sr. # | Solution | No. of Scan |
|---|---|---|
| 1 | Blank | 1 |
| 2 | Standard solution | 6 |
| 3 | Sample solution-1 | 1 |
| 4 | Sample solution-2 | 1 |
| 5 | Sample solution-3 | 1 |

### H. System Suitability Requirements

% RSD for absorbance of simethicone from six replicate spectra of standard solution – NMT 10.0%.

### I. Calculation

Calculate% Assay of Simethicone in the form of Polydimethylsiloxane by using following formula,

$$\%Assay = \frac{Au}{As} \times \frac{Ws}{20} \times \frac{72}{L} \times \frac{P}{100} \times 100$$

Where,

Au = Absorbance of sample solution at about 1260 $cm^{-1}$ (7.9 µm)

$A_S$ = Absorbance of standard solution at about 1260 $cm^{-1}$ (7.9 µm)

Ws = Weight of Polydimethylsiloxane standard (mg)

L = Label Claim of Simethicone (mg/Capsule)

P = Potency of Polydimethylsiloxane standard % as is

### J. Acceptance Criteria

Between 85.0% to 115.0%

## IV. METHOD VERIFICATION PARAMETERS

### A. System Precision

The system precision expresses the instrument precision over a short period of time. Prepared blank solution, standard solution and sample solution as per test method. Prepared the sample solution in six replicates. Analyzed the samples as per test method. Calculated the % Assay for each sample solution and calculated the %RSD for the obtained assay results.

*i. Experimental Condition*

Instrument: IR Spectrophotometer
Method Type: Data collect only
Background valid time limit: 2.0 Hours
Y-Axis units: Absorbance
Scan range: 1100 cm-1 to 1300 cm-1
Background Scans: 32
Sample Scans: 32
Resolution: 8
IR Range: MID
Apodization: HappGenzel
Beam: Internal
Sampling Technology: Transmission cell
Pathlength(mm): 0.50 mm
Gain: Auto
Measurement Mode: Absorbance
Detector Type: Standard

Analytical Wavelength: Wavelength of Maximum absorbance at about 1260 $cm^{-1}$ (About 7.9 µm).

*ii. Preparation of 6N Hydrochloric Acid*

Transferred 170 mL of water into a 500-mL volumetric flask. Added 255 mL of concentrated Hydrochloric acid made up the flask up to the mark with water and mixed well.

*iii. Preparation of Blank*

Transferred 10.0 mL toluene into a 100-mL volumetric flask. Added 20 mL of 6 N Hydrochloric acid. Vortexed the solution for 10 minutes at high speed. Transferred the solution into separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred 10.0 mL upper layer (toluene layer) into centrifuge tube and added 0.5005 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

*iv. Preparation of Standard Solution*

Accurately weighed and transferred about 51.83 mg of Polydimethylsiloxane into 20-mL volumetric flask. Added about 15 mL toluene and sonicated the solution for 20 minutes. Diluted up to the mark with Toluene and mixed well. Transferred 20.0 mL standard stock in 100-mL volumetric flask. Added 20 mL of 6 N Hydrochloric acid and mixed well. Vortexed the solution for 20 minutes at high speed.

Transferred the solution into a separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred 20.0 mL upper layer (toluene layer) into centrifuge tube and added 0.5000 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

*v. Preparation of Sample Solution*

Accurately weighed and transferred 6 capsules of Simethicone 180 mg into an individual 200-mL volumetric flask, added 20 mL of 6 N hydrochloric acid and swirled it occasionally until dispersed the capsule. Added 72 mL of toluene, mixed vigorously and vortexed it at high speed for 20 minutes. Transferred the solution into a separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred the upper layer (toluene layer) in a centrifuge tube and added about 0.5 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

