



Forced degradation studies of vildagliptin raw material and in the presence of excipients by HPLC-UV method

Forced Degradation Studies

Forced degradation of vildagliptin raw material

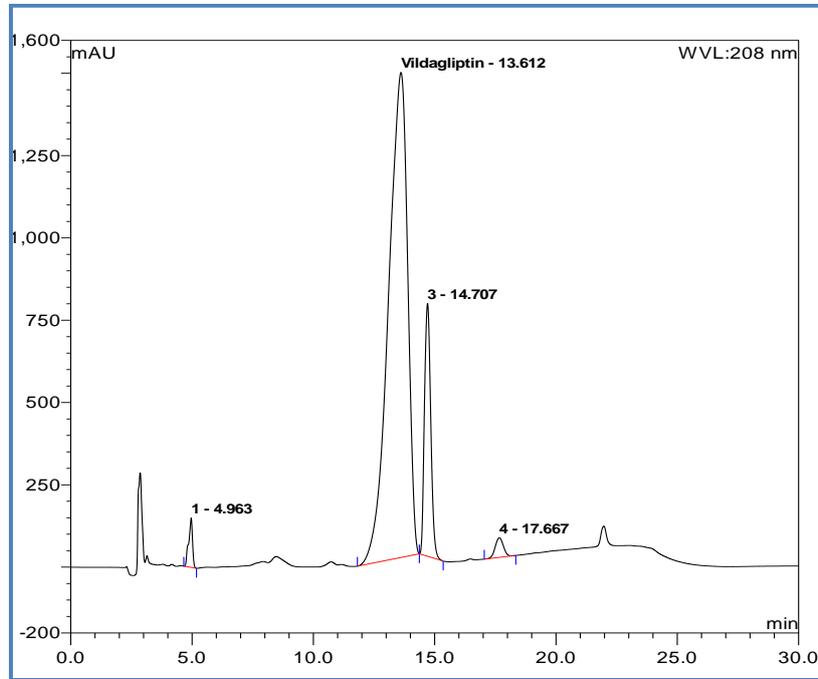


Figure S1 HPLC Chromatogram of acidic degradation of vildagliptin (1.0 M HCl at 80 °C) for 3 hrs

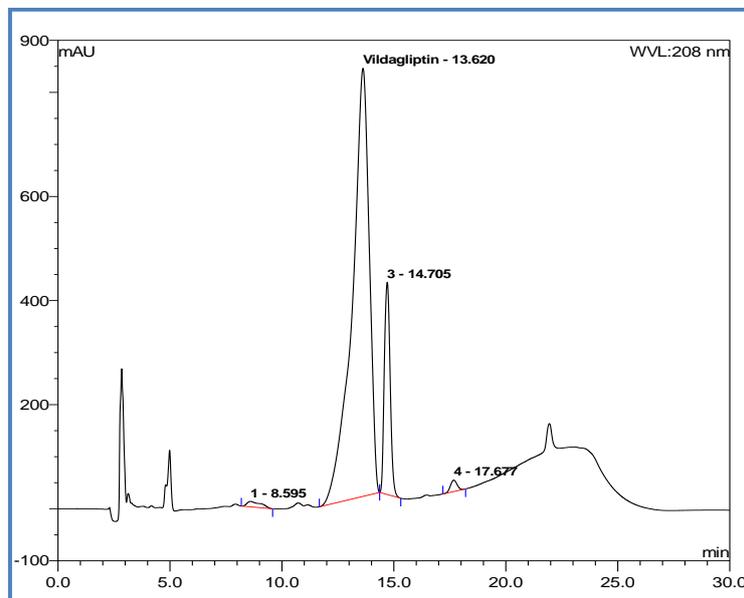


Figure S2 HPLC Chromatogram of acidic degradation of vildagliptin(1 M HCl at 80 °C) for 5 hrs

