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REVIEW ARTICLE

An Updated Review on Analytical Method for Estimation of Teneligliptin and Rosuvastatin Calcium

Ayushi Patel, Pinkal Patel*
Department of Quality assurance, Parul Institute of Pharmacy & Research, Parul University, Limda, Vadodara, Gujarat, India
Correspondence: Dr. Pinkal Patel
Email id: pinkal.patel@paruluniversity.ac.in

ABSTRACT
Patients with Type 2 diabetes can have elevated lipid levels and elevated blood pressure. The patients from hyperlipidaemia which lower the levels of lipids and lipoproteins in blood. Disorder that is prevalent in developed nations and the main factor in coronary heart disease. Teneligliptin work by the inhibiting the action of Dipeptide peptidase-4 (DPP) enzymes and slows down the rapid degradation of incretins. It also increases insulin synthesis by the pancreas and decreases glucagon levels which are a counter-hormone of insulin, thereby further decreasing blood sugar levels. Rosuvastatin calcium belongs to the group of medicines known as HMG-CoA reductase inhibitors (statins). It functions by lessening the amount of cholesterol that could build up on the walls of the arteries and obstruct blood flow to the heart, brain, and other parts of the body.
Keywords: *Teneligliptin, Rosuvastatin calcium, UV Spectrophotometry, RP-HPLC, HPTLC, LC-MS, UPLC*

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INTRODUCTION

Teneligliptin, also referred to as [(2S,4S) -4 The compound is known as [4-(5-methyl-2-phenylpyrazol-3-yl) piperazin-1-yl] pyrrolidin-2-yl]. Methadone containing 1,3-thiazolidin-3-yl. Gliptin is a class of drug. Teneligliptin's molecular structure is C22H30N6OS. Teneligliptin is 426.58 g/mol in terms of molecular weight. Its physical appearance Pale white colour. Lowering blood glucose levels using it is very effective. This medication prevents the breakdown of incretin, a hormone that regulates blood glucose levels, by dipeptidyl peptidase-4. Type-2 diabetes mellitus can be effectively treated with it. Figure No. 1 shows the chemical structure. [1, 2]

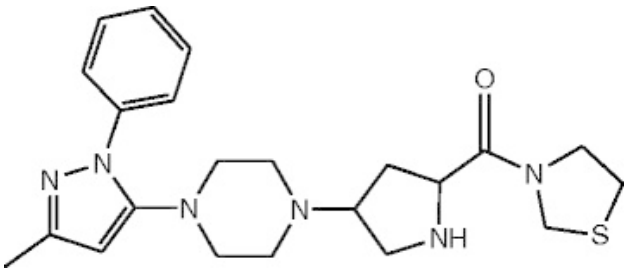

Fig. 1: Chemical structure of Teneligliptin

INTRODUCTION OF ROSUVASTATIN CALCIUM:

Other names for rosuvastatin calcium (3R,5S,6E) -7-[4-(4-Fluorophenyl) -2-(N-methyl methane sulphonamide) (N-methyl methane sulphonamide) "-6-(propan-2-yl) pyrimidin-5-yl" -3,5-dihydroxyhept-6-enoic acid. Drug class is statin. Rosuvastatin calcium has the molecular formula (C22H27FN3O6S)2 Ca.

Rosuvastatin has a molecular weight of 1001.14 g/mol. Its outward appearance Off-white to white powder. It works on plasma lipids as a synthetic lipid-lowering agent. It is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A, an enzyme that converts HMG-CoA to mevalonate, a rate-limiting step in cholesterol biosynthesis given below in figure no- 2 [1-3]