**Table 5: Weights of Sample and Sodium Sulphate Anhydrous**

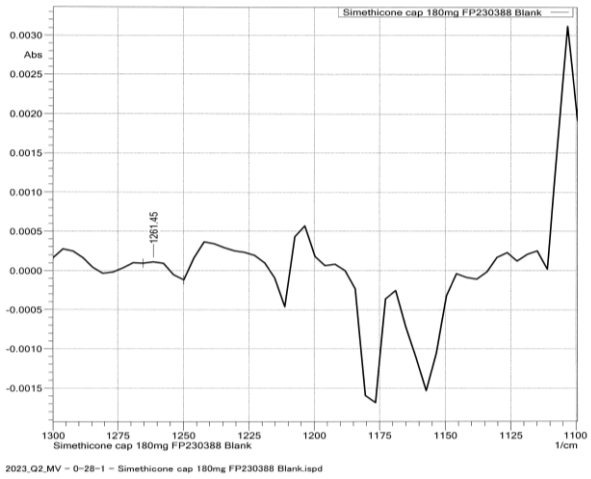
| Sr. # | Weight of Capsule (g) | Weight of Sodium Sulphate Anhydrous (g) |
|---|---|---|
| 1 | 0.3039 | 0.5001 |
| 2 | 0.3018 | 0.5007 |
| 3 | 0.2914 | 0.5007 |
| 4 | 0.3011 | 0.5005 |
| 5 | 0.3051 | 0.5008 |
| 6 | 0.2950 | 0.5006 |

*vi. Procedure*

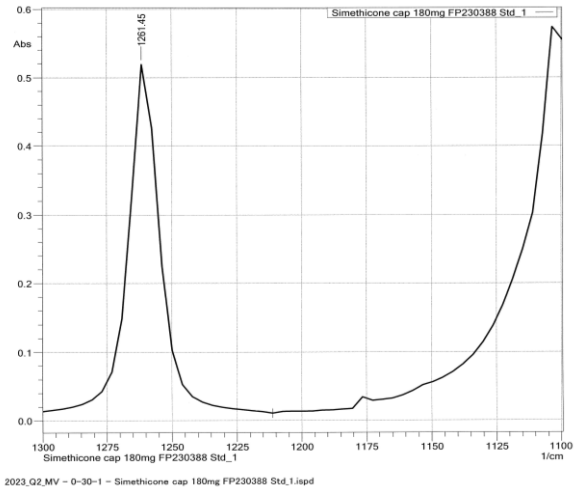
Filled up the liquid cell for IR spectrophotometer (path length 0.5 mm) by using syringe with solutions as mentioned in below table individually. Scan the solutions range of 1100 $cm^{-1}$ to 1300 $cm^{-1}$ for absorbance. Determined the absorbance at about (7.9 µm) 1260 $cm^{-1}$. Performed background correction using blank solution.

**Table 6: Absorbances of Standard Solution**

| Standard Scan # | Absorbance |
|---|---|
| 1 | 0.519096 |
| 2 | 0.518048 |
| 3 | 0.517013 |
| 4 | 0.516868 |
| 5 | 0.516902 |
| 6 | 0.516751 |
| Average | 0.517446333 |
| %RSD | 0.2 |




**[Fig.2: Typical Spectra of Blank]**




**[Fig.3: Typical Spectra of Standard]**

*vii. Acceptance Criteria*

% RSD for absorbance of simethicone from six replicate spectra of standard solution – not more than 10.0%.

*viii. Observation*

The %RSD for system suitability criteria was determined as 0.2% and well within the acceptance criteria.

**B. Method 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.

Prepared blank solution, standard solution and sample solution as per test method. Prepared the sample solution in six replicates. Analyzed the samples as per test method. Calculated the %Assay for each sample solution and calculated the %RSD for the obtained assay results.