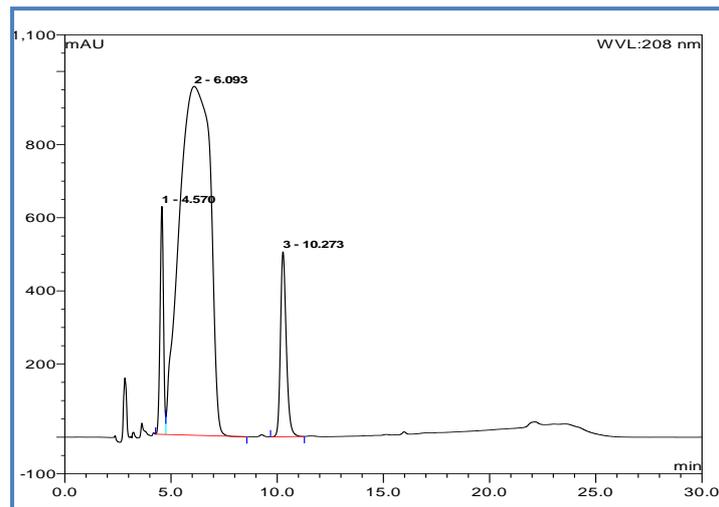


Figure S3 HPLC Chromatogram of basic degradation of vildagliptin in (0.1 M NaOH at 80 °C) for 1 hr

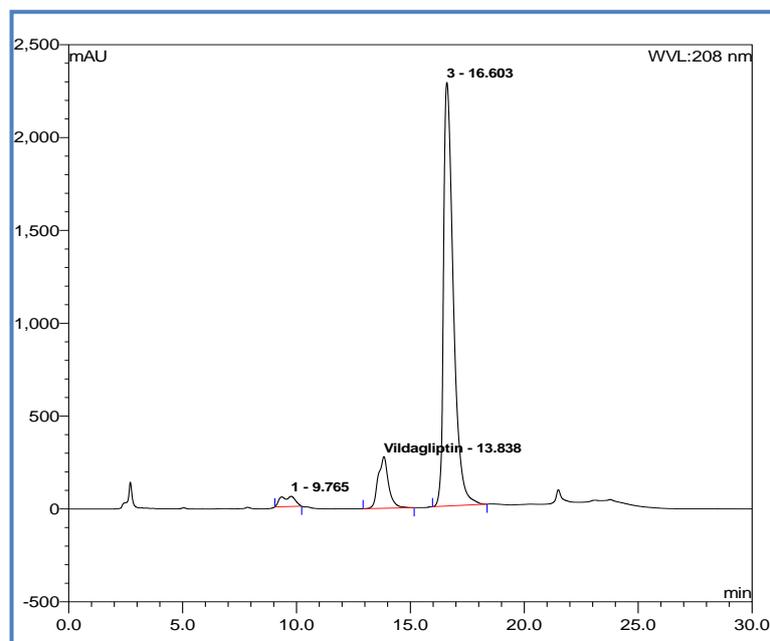


Figure S4 HPLC Chromatogram of basic degradation of vildagliptin(0.1 M NaOH at RT) for 3 hrs