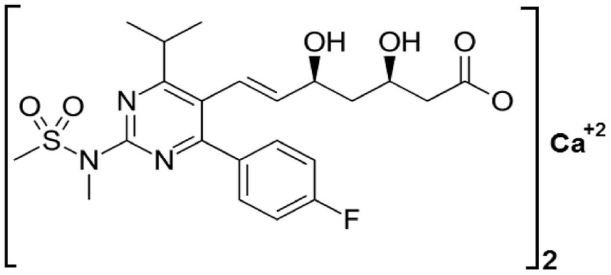

Fig. 2: Chemical structure of Rosuvastatin calcium

REPORTED METHOD FOR TENELIGLIPTIN

SR.NO.	TITLE	METHOD	DESCRIPTION	REF. NO.
1.	Teneligliptin	UV Spectroscopy	**Model:** Shimadzu 1700 AD **Solvent:** Methanol **Wavelength:** 246 nm **Linearity:** 10-50 µg/mL	4
2.	Teneligliptin	UV Spectroscopy	**Model:** Shimadzu 1800 **Solvent:** Distilled water **Wavelength:** 238.6-247.8 nm **Linearity:** Zero order**:** 5-70 µg/mL First order**:** 5-80 µg/mL	5
3.	Teneligliptin Hydrobromide Hydrate	UV Spectroscopy	**Model:** UV-visible spectrophotometer **Solvent:** Dimethyl Sulphoxide **Wavelength:** 267.2 nm **Linearity:** 20-100 µg/mL	6
4.	Teneligliptin and Metformin Hydrochloride	UV Spectroscopy	**Model:** Shimadzu UV-1800 **Solvent:** Distilled water **Wavelength:** **Teneligliptin:** 245 nm **Metformin Hydrochloride:** 233 nm **Linearity:** 1-30 µg/mL	7
5.	Teneligliptin hydrobromide hydrate and Metformin hydrochloride	UV Spectroscopy	**Model:** Shimadzu 1800 **Solvent:** Methanol **Wavelength:** **Simultaneous equation method:** Metformin Hydrochloride: 237 nm Teneligliptin Hydrobromide Hydrate: 246 nm **Absorbance ratio method:** Iso-absorptive Point: 247.5 nm Metformin Hydrochloride: 237 nm **First derivative method:** Zero-crossing Points: Metformin Hydrochloride: 237 nm Teneligliptin Hydrobromide Hydrate: 246 nm **Linearity:** Metformin Hydrochloride: 1-20 µg/mL Teneligliptin Hydrobromide Hydrate: 1-20 µg/mL	8
6.	Teneligliptin	RP-HPLC	**Stationary phase:** Grace Smart C_{18} column (250 x 4.6mm, 5µm) **Mobile phase:** Potassium dihydrogen phosphate: Acetonitrile (80:20 % v/v) (pH-4)	9

			Flow rate: 1 mL/min **Wavelength:** 242 nm **Linearity:** 500-3000 µg/mL **Retention time:** 7.443 min	
8.	Teneligliptin	RP-HPLC	**Stationary phase:** Kromasil 100- 5C_{18} (250 x 4.6 mm, 5 µm) **Mobile phase:** Phosphate buffer (pH: 6.0): acetonitrile (60:40 % v/v) **Flow rate:** 1.0 mL/min **Wavelength:** 246 nm **Linearity:** 100-500 µg/mL **Retention time:** 1.345 min	10
9.	Teneligliptin	RP-HPLC	**Stationary phase:** Zodiac C_{18} column (250 mm×4.6 mm, 5µm) **Mobile phase:** Methanol: Acetonitrile (90:10% v/v), pH:5.2 **Flow rate:** 1.0 mL/min **Wavelength:** 235 nm **Linearity:** 25 -150 µg/mL **Retention time:** 5.843 min	11
10.	Teneligliptin	RP-HPLC, UV-Spectrophotometry	**UV:** **Model:** Jasco V-630, Shimadzu-1700 double beam **Stationary phase:** Shodex C_{18} (5 µm, 250 × 4.6 mm) **Mobile phase:** Methanol: Phosphate buffer pH 7.2 (70:30% v/v) **Flow rate:** 1 mL/min **Wavelength:** 245.6 nm **Linearity:** 10-60 µg/mL **Retention time:** 5.615 min	12
11.	Teneligliptin	RP-HPLC	**Stationary phase:** Cosmosil C_{18} (250 mm x 4.6, 5 µm) **Mobile phase:** Methanol: Phosphate buffer (70:30 % v/v) pH:3 **Flow rate:** 0.8 mL/min **Wavelength:** 246 nm **Linearity:** 10 to 50 µg/mL **Retention time:** 4.34 min	13
12.	Teneligliptin	RP-HPLC	**Stationary phase:** Kromasil C_{18} (150 mm x 4.6 mm, 5.0 µm) **Mobile phase A:** Acetonitrile: water: trifluoroacetic acid (60: 1940: 2 % v/v) **Mobile phase B:** Acetonitrile: Trifluoroacetic Acid (2000: 2 % v/v) **Flow rate:** 1.0 mL/min **Wavelength:** 245 nm **Linearity:** 50-150 µg/mL **Retention time:** 11.2 min	14
13.	Teneligliptin	RP-HPLC	**Stationary phase:** Reverse phase column thermos C_{18} (4.6x100 mm, 5µm) **Mobile phase:** Methanol: potassium phosphate buffer (60:40 %v/v) **Flow rate:** 1 mL/min **Wavelength:** 246 nm **Linearity:** 7.20 - 470 ng/mL **Retention time:** 3.9 min	15
15.	Teneligliptin hydrobromide hydrate	RP-HPLC	**Stationary phase:** BDS Hypersil C_{18} 250×4.6 mm, 5µ column **Mobile phase:** **Phase A:** octane sulfonic acid: phosphate buffer with triethylamine at (pH 3.0) **Phase B:** acetonitrile **Flow rate:** 1.0 mL/min	16

