Research Article

Development and Validation of RP-HPLC Method for Estimation of Teneligliptin and its Impurity in Tablet

Bhoomi Dineshkumar Patel1*, Nidhi J. Dharsandiya2, Ankit Chaudhary3

1*Assistant Professor, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.
2Research Scholar, School of pharmacy, RK University, Rajkot, Gujarat, India.
3Student, Saraswati Institute of Pharmaceutical Sciences, Dhanap, Gandhinagar, Gujarat, India.

Received: 03-06-2021; Revised: 22-07-2021; Accepted: 30-07-2021; Published on: 15-08-2021.

ABSTRACT

The objective of the study is a simple, precise and accurate stability RP-HPLC method has been developed and subsequently validated for the estimation of Teneligliptin and its impurity in tablet formulation. The adequate separation was carried out using Grace Smart C18 column (250mm x 4.6mm, 5μm particle size), mixture of 0.05M Potassium dihydrogen phosphate PH 4.0 and Acetonitrile 80:20 % v/v as a mobile phase with a flow rate of 1 ml/min and the effluent was monitored at 242 nm using PDA detector. The retention time of Teneligliptin, Impurity B and Impurity G were 7.443 min, 6.650 min and 8.473 min respectively. Linearity for Teneligliptin, Impurity B and Impurity G were found to be in range of 99.315 ± 0.283 for Teneligliptin. Precision studies were carried out and the RSD values were less than two.

Teneligliptin impurity B and Impurity G were 7.443 min, 6.650 min and 8.473 min respectively. Linearity for Teneligliptin, Impurity B and Impurity G were 7.443 min, 6.650 min and 8.473 min respectively. Linearity for Teneligliptin, Impurity B and Impurity G were found to be in range of 99.315 ± 0.283 for Teneligliptin. Precision studies were carried out and the RSD values were less than two. The method was found to be robust. The proposed method was found to be specific, accurate, precise and robust can be used for simultaneous estimation of these drugs in tablet dosage form.

Keywords: Teneligliptin, Impurity B, Impurity G, Reversed phase HPLC, Validation.

INTRODUCTION

Teneligliptin (TEN) is designated chemically as [(2S,4S)-4-(4-(3-methyl-2-phenylpyrazol-3-y1)piperazin-1-yl)-(1,3-thiazolidin-3-yl)] methanone (Figure-1), represents the class of Thiazoles, DDP-4 Receptor Blocker, reduce the glucose level in blood, used in treatment of type-2 diabetes mellitus1−3. Various analytical methods have been reported for the estimation of Teneligliptin as alone as well as in combination with other drugs. They include spectrophotometric methods HPLC4−6, HPTLC7−8, Ultra-fast liquid chromatography9, UV Spectroscopy stability indicating UPLC method10−14.

Teneligliptin impurity B is designated chemically as tert-butyl (2S,4S)-4-(4-(3-methyl-1-phenyl-1H-pyrazol-5-y1)piperazin-1-yl)-2-(thiazolidine-3-carbonyl) pyrrolidine-1-carboxylate (Figure-2)15.

Teneligliptin impurity G is designated chemically as 1-(4-(35,5S)-5-(thiazolidine-3-carbonyl) pyrrolidin-3-y1)piperazin-1-yl)butane-1,3-dione (Figure-3)16.

Figure 1: Chemical Structure of Teneligliptin

Figure 2: Chemical Structure of Teneligliptin impurity B

Figure 3: Chemical Structure of Teneligliptin impurity G
However, an extensive literature search didn’t reveal any estimation method for both the drugs in their combined dosage form. Therefore, attempt was made to develop and validate simple, precise, and accurate RP-HPLC method for simultaneous determination of drug and its impurity in tablet dose form.

**MATERIALS AND METHODS**

**Apparatus**

Young lin HPLC system was used for method development and validation. Data acquisition was performed on YL 9100 HPLC software. The separation were achieved on Grace Smart C18 (250 × 4.6 mm, 5µm) column. Digital balance (SartoriousCP224S, Sensitivity: 0.1mg), Ultrasonic cleaner (PCI, 1.5L, 5H), pH meter (Systonic) and Pipettes and volumetric flask (Borosil) used during study.

**Reagents and Materials**

Teneligliptin dosage form tablets were purchased from local market. HPLC grade Acetonitrile, Water, Methanol and Potassium Dihydrogen Phosphate of analytical grade were obtained from SD Fine Chem Ltd.