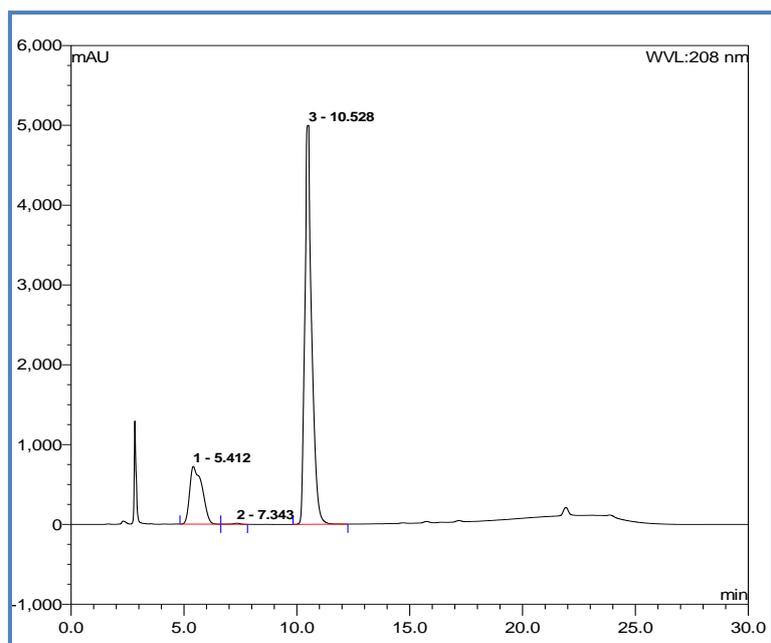


Figure S5 HPLC Chromatogram of basic degradation of vildagliptin (1.0 ml of 1 M NaOH at 70 °C) for 1 hr

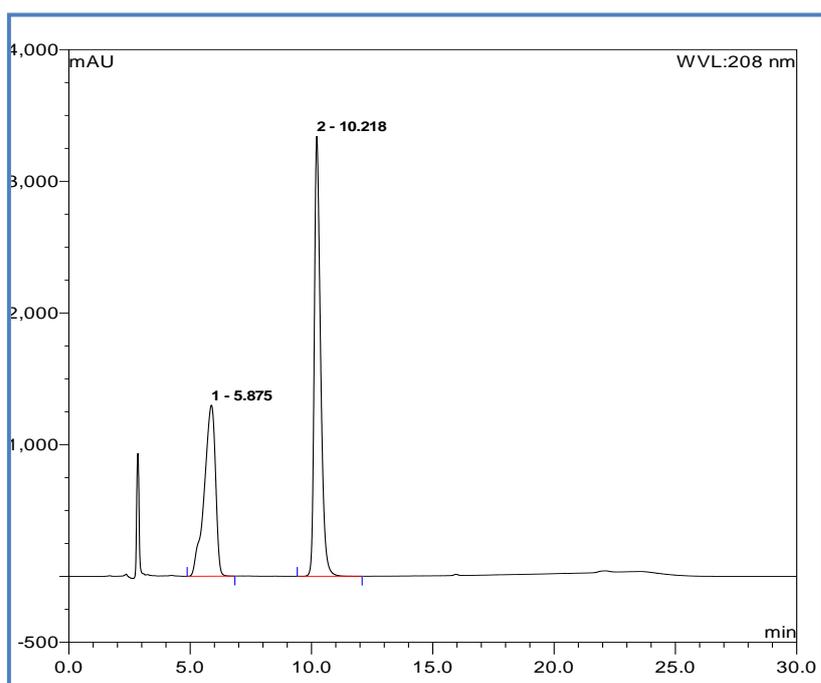


Figure S6 HPLC Chromatogram of basic degradation of vildagliptin (2.0 ml of 1 M NaOH at 70 °C) for 1 hr