			Wavelength: 210 nm **Linearity:** 20-150 % **Retention time:** 6.20 min	
17.	Teneligliptin and Metformin	RP-HPLC	**Stationary phase:** Kromasil C_{18} column (250×4.6 mm, 5 µm) **Mobile phase:** Acetonitrile: Methanol (65:25:10 % v/v/v) **Flow rate:** 1.0 mL/min **Wavelength:** 254 nm **Linearity:** Teneligliptin: 5-30 µg/mL Metformin: 125-750 µg/mL **Retention time:** Teneligliptin: 2.842 min Metformin: 2.017 min	17
18.	Metformin hydrochloride and Teneligliptin hydrobromide	RP-HPLC	**Stationary phase:** YMC C_{18} column (150mm x 4.6mm ,5µm) **Mobile phase:** Phosphate buffer: Acetonitrile (80:20 % v/v) pH 3 **Flow rate:** 0.8 mL/min **Wavelength:** 220 nm **Linearity:** Metformin hydrochloride: 9.98-600 µg/mL Teneligliptin hydrobromide: 0.51-24 µg/mL **Retention time:** Metformin hydrochloride: 2.138 min Teneligliptin hydrobromide: 2.943 min	18
19.	Teneligliptin	HPTLC	**Stationary phase:** Silica gel 60F_{254} **Mobile phase:** Methanol: Toluene: Triethylamine (1:3:1% v/v) **Wavelength:** 245 nm **Linearity:** 500-1000 ng/band **Rf value:** 0.63	19
20.	Teneligliptin Hydrobromide Hydrate	HPTLC	**Stationary phase:** Silica gel 60 F_{254} **Mobile phase:** Butanol: water: glacial acetic acid (6:2:2 % v/v/v) **Wavelength:** 245 nm **Linearity:** 250-1250 ng/band **Rf value:** 0.65	20
21.	Teneligliptin hydrobromide and Metformin hydrochloride	HPTLC	**Stationary phase:** Silica gel G60 F_{254} Aluminium sheets 10x10 cm **Mobile phase:** Methanol: Ammonium Sulfate (0.5 %w/v): Triethylamine (9: 2.7: 0.5 % v/v/v) **Wavelength:** 237 nm **Linearity:** Teneligliptin Hydrobromide: 4-28 ng/band Metformin hydrochloride :100-700 ng/band **Rf value:** Teneligliptin Hydrobromide: 0.63 Metformin hydrochloride: 0.19	21

OFFICIAL METHOD FOE ROSUVASTATIN CALCIUM

SR.NO.	TITLE	METHOD	DESCRIPTION	REF. NO.
1.	IP (2017) Volume 3	Liquid chromatography	**Column:** 25 cm x 4.6 mm **Stationary phase:** Porous silica (5 µm) **Mobile phase:** Acetic acid: acetonitrile (25:25 % v/v) **Flow rate:** 1 mL/min **Wavelength:** 248 nm	22