*i. Experimental Condition*

Instrument: IR Spectrophotometer
Method Type: Data collect only
Background valid time limit: 2.0 Hours
Y-Axis units: Absorbance
Scan range: 1100 cm-1 to 1300 cm-1
Background Scans: 32
Sample Scans: 32
Resolution: 8
IR Range: MID
Apodization: HappGenzel
Beam: Internal
Sampling Technology: Transmission cell
Pathlength(mm): 0.50 mm
Gain: Auto
Measurement Mode: Absorbance
Detector Type: Standard
Analytical Wavelength: Wavelength of Maximum absorbance at about 1260 $cm^{-1}$ (About 7.9 µm).

*ii. Preparation of 6N Hydrochloric Acid*

Transferred 170 mL of water into a 500-mL volumetric flask. Added 255 mL of concentrated Hydrochloric acid made up the flask up to the mark with water and mixed well.

*iii. Preparation of Blank*

Transferred 10.0 mL toluene into a 100-mL volumetric flask. Added 20 mL of 6 N Hydrochloric acid. Vortexed the solution for 10 minutes at high speed. Transferred the solution into separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred 10.0 mL upper layer (toluene layer) into centrifuge tube and added 0.5005 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

*iv. Preparation of Standard Solution*

Accurately weighed and transferred about 51.83 mg of Polydimethylsiloxane into 20-mL volumetric flask. Added about 15 mL toluene and sonicated the solution for 20 minutes. Diluted up to the mark with Toluene and mixed well. Transferred 20.0 mL standard stock in 100-mL volumetric flask. Added 20 mL of 6 N Hydrochloric acid and mixed well. Vortexed the solution for 20 minutes at high speed.

Transferred the solution into a separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred 20.0 mL upper layer (toluene layer) into centrifuge tube and added 0.5000 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

*v. Preparation of Sample Solution*

Accurately weighed and transferred 6 capsules of Simethicone 180 mg into an individual 200-mL volumetric flask, added 20 mL of 6 N hydrochloric acid and swirled it occasionally until dispersed the capsule. Added 72 mL of toluene, mixed vigorously and vortexed it at high speed for 20 minutes.

Transferred the solution into a separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred the upper layer (toluene layer) into a centrifuge tube and added about 0.5 g of sodium sulphate anhydrous. Mixed

well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

**Table 7: Weights of Sample and Sodium Sulphate Anhydrous**

| Sr. # | Weight of Capsule (g) | Weight of Sodium Sulphate Anhydrous (g) |
|---|---|---|
| 1 | 0.3039 | 0.5001 |
| 2 | 0.3018 | 0.5007 |
| 3 | 0.2914 | 0.5007 |
| 4 | 0.3011 | 0.5005 |
| 5 | 0.3051 | 0.5008 |
| 6 | 0.2950 | 0.5006 |

*vi. Procedure*

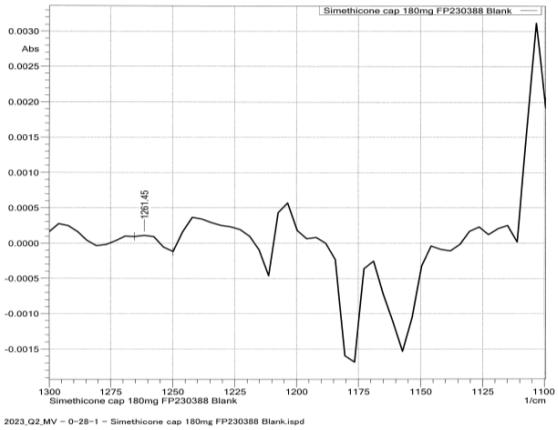
Filled up the liquid cell for IR spectrophotometer (path length 0.5 mm) by using syringe with solutions as mentioned in below table individually. Scan the solutions range of 1100 $cm^{-1}$ to 1300 $cm^{-1}$ for absorbance. Determined the absorbance at about (7.9 µm) 1260 $cm^{-1}$. Performed background correction using blank solution.