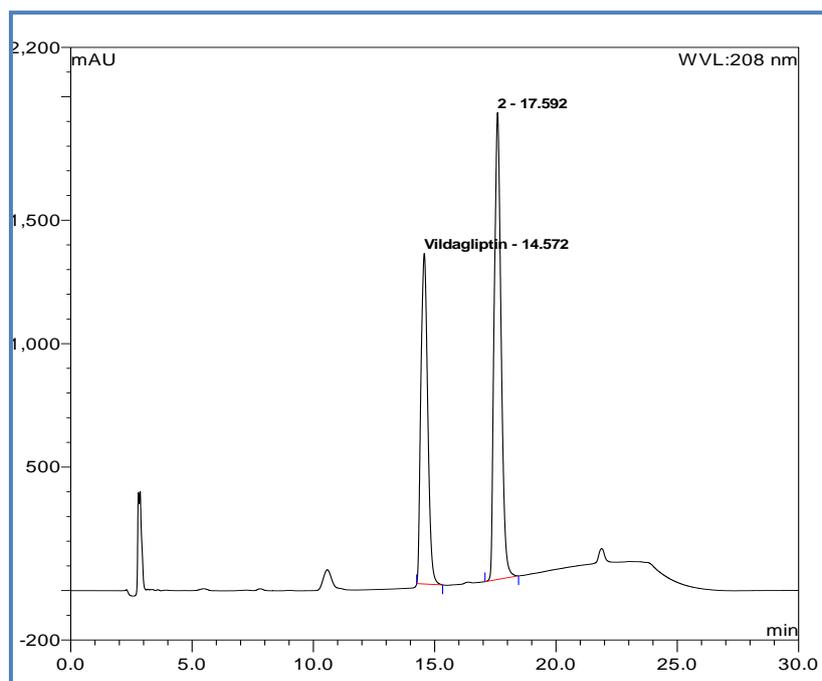


Figure S7 HPLC Chromatogram of basic degradation of vildagliptin, (5 ml of 1 M NaOH) at room temperature after 1 min

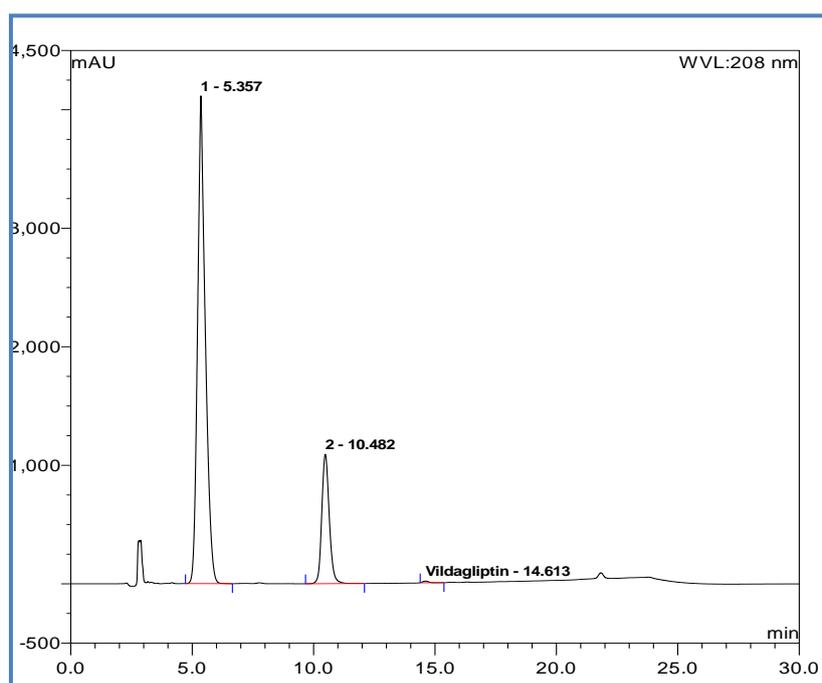


Figure S8 HPLC Chromatogram of basic degradation of vildagliptin, (1 M NaOH at 80 °C) for 1 hr