**Chromatographic Conditions**

The column was maintained at room temperature and the eluent was monitored at 242 nm using PDA detector. The mixture of 0.05M Potassium dihydrogen phosphate PH 4.0 and Acetonitrile in proportion of 80:20 % v/v at a flow rate of 1.0 ml/min was used as a mobile phase. The injection volume was 20µl.

Preparation of stock Standard solution (Teneligliptin 10000 µg/ml, Impurity B 20 µg/ml and Impurity G 20 µg/ml).

An accurately weighed quantity of standard Teneligliptin (1000 mg), Impurity B (2 mg) and Impurity G (2 mg) were transferred to 100 ml volumetric flasks and volumes were made up to mark with mobile phase individually.

Preparation of Mobile phase: (0.05 M KH₂PO₄ pH-4 Adjusted with 1%o-phosphoric acid: Acetonitrile (80:20 %/V/V).

An accurately weighed 0.68 gm of potassium dihydrogen phosphate was transferred into 100ml volumetric flask, followed by addition of 95ml HPLC grade water, pH 4 was adjusted with 1% o-phosphoric acid, volume was made up to mark with HPLC grade water. Above solution filtered with vacuum filter using filter membrane. 80ml of buffer and 20ml Acetonitrile was mixed and solution was sonicated for degassing.

TEN, Impurity B and Impurity G Working Standard Solutions.

2 ml of standard stock solution of Teneligliptin (2000 µg/ml), 1 ml standard stock solution of Teneligliptin impurity B (20 µg/ml), and 1 ml standard stock solution of Teneligliptin impurity G (20 µg/ml) were transferred in to 10 ml volumetric flask and volume made up to the mark with methanol and mixed thoroughly.

**Preparation of Sample Solution**

Average weight of 20 tablets was determined and tablets were crushed into powder form. Accurately weighed amount of powder equivalent to 200 mg of teneligliptin was transferred into 100 ml volumetric flask. About 60 ml of methanol was added and solution was sonicated for 30 min. to ensure complete solubilization of drugs. Then solution was filtered through Whatman filter paper and then volume was made up to the mark with methanol (2000 µg/ml).

**System suitability parameters**

System suitability tests were performed to verify that the resolution and repeatability of the system were adequate for the analysis intended. The parameters monitored for system suitability includes retention time, theoretical plate number, peak area, tailing factor and resolution. The repeatability of these parameters was checked by injecting three times the test solution of 2000 µg/ml TEN, 20 µg/ml impurity B and 20 µg/ml impurity G. The results shown in Table 1 were within acceptable limits.

**Method Validation**

**Specificity**

Specificity of method can be termed as absence of any interference at retention times of samples. Specificity was performed by injecting blank and standard preparations. Chromatograms were recorded and retention times from sample and standard preparations were compared for identification of analytes.

**Calibration curve (Linearity)**

A series of standard solutions 500-3000 µg/ml of TEN and 5-30 µg/ml of both impurities were prepared. An aliquot of 20µl of each solution was injected 3 times for each standard solutions and peak area was observed. Plot of average peak area versus the concentration is plotted and from this the correlation coefficient and regression equation were generated. The calibration data of TEN and both impurities is given in Table 3, while Figure 5, Figure 6 and Figure 7 represents linearity graphs of both drugs respectively.

**Accuracy (% Recovery)**

Accuracy was determined by calculating recovery of TEN and both impurities by the standard addition method. Known amounts of standard solutions of TEN (250, 500 and 750 µg/ml) were added to a pre quantified test solution of TEN (2000µg/ml). Each solution was injected in triplicate and the recovery was calculated by measuring peak areas. Results obtained are shown in Table 4.

**Method Precision**

The method was validated in terms of intra-day inter-day precision. The solution containing 2000µg/ml of TEN, 20 µg/ml of imp. B and 20µg/ml of imp. G was injected six times for repeatability study. Inter-day and Intra-day study were performed by injecting 1500, 2000 and 2500 µg/ml
of TEN and 15, 20, 25 µg/ml of both impurity solutions three times for each aliquot. The %RSD for precision study was found less than 2% as shown in Table 5.