REPORTED METHOD FOR ROSUVASTATIN CALCIUM

SR.NO.	TITLE	METHOD	DESCRIPTION	REF. NO.
1.	Rosuvastatin calcium	UV	**Model:** Aglient 8453 model UV-VIS spectrophotometer **Solvent:** Methanol **Wavelength:** 243 nm **Linearity:** 1.0–60.0 µg/mL	23
2.	Rosuvastatin calcium	Spectrophotometry	**Model:** Shimadzu (model UV- 1800) **Solvent:** Methanol **Wavelength:** 242 nm **Linearity:** 0.034-0.517 µg/mL	24
3.	Rosuvastatin calcium	UV	**Model:** A GBC Cintra-10 double beam UV-Visible spectrophotometer **Solvent:** Methanol **Wavelength:** 244 nm **Linearity:** 2-18 µg/mL	25
4.	Rosuvastatin calcium	UV	**Model:** Shimadzu UV- 1700 **Solvent:** Methanol **Wavelength:** 244 nm **Linearity:** 2-18 µg /mL	26
5.	Rosuvastatin Calcium and Clopidogrel Bisulphate	UV	**Model:** JASCO UV- V-550 **Solvent:** Methanol **Wavelength:** Rosuvastatin Calcium: 244 nm Clopidogrel Bisulphate: 219 nm **Linearity:** 2-10 µg/mL	27
6.	Rosuvastatin Calcium	RP-HPLC	**Stationary phase:** YMC C_8, 150x4.6 mm **Mobile phase:** Acetonitrile: water (40:60 % v/v) pH 3.5 **Flow rate:**1.5 mL/min **Wavelength:** 242 nm **Linearity:** 0.5-80 µg/mL **Retention time:** 10 min	28
7.	Rosuvastatin calcium	RP-HPLC	**Stationary phase:** A Thermo hypersil reversed phase C_{18}, 5 µm column **Mobile phase:** Acetonitrile: Potassium dihydrogen orthophosphate (50: 50 % v/v), pH 3 **Flow rate:** 0.5 ml / min **Wavelength:** 243 nm **Linearity:** 5-30 µg/mL **Retention time:** 3.333 ± 0.004 min	29
8.	Rosuvastatin Calcium	Green HPLC	**Stationary phase:** Zorbax C_{18} column (4.6 x 150 mm, 5 µm) **Mobile phase: 0**.5% v/v acetic acid: ethanol (52.7:47.3 % v/v) **Flow rate:** 0.978 mL/min **Wavelength:** 246 nm **Linearity:** 10 -150 µg/mL **Retention time:** 12 min	30
9.	Rosuvastatin	Green RP-HPLC	**Stationary phase:** NUCLEODUR 150 mm x 4.6 mm RP C_8 column	31

			Mobile phase: ethanol: methanol: ethyl acetate (6:3:1 % v/v) **Flow rate:** 1.0 mL/min **Wavelength:** 254 nm **Linearity:** 0.1 - 100 µg/mL **Retention time:** 2.84 min	
10.	Rosuvastatin Calcium	RP-HPLC	**Stationary phase:** Agilent Eclipse XDB C_8 column (250 mm x 4.6 mm, 5µm) **Mobile phase:** 0.05M sodium dihydrogen phosphate: acetonitrile (50:50 % v/v) pH 4.5 **Flow rate :**1.2 mL/min **Wavelength:** 245 nm **Linearity:** 5-100 µg/mL **Retention time:** 5.0 min	32
11.	Rosuvastatin and Amlodipine	RP-HPLC	**Stationary phase:** C_{18}, 5 µm column having 4.6 mm x 250 mm **Mobile phase:** acetonitrile: phosphate buffer (pH 3.8): methanol (30:60:10 % v/v) **Flow rate:** 1 mL/min **Wavelength:** 251 nm **Linearity:** Rosuvastatin: 5-25 µg/mL Amlodipine: 2.5-12.5 µg/mL **Retention time:** Rosuvastatin :2.577 min Amlodipine :3.408 min	33
12.	Rosuvastatin and Amlodipine in	HPLC	**Stationary phase:** C_{18} column (250 mm x4.6 mm, 5 µm) **Mobile phase:** Acetonitrile and 0.1 M ammonium acetate buffer (pH 5), (30:70 % v/v) **Flow rate:** 1.5 mL/min **Wavelength:** 240 nm **Linearity:** Rosuvastatin: 1-200 µg/mL Amlodipine: 0.5-100 µg/mL **Retention time:** Rosuvastatin: 13.9 min Amlodipine :19.3 min	34
13.	Rosuvastatin calcium and Losartan potassium	RP-HPLC	**Stationary phase:** Column C_{18} (Shim-pack) 250 x 4.6 mm, 5 µm **Mobile phase:** Acetonitrile, methanol and water pH 3 (orthophosphoric acid) (20:25:55 %v/v) **Flow rate:** 0.1 mL/min **Wavelength:** 233 nm **Linearity:** Rosuvastatin calcium: 20-100 µg/mL Losartan potassium: 15-75 µg/mL **Retention time:** Rosuvastatin calcium: 3.55 min Losartan potassium: 4.64 min	35
14.	Atorvastatin and Rosuvastatin	RP-HPLC, with UV detection	**UV:** **Model:** UV 1000 **Solvent:** Methanol **RP-HPLC:** **Stationary phase:** BDS hypersil C_{18} column (250 mm x 4.6 mm, 5µm) **Mobile phase:** methanol: water (68:32% v/v) and (63:37 %v/v) **Flow rate:** 1 mL/min **Wavelength:** 241 nm	36