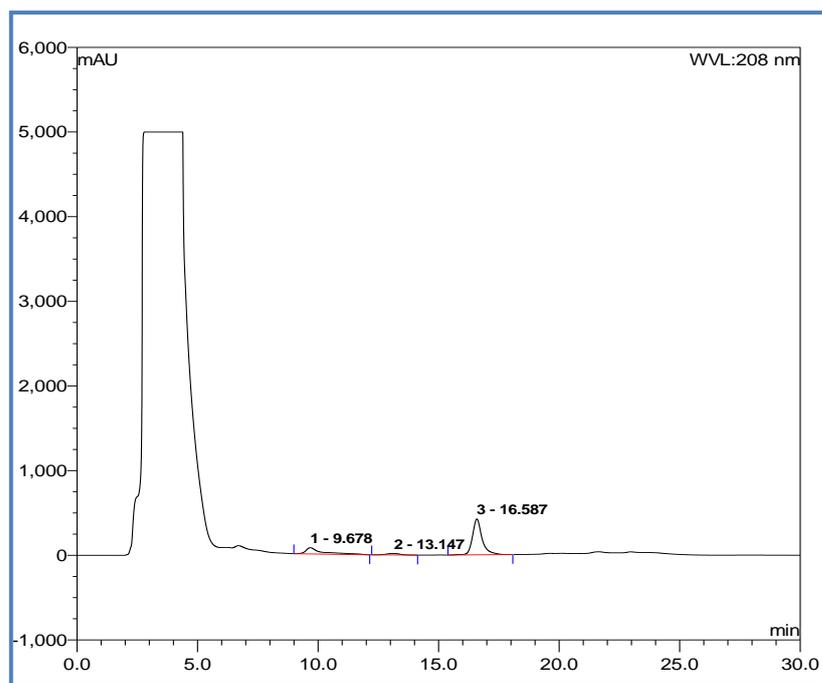


Figure S9 HPLC Chromatogram of oxidative degradation of vildagliptin, (30% H₂O₂ at room temperature) for 1 hr

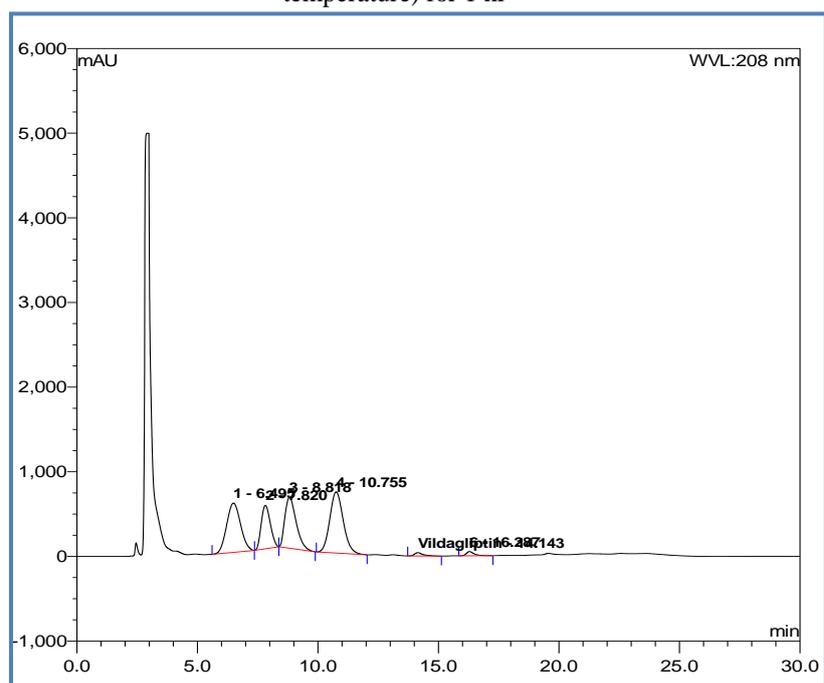


Figure S10 HPLC Chromatogram of oxidative degradation of vildagliptin, (3% H₂O₂ at room temperature) for 1 hr