*vii. System Suitability Results*

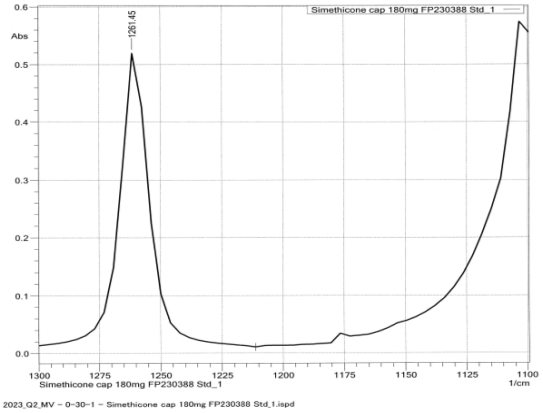
% RSD for absorbance of simethicone from six replicate spectra of standard solution – 0.2% [NMT 10.0%].

**Table 8: Absorbances of Standard Solution**

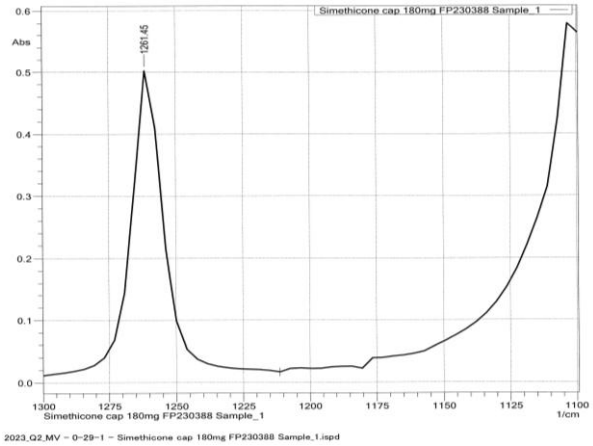
| Standard Scan # | Absorbance |
|---|---|
| 1 | 0.519096 |
| 2 | 0.518048 |
| 3 | 0.517013 |
| 4 | 0.516868 |
| 5 | 0.516902 |
| 6 | 0.516751 |
| Average | 0.517446333 |
| %RSD | 0.2 |




**[Fig.4: Typical Spectra of Blank]**




**[Fig.5: Typical Spectra of Standard]**




**[Fig.6: Typical Spectra of Sample]**

**Table 9: Results of Method Precision**

| Set # | % Assay |
|---|---|
| 1 | 100.62 |
| 2 | 103.04 |
| 3 | 100.44 |
| 4 | 105.78 |
| 5 | 106.09 |
| 6 | 100.31 |
| Average | 102.71 ~ 102.7 |
| %RSD | 2.6 |

*viii. Acceptance Criteria*

% Assay of individual samples should be between 85.0% to 115.0%.

% RSD for % assay results of six samples should not be more than 10.0.

*ix. Observation*

The system suitability criteria and method precision results were obtained to be well within the acceptance criteria.

## C. Intermediate Precision

Intermediate precision was carried out with a second analyst on different days using a new blank solution, standard solution and sample solution as per test method. Prepared the sample solution in six replicates.

*i. Preparation of Blank*

Transferred 10.0 mL toluene into a 100-mL volumetric flask. Added 20 mL of 6 N Hydrochloric acid. Vortexed the solution for 10 minutes at high speed. Transferred the solution into separating funnel and gently shake. Allowed to separate two layers and discarded lower aqueous layer and collected the upper layer (toluene layer).

Transferred 10.0 mL upper layer (toluene layer) into centrifuge tube and added 0.5043 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

*ii. Preparation of Standard Solution*

Accurately weighed and transferred about 52.03 mg of Polydimethylsiloxane into 20-mL volumetric flask. Added about 15 mL toluene and sonicated the solution for 20 minutes. Diluted up to the mark with Toluene and mixed well. Transferred 20.0 mL standard stock in 100-mL volumetric flask. Added 20 mL of 6 N Hydrochloric acid and

mixed well. Vortexed the solution for 20 minutes at high speed. Transferred the solution into a separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred 20.0 mL upper layer (toluene layer) into centrifuge tube and added about 0.5040 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

*iii. Preparation of Sample Solution*

Accurately weighed and transferred 6 capsules of Simethicone 180 mg into an individual 200-mL volumetric flask, added 20 mL of 6 N hydrochloric acid and swirled it occasionally until dispersed the capsule. Added 72 mL of toluene, mixed vigorously and vortexed it at high speed for 20 minutes.