			Linearity: 20-200 ng/mL **Retention time:** Rosuvastatin: 11.35 min Atorvastatin: 6.65min	
15.	Rosuvastatin and Glipalamide	RP-HPLC	**Stationary phase:** C_{18} (ZORBAX Eclipse Plus 4.6 mm×150 mm, 5µm) **Mobile phase:** methanol: acetonitrile: 0.02 M phosphate buffer pH 3.5 (60:20:20 % v/v/v) **Flow rate :**1.0 mL/min **Wavelength:** 237 nm **Linearity:** 5-22 µg/mL **Retention time:** Rosuvastatin: 4.57 min Glibenclamide: 7.72 min	37
16.	Bisoprolol fumarate and Rosuvastatin calcium	RP-HPLC	**Stationary phase:** C_{18} column (150x4.6 mm, 0.5 µm) **Mobile phase:** Acetonitrile: orthophosphoric acid (65:35 % v: v) **Flow rate:** 1 mL/min **Wavelength:** 230 nm **Linearity:** 0.2-50 µg/mL **Retention time:** Bisoprolol fumarate: 2.758 min Rosuvastatin calcium: 4.974 min	38
17.	Aspirin and Rosuvastatin Calcium	RP-HPLC	**Stationary phase:** Merck hibar 250-4.6 RP_{18} (5 µm) column (150 mm x 3.0 mm) **Mobile phase:** 20 mM KH2PO4: Methanol (30:70 % v/v) **Flow rate:** 1.0 mL/min **Linearity:** Aspirin: 15 - 90 µg/mL Rosuvastatin Calcium: 2 -12 µg/mL **Retention time:** Aspirin: 3.747 min Rosuvastatin Calcium: 5.969 min	39
18.	Rosuvastatin and Aspirin	RP-HPLC	**Stationary phase:** Chromolith C_{18} monolithic column **Mobile phase:** Phosphate buffer (pH 3): acetonitrile: methanol (50:20:30 %v/v) **Flow rate:** 2 mL/min **Wavelength:** 240 nm **Linearity:** Rosuvastatin: 1 to 15 µg/mL Aspirin: 10 to 150 µg/mL **Retention time:** Rosuvastatin: 1.59 min Aspirin: 0.66 min	40
19.	Rosuvastatin calcium and Clopidogrel bisulfate	RP-HPLC	**Stationary phase:** Princeton C_{18} column with dimensions (250×4.6 mm, 5µ) **Mobile phase:** water (pH 3.0, adjusted with ortho phosphoric acid) and methanol (20:80 % v/v) **Flow rate :**1.0 mL/min **Wavelength:** 240 nm **Linearity:** Rosuvastatin calcium: 6-16 µg/mL Clopidogrel bisulfate: 45-120 µg/mL **Retention time:** Rosuvastatin calcium: 2.844 min Clopidogrel bisulfate: 4.388 min	41
20.	Rosuvastatin calcium and	RP-HPLC	**Stationary phase:** C $_{18G}$ column (250 x 4.6 mm, 0.5 µm)	42