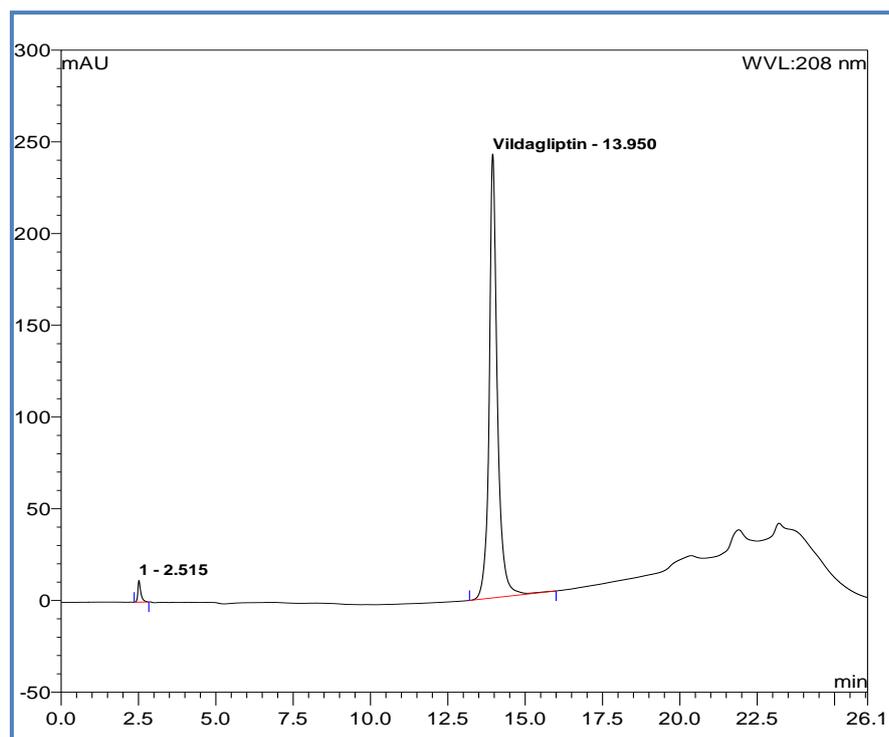


Figure S11 HPLC Chromatogram of heat solid degradation of vildagliptin at 120 °C in oven for 3 hrs

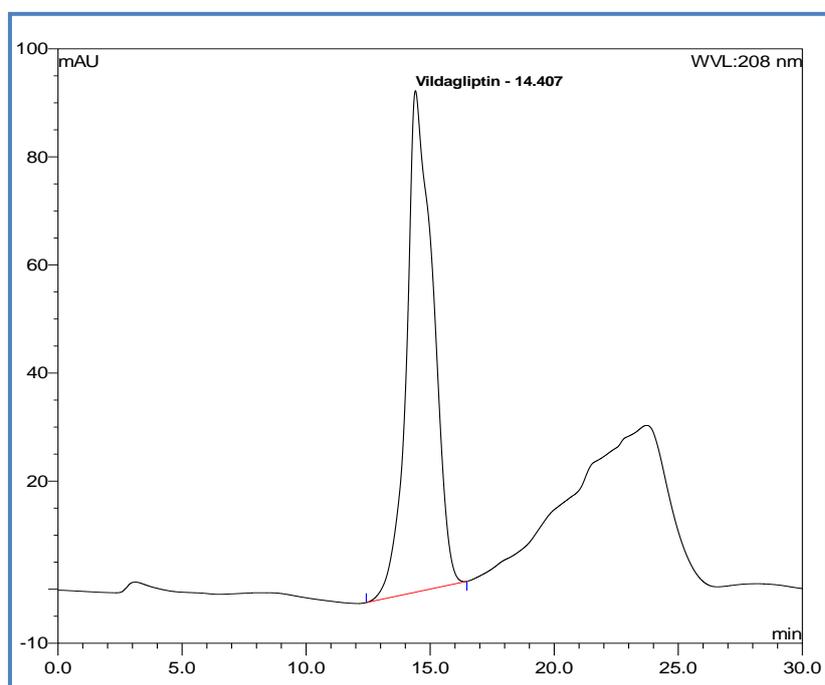


Figure S12 HPLC Chromatogram of UV degradation of vildagliptin in solid state at 254 nm for 1 day