Transferred the solution into a separating funnel and gently shaken. Allowed to separate two layers and discarded the lower aqueous layer and collected the upper layer (toluene layer).

Transferred the upper layer (toluene layer) into a centrifuge tube and added about 0.5 g of sodium sulphate anhydrous. Mixed well and allowed to settle down the sodium sulphate anhydrous, Centrifuged the solution at 2000 rpm for 2 minutes.

**Table 10: Weights of Sample and Sodium Sulphate Anhydrous**

| Sr. # | Weight of Capsule (g) | Weight of Sodium Sulphate Anhydrous (g) |
|---|---|---|
| 1 | 0.3054 | 0.5024 |
| 2 | 0.3035 | 0.5022 |
| 3 | 0.2807 | 0.5023 |
| 4 | 0.2794 | 0.5014 |
| 5 | 0.2856 | 0.5009 |
| 6 | 0.2795 | 0.5016 |

*iv. Procedure*

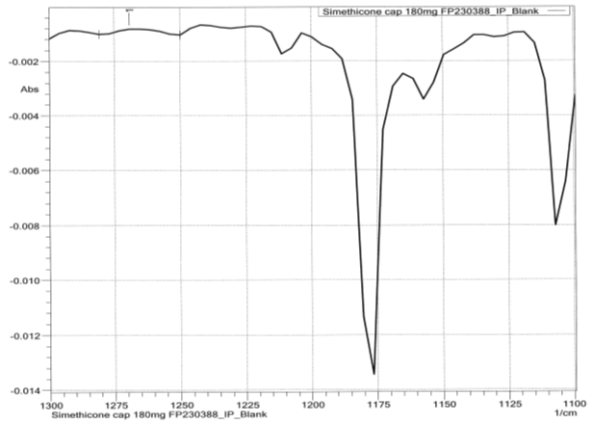
Filled up the liquid cell for IR spectrophotometer (path length 0.5 mm) by using syringe with solutions as mentioned in below table individually. Scan the solutions range of 1100 $cm^{-1}$ to 1300 $cm^{-1}$ for absorbance. Determined the absorbance at about (7.9 µm) 1260 $cm^{-1}$. Performed background correction using blank solution.

*v. System Suitability Results*

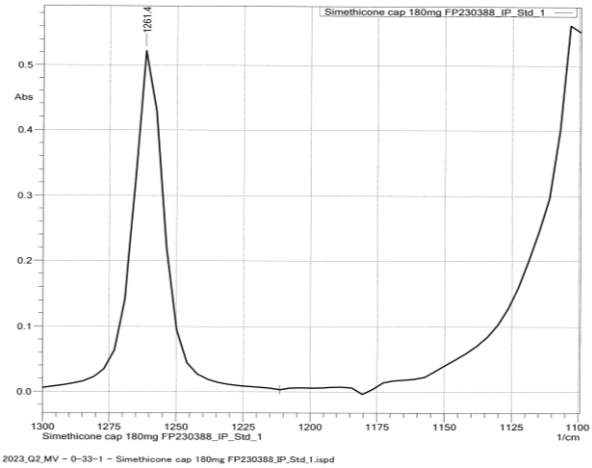
% RSD for absorbance of simethicone from six replicate spectra of standard solution – 0.0% [NMT 10.0%].