	Ezetimibe		**Mobile phase:** acetonitrile: acetic acid (80:20 %v/v) **Flow rate:** 1 mL/min **Wavelength:** 252 nm **Linearity:** Rosuvastatin calcium: 0.5-250 µg/mL Ezetimibe: 0.5-250 µg/mL **Retention time:** Rosuvastatin calcium: 2.928 min Ezetimibe: 6.553 min	
21.	Rosuvastatin calcium and Ezetimibe	RP-HPLC	**Stationary phase:** Licrosphere C_{18} column (250 x 4.6mm) **Mobile phase:** Methanol: Acetonitrile: Phosphate buffer, pH 3.5(60:20:20 %v/v) **Flow rate:** 1.0 mL/min **Wavelength:** 279 nm **Linearity:** 5- 25 µg/mL **Retention time:** Rosuvastatin calcium: 3.245 min Ezetimibe: 4.577 min	43
22.	Metformin Hydrochloride and Rosuvastatin Calcium	RP-HPLC	**Stationary phase:** Phenomenex C_{18} (250x4.6 mm) **Mobile phase:** Phosphate buffer pH 2.8: Acetonitrile (65:35 % v/v) pH 3.8 **Flow rate:** 1.0 mL/min **Wavelength:** 252 nm **Linearity:** Rosuvastatin calcium: 0.4 µg/ml - 1- 2.4 µg/ml Metformin Hydrochloride: 5 µg/ml - 1-30 µg/ml **Retention time:** Rosuvastatin calcium: 3.80 min Metformin Hydrochloride: 2.147 min	44
23.	Rosuvastatin Calcium and Telmisartan	RP-HPLC	**Stationary phase:** Inertsil ODS 3V C_{18} (250 x 4.6 mm, 5 µm) **Mobile phase:** Ammonium Dihydrogen Phosphate (pH 3) Buffer solution: Methanol (65:35 %v/v), (pH 3.0) **Flow rate:** 1.5 mL/min **Wavelength:** 298 nm **Linearity:** Rosuvastatin calcium: 6- 18 µg/mL Telmisartan: 24-72 µg/mL **Retention time:** Rosuvastatin calcium: 6.1 min Telmisartan: 16.2 min	45
24.	Fenofibrate and Rosuvastatin	HPTLC	**Stationary phase:** Silica gel $60F_{254}$ **Mobile phase:** Toluene: Chloroform: n-butanol: Formic acid (6:2:1.5:0.5 %v/v) **Wavelength:** 261 nm **Linearity:** **Fenofibrate:** 100-500 ng/spot **Rosuvastatin:** 100-500 ng /spot **Rf value:** Fenofibrate: 0.73 ± 0.02 Rosuvastatin: 0.43 ± 0.02	46

Literature Review of analytical method Teneligliptin and Rosuvastatin calcium

SR.NO.	TITLE	METHOD	DESCRIPTION	REF. NO.
1.	Rosuvastatin and Teneligliptin	UV	**Model:** Shimadzu (model UV- 1800) **Solvent:** Methanol **Wavelength:** 240 nm **Linearity:** 5-15 µg/mL	47
2.	Rosuvastatin Calcium and Teneligliptin Hydrobromide Hydrate	UV- First order	**Model:** Shimadzu UV-visible spectrophotometer (model UV-1800 series) **Solvent:** Methanol **Linearity:** 1 - 42 µg/ml **Wavelength:** Rosuvastatin Calcium: 222.66 nm Teneligliptin Hydrobromide Hydrate: 230.03 nm	48
3.	Teneligliptin Hydrobromide Hydrtae and Rosuvastatin Calcium	RP-HPLC	**Stationary phase:** Hyperchrom ODS BP column (250 x4.6 mm, 5µm**)** **Mobile phase:** Phosphate Buffer (pH 3.5): Methanol (70:30 % v/v) **Flow rate:** 1 mL/min **Wavelength:** 240 nm **Linearity:** 10-30 µg/mL **Retention time:** Teneligliptin Hydrobromide Hydrtae: 4.313 min Rosuvastatin Calcium: 4.933 min	49
4.	Teneligliptin hemihydrate hydrobromide and Rosuvastatin calcium	Stability indicating HPTLC	**Stationary phase:** Silica gel 60F_{254} plates **Mobile phase:** Ethyl acetate: Toluene: Acetonitrile: Formic Acid (6:3.5:0.5:0.2 % v/v/v/v) **Wavelength:** 243 nm **Linearity:** Teneligliptin hemihydrate hu5]8uiooi888hydrobromide: 50- 500 ng/band Rosuvastatin calcium: 50- 500 ng/band **Rf value:** Teneligliptin hemihydrate hydrobromide: 0.76 ± 0.01 Rosuvastatin calcium: 0.37 ± 0.01	50

CONCLUSION

Various method for determination of Teneligliptin and Rosuvastatin calcium have been reported. According to this review it was concluded that the different analytical methods are reported for estimation Teneligliptin and Rosuvastatin calcium individual and other combination like UV Spectroscopy, HPLC, HPTLC all method are found to be simple, accurate, precise and reproducible in nature. This review will help in future to develop the analytical method for this new combination and also gives the knowledge about its characteristics of both drugs.

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