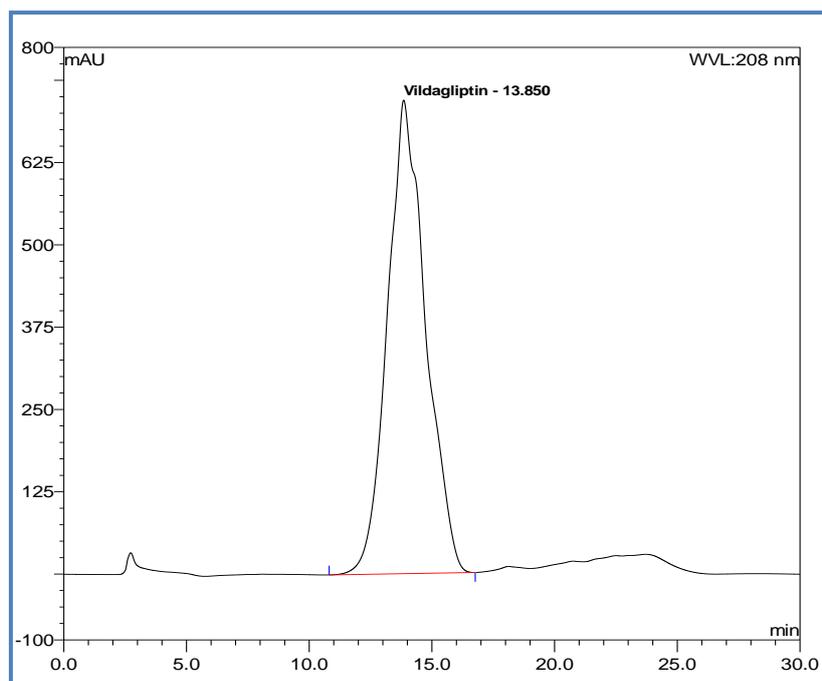


Figure S13 HPLC Chromatogram of UV degradation of vildagliptin in liquid state at 254 nm for 8 hrs

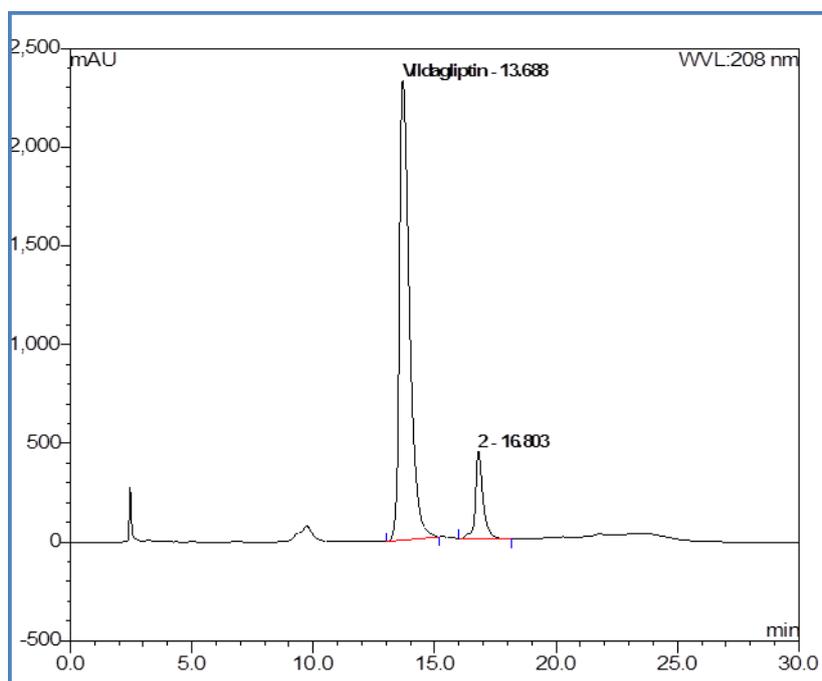


Figure S14 HPLC Chromatogram of neutral hydrolysis degradation of vildagliptin at 80 °C for 1hr