**Table 11: Absorbances of Standard Solution**

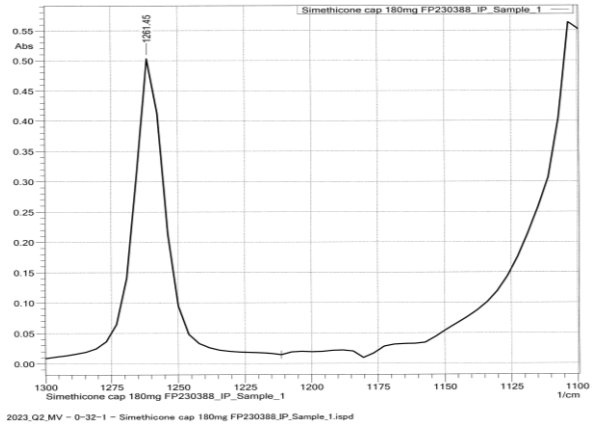
| Standard Scan # | Absorbance |
|---|---|
| 1 | 0.522351 |
| 2 | 0.522634 |
| 3 | 0.522471 |
| 4 | 0.522391 |
| 5 | 0.522488 |
| 6 | 0.522258 |
| Average | 0.522432167 |
| %RSD | 0.0 |




**[Fig.7: Typical Spectra of Blank from Intermediate Precision]**




**[Fig.8: Typical Spectra of Standard from Intermediate Precision]**




**[Fig.9: Typical Spectra of Sample from Intermediate Precision]**

**Table 12: Results of Intermediate Precision**

| Set # | % Assay |
|---|---|
| 1 | 100.21 |
| 2 | 104.28 |
| 3 | 92.41 |
| 4 | 89.82 |
| 5 | 102.15 |
| 6 | 102.19 |
| Average | 98.51 ~ 98.5 |
| %RSD | 6.0 |

**Table 13: Results of Overall Precision**

| Set # | % Assay (MP) | % Assay (IP) |
|---|---|---|
| 1 | 100.62 | 100.21 |
| 2 | 103.04 | 104.28 |
| 3 | 100.44 | 92.41 |
| 4 | 105.78 | 89.82 |
| 5 | 106.09 | 102.15 |
| 6 | 100.31 | 102.19 |
| Average | 100.6 | |
| %RSD | 4.9 | |

*vi. Acceptance Criteria*

% Assay of individual samples should be between 85.0% to 115.0%.

% RSD for % assay results of six samples should not be more than 10.0.

% RSD for % assay results of both method precision and intermediate precision should not be more than 10.0.

*vii. Observation*

The system suitability criteria are well within the specification limit. The intermediate precision results were well within the acceptance criteria.

## V. RESULTS AND DISCUSSION

The analytical method obtained precise results. The acceptance criteria for %RSD of method precision was obtained to be 2.6%. Whereas the %RSD of intermediate precision was determined to be 6.0%. Thus, the overall %RSD of precision study was established as 4.9% with respect to not more than 10.0% of specification limit. Though it has been observed to have a little variability in %RSD which was well within the acceptance criteria, it requires precautions to be taken while performing analysis. Hence, the method was determined as Precise for determination of %Assay of Simethicone in Simethicone Soft Gel capsules in the form of Polydimethylsiloxane by FT-IR.

## VI. CONCLUSION

The analytical method is quite simple; however, it requires some precautions for preparation and scanning of solutions to produce accurate and precise results. The method was verified according to ICH Q2R(2) guidelines and produces precise results for precision study [12]. Thus, it is suitable for the determination of %Assay of Simethicone in Simethicone Soft Gel capsules in the form of Polydimethylsiloxane by FT-IR for Finished product and Stability analysis in Quality Control. It can be concluded that due to the complex nature of molecules USP has adopted the FT-IR method for the quantification and determination of Assay for all forms of dosage forms for Simethicone molecule [13].

## ACKNOWLEDGMENT

The Author would like to acknowledge the support of Apnar Pharma LLP for their consent on the development and publication of the research work.

## DECLARATION STATEMENT

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 solely.

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