Limit of Detection and Limit of Quantification

The limit of detection (LOD) and the limit of quantification (LOQ) of the drug were derived by calculating the signal-to-noise ratio (S/N, i.e., 3.3 for LOD and 10 for LOQ) using the following equations as per International Conference on Harmonization (ICH) guidelines.

\[
\text{LOD} = 3.3 \times \sigma / S
\]
\[
\text{LOQ} = 10 \times \sigma / S
\]

Where \(\sigma\) = the standard deviation of the response and \(S\) = Slope of calibration curve.

Robustness

Robustness was carried by varying three parameters from the optimized chromatographic conditions. No significant change was observed.

Analysis Teneligliptin in tablet Dosage Forms

Pharmaceutical formulation of Teneligliptin in tablet dosage form was purchased from local pharmacy. The responses of tablet dosage form was measured at 242 nm for quantification of TEN by using RP-HPLC. The amounts of TEN present in sample solution were determined by the responses into the regression equation for TEN in the method. Results are given in Table 7.

RESULT AND DISCUSSION

To optimize the RP-HPLC parameters, several mobile phase compositions were tried. A satisfactory separation and good peak symmetry was found in a mixture of 0.05M Potassium dihydrogen phosphate pH 4.0 and Acetonitrile 80:20 v/v and 1.0 ml/min flow rate proved to be better than the other mixtures in terms of resolution and peak shape. The effluent was monitored at 242 nm using PDA detector. As it was shown in Fig. 3 the retention time of EN, imp B and imp G were 7.443 min, 6.450 min and 6.470 min respectively. The method was validated in terms of linearity, precision, accuracy, specificity, limit of detection and limit of quantification. Linearity of TEN and both impurities were in the range of 500-3000 µg/ml and 5-30 µg/ml respectively. The proposed method enables rapid quantification and simultaneous analysis of both drugs for commercial formulations without any excipients interference. The method can be used for routine analysis of marketed products of TEN in tablet formulation. System suitability test parameters for TEN and both impurity for the RP-HPLC method are reported in Table1. The optical and regression characteristics and validation parameters are reported in Table 2.

### Table 1: Results for System suitability parameters

| Parameters               | TEN (mean ± SD)* | Impurity B (mean ± SD)* | Impurity G (mean ± SD)* |
|--------------------------|------------------|-------------------------|-------------------------|
| Theoretical plate        | 7701 ± 45.796    | 4274 ± 15.307           | 7675 ± 19.655           |
| Tailing factor           | 1.245 ± 0.103    | 1.310 ± 0.034           | 1.232 ± 0.039           |
| Resolution               | 2.381 ± 0.046    | 2.703 ± 0.085           |                         |

* = average of three determinations, SD=Standard deviation

### Table 2: Optical and Regression characteristics and validation parameters of HPLC method for analysis of TEN and Impurities

| Parameter               | TEN           | Impurity B    | Impurity G    |
|-------------------------|---------------|---------------|---------------|
| Calibration Range       | 500-3000 µg/ml| 5-30 µg/ml    | 5-30 µg/ml    |
| Regression Equation     | Y = 1.899x + 119.9 | Y = 9.613x + 14.953 | Y = 7.336x + 9.085 |
| Slope (m)               | 1.899         | 9.613         | 7.336         |
| Intercept (c)           | 119.9         | 14.953        | 9.085         |
| Correlation co-efficient (R²) | 0.9983       | 0.9942        | 0.9980        |
| Inter Day (%RSD)        | 0.063 – 0.116 | 0.203 – 0.697 | 0.265 – 0.416 |
| Intra Day (%RSD)        | 0.052 – 0.114 | 0.425 – 0.764 | 0.540 – 0.780 |
| Repeatability (%RSD)    | 0.327         | 2.023         | 1.691         |
| Detection Limit(µg/ml)  | 9.539 µg/ml   | 0.410 µg/ml   | 0.406 µg/ml   |
| Quantitation Limit(µg/ml)| 59.210 µg/ml | 1.245 µg/ml   | 1.232 µg/ml   |
**Table 3:** Linearity study data for TEN, Impurity B and Impurity G

| Sr No | TEN (μg/ml) | Impurity B (μg/ml) | Impurity G (μg/ml) |
|-------|-------------|--------------------|--------------------|
|       | Conc | Avg. area * ± SD | %RSD | Conc | Avg. area * ± SD | %RSD | Conc | Avg. area * ± SD | %RSD |
| 1     | 500  | 1100.379 ± 11.115 | 0.998 | 5    | 71.195 ± 0.965  | 1.337 | 5    | 98.770 ± 0.964  | 1.973 |
| 2     | 1000 | 1990.491 ± 0.246  | 0.010 | 10   | 104.631 ± 1.133 | 1.072 | 10   | 79.185 ± 1.112  | 1.401 |
| 3     | 1500 | 2970.993 ± 12.567 | 0.422 | 15   | 156.538 ± 1.062 | 0.674 | 15   | 118.731 ± 0.880 | 0.736 |
| 4     | 2000 | 3960.910 ± 26.371 | 0.664 | 20   | 207.295 ± 0.900 | 0.434 | 20   | 157.473 ± 1.219 | 0.768 |
| 5     | 2500 | 4740.167 ± 10.046 | 0.211 | 25   | 247.875 ± 2.024 | 0.814 | 25   | 188.475 ± 0.950 | 0.504 |
| 6     | 3000 | 5900.652 ± 7.124  | 0.120 | 30   | 311.642 ± 1.101 | 0.353 | 30   | 232.231 ± 1.208 | 0.517 |

* = average of three determinations, RSD=Relative standard deviation

**Table 4:** Recovery data for TEN and Impurities by HPLC method

| Sr. No. | Accuracy Level % | Amount taken (μg/ml) | Amount Added (μg/ml) | Total Amount found* (μg/ml) | % Recovery | % Mean recovery ± S.D. | %R.S.D. |
|---------|-------------------|----------------------|----------------------|----------------------------|------------|-------------------------|---------|
| 1       | 50 %              | 500                  | 250                  | 248.241                    | 99.296     | 99.502 ± 0.441          | 0.444   |
| 2       | 500               | 500                  | 250                  | 248.006                    | 99.202     | 100.202 ± 0.248         | 0.247   |
| 3       | 500               | 500                  | 250                  | 250.023                    | 100.009    | 100.469 ± 0.184         | 0.186   |
| 4       | 100 %             | 500                  | 500                  | 501.012                    | 100.202    | 100.110 ± 0.184         | 0.186   |
| 5       | 500               | 500                  | 500                  | 502.345                    | 100.469    | 100.110 ± 0.184         | 0.186   |
| 6       | 500               | 500                  | 500                  | 499.873                    | 99.974     | 100.215 ± 0.248         | 0.247   |
| 7       | 500               | 750                  | 750                  | 751.132                    | 100.150    | 100.110 ± 0.184         | 0.186   |
| 8       | 500               | 750                  | 750                  | 749.320                    | 99.909     | 100.110 ± 0.184         | 0.186   |
| 9       | 500               | 750                  | 750                  | 752.034                    | 100.271    | 100.215 ± 0.248         | 0.247   |

* = average of three determinations

**Table 5:** Precision study for TEN and Impurities

| Parameters      | Conc. | % RSD |
|-----------------|-------|-------|
|                 | TEN (μg/ml) | Imp.B (μg/ml) | Imp.G (μg/ml) | TEN | Imp.B | Imp.G |
| Intra-day* precision | 1500 | 15 | 15 | 0.114 | 0.764 | 0.780 |
|                  | 2000 | 20 | 20 | 0.023 | 0.539 | 0.953 |
|                  | 2500 | 25 | 25 | 0.052 | 0.425 | 0.540 |
| Inter-day* precision | 1500 | 15 | 15 | 0.063 | 0.697 | 0.416 |
|                  | 2000 | 20 | 20 | 0.116 | 0.635 | 0.265 |
|                  | 2500 | 25 | 25 | 0.071 | 0.203 | 0.337 |
| Repeatability**  | 2000 | 20 | 20 | 0.327 | 2.023 | 1.691 |

* = average of three determinations; ** = average of six determinations
### Table 6: Robustness

| Parameter | Change Level | Peak Area TEN |  | Peak Area Imp. B |  | Peak Area Imp. G |  |
|-----------|--------------|--------------|---|----------------|---|----------------|---|
| pH (±0.2) | 3.8          | 3934.268     | 203.879 | 156.507        |  |  |  |
|           | 4.0 #        | 3965.935     | 207.314 | 157.566        |  |  |  |
|           | 4.2          | 3990.126     | 209.125 | 154.950        |  |  |  |
|           | Mean ± SD    | 3980.110 ± 12.620 | 206.772 ± 2.664 | 156.341 ± 1.315 |  |  |  |
|           | %RSD         | 0.317        | 1.288   | 0.841        |  |  |  |
| Flow Rate (±0.02 ml/min) | 0.98 ml/min | 3963.615     | 204.373 | 154.328        |  |  |  |
|           | 1.0 ml/min#  | 3947.135     | 207.147 | 156.985        |  |  |  |
|           | 1.02 ml/min  | 3974.320     | 205.845 | 153.868        |  |  |  |
|           | Mean ± SD    | 3961.690 ± 13.694 | 205.788 ± 1.387 | 155.060 ± 1.682 |  |  |  |
|           | %RSD         | 0.345        | 0.674   | 1.085        |  |  |  |
| Mobile phase Composition (±2.0 ml) | 78:18        | 3924.985     | 206.417 | 158.182        |  |  |  |
|           | 80:20 #      | 3938.526     | 207.814 | 156.438        |  |  |  |
|           | 82:22        | 3968.689     | 209.312 | 159.343        |  |  |  |
|           | Mean ± SD    | 3944.067 ± 22.372 | 207.847 ± 1.447 | 157.987 ± 1.462 |  |  |  |
|           | %RSD         | 0.567        | 0.969  | 0.925        |  |  |  |

#= actual parameter as control standard

### Table 7: Analysis on marketed formulation

| Teneligliptin | Labelled amount (mg) | Amount found (mg) (n = 3) | % Assay (n =3) |
|---------------|----------------------|--------------------------|---------------|
| 20 mg         | 19.798               | 19.889                   | 19.902        |
|               | 98.990               | 99.445                   | 99.510        |
| Mean ± SD     | 19.863 ± 0.056       | 99.315 ± 0.283           | 99.315 ± 0.283|
| % R.S.D.      | 0.2852               | 0.285                    | 0.285         |

### Table 8: % of Known impurity of Teneligliptin impurity B & Teneligliptin impurity G by Proposed method

| % Known impurity | Impurity | Area of known impurity in standard Preparation of impurity | STD Impurity Concentration (µg/ml) | Test Preparation Concentration (µg/ml) | Area of Known Impurity Present in Test preparation | % of Known impurity | Mean ± SD | % R.S.D. |
|------------------|----------|-----------------------------------------------------------|----------------------------------|--------------------------------------|-------------------------------------------------|--------------------|----------|----------|
|                  | Teneligliptin Impurity B | 206.196 | 20 | 2000 | 70.080 | 0.340 | 0.340 ± 0.001 | 0.159 |
|                  | Teneligliptin Impurity G | 156.593 | 20 | 2000 | 61.069 | 0.348 | 0.348 ± 0.001 | 0.169 |
Table 9: % of total unknown impurities of Teneligliptin test formulation by Proposed method

| Area of Teneligliptin Standard preparation | STD Impurity Concentration (µg/ml) | Test Preparation Concentration (µg/ml) | Areas of Total Unknown Impurity Present In test preparation | % of Total Unknown impurities | Mean ± SD | % R.S.D. |
|-------------------------------------------|-----------------------------------|----------------------------------------|----------------------------------------------------------|-----------------------------|----------|---------|
| 3960.910                                   | 20                                | 2000                                   | 273.534                                                  | 0.069                       | 0.070 ± 0.002 | 1.803   |
|                                           |                                   |                                        | 281.124                                                  | 0.071                       |          |         |
|                                           |                                   |                                        | 283.063                                                  | 0.070                       |          |         |

Figure 4: Optimized condition chromatogram of TEN, Imp B, Imp G

Figure 5: Calibration Curve of Teneligliptin (500-3000 µg/ml)

Figure 6: Calibration Curve of Impurity B (5-30 µg/ml)

Figure 7: Calibration Curve of Impurity G (5-30 µg/ml)
CONCLUSION

Results for validation parameters are in good agreement with label claim, which indicates that there is no interference of excipients in routinely used experiment. The proposed method is found to be accurate and precise, therefore proposed method can be used for routine analysis of Teneligliptin and both impurities in tablet dosage form.

Acknowledgement: The authors are also thankful to Saraswati Institute of Pharmaceutical Sciences for providing necessary equipment, facility & chemicals to complete research work and sincere thanks to my highly respected and esteemed, Principal, Dr Shrenik Shah, Director and HOD of PG Department Dr Ankit B Chaudhary. I would like to express thanks to my parents without their encouragement love and blessings I would not have reached this level manuscript.

REFERENCES

1. Rang and Del’s Pharmacology, 6th Edition, Churchill livingstone Publishers (P) Ltd, New York, 2004; 277-285.
2. Drug profile for Teneligliptin. Available from: www.drugbank.ca/drugs/DB11950
3. Shailesh VL and Kamna RP, “Simultaneous Estimation of Teneligliptin Hydrobromide Hydrate and its Degradation Product by RP-HPLC Method.” J. Pharm. Sci Bioscientific. Res. 2016; 6(3): 254-261.
4. Vidyadhara S, Niteen AN, Silpa YS, “Method development, validation, and stability studies of teneligliptin by RP-HPLC and identification of degradation products by UPLC tandem mass spectroscopy.” J. Ana. Sci. Tech. 2016; 7(27).
5. Deepak P, Lalit T, “Analytical method development and validation for the simultaneous estimation of Metformin and Teneligliptin by RP-HPLC in bulk and tablet dosage forms.” J. Pharm. Res. 2017; 11(6): 676-681.
6. Patel BD, Bhavya M, Ankit BC. Method Development and Validation For Simultaneous Estimation of Lamivudine and Zidovudine in Tablet by Reverse-Phase High-Performance Liquid Chromatography. Asian Journal of Pharmaceutical and clinical Research. 2020 June; 13(6): 73-77.
7. Sandesh RL, Sunny AP, Karishma DP, “Development and validation of HPLC method for estimation of Teneligliptin Hydrobromide Hydrate in tablet dosage form.” J.Pharm.App.Sci.2016; 3(1): 26-33.
8. Patel BD, Chaudhary A, Gami S, “RP-HPLC Method Development and Validation for Simultaneous Estimation of Benidipine Hydrochloride, Telmisartan and Chlorthalidone in Tablet” Journal of Emerging Technologies and Innovative Research. 2019; 6(3): 110-124.
9. Denish NH, Dhanya BS, Rajesh AM, “Analytical method development and validation for simultaneous estimation of Teneligliptin hydrobromide hydrate and Metformin hydrochloride from its pharmaceutical dosage form by three different UV spectrophotometric methods.” J.App.Pharm.Sci.2016; 6(9): 157-165.
10. Patel BK, Chaudhary AB, Bhadani SM, Patel BD. Development and validation of stability indicating RP-HPLC method for simultaneous estimation of Aceclofenac and Cycloenzaprine Hydrochloride in pharmaceutical dosage form. World Journal of Pharmacy and Pharmaceutical Sciences, 2018 April; 7(5): 874-888.
11. Patel DM, Chaudhary AB and Patel BD. Development and validation of RP-HPLC method for simultaneous estimation Beclomethasone Dipropionate, Phenylephrine Hydrochloride and Lignocaine Hydrochloride in cream. World Journal of Pharmacy and Pharmaceutical Sciences. 2018 April; 7(5): 829-841.
12. Patel B, Patel M, Chaudhary A. A Comprehensive and Comparative Study on Regulations of Medical Countermeasures in USA and INDIA. International Journal of Emerging Technologies and Innovative. 2019 May; 6(5): 289-304.
13. Trivedi DG, Chaudhary AB and Patel BD. Method Development and Validation for Estimation of Clotrimazole, Fusidic acid and Mometasone Furoate in Cream by RP-HPLC, World Journal of Pharmacy and Pharmaceutical Sciences. 2017 April; 6(5): 1204-1219.
14. Bhoomi DP, Ankit BC, Pooja JP, Vidhi NP. Development and Validation of Reversed Phase High Performance Liquid Chromatography method for simultaneous estimation of Nebivolol HCl and Cilnidipine in combined tablet dosage form, Pharmaceutical and Biological Evaluations Journal. 2016 April; 3(2): 208-214.
15. Drug profile for Impurity B. Available from: synzeal.com/teneligliptinimpurity-b
16. Drug profile for Impurity B. Available from: www.trccanada.com/product-detail/?D297285
17. ICH Topic Q2 (R1) Validation of Analytical Procedures; Methodology, Q2 (R1), International Conference on Harmonization, IFPMA, Geneva 1996.

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

For any question relates to this article, please reach us at: editor@globalresearchonline.net
New manuscripts for publication can be submitted at: submit@globalresearchonline.net and submit_iipsrr@rediffmail.com