b) Forced degradation of vildagliptin in the presence of excipients

Forced degradation study of vildagliptin with excipients mixture

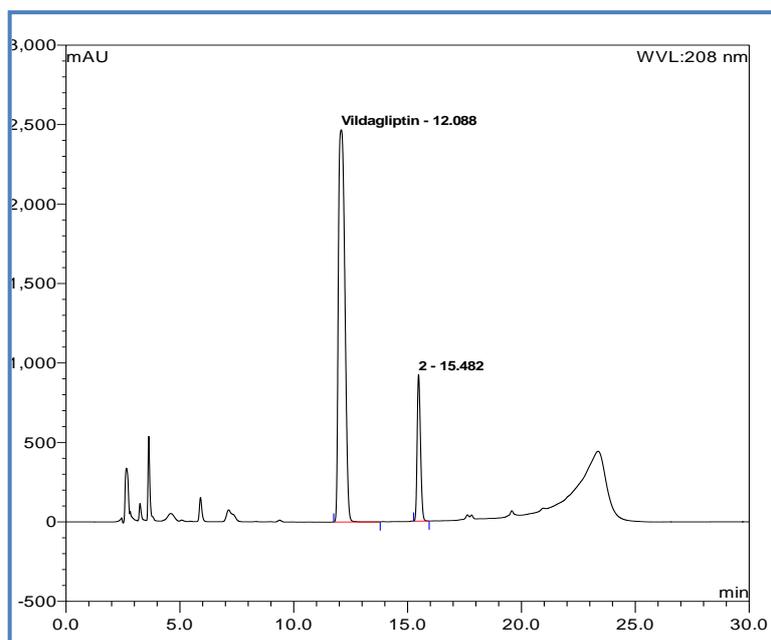


Figure S15 HPLC Chromatogram of acidic degradation of vildagliptin with excipients mixture, (1 M HCl at 80 °C) for 9 hrs

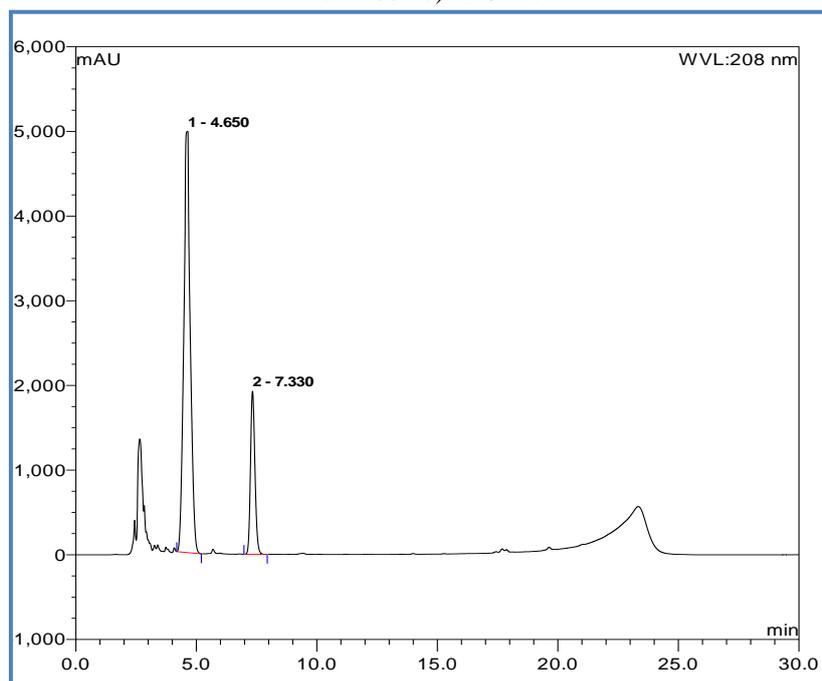


Figure S16 HPLC Chromatogram of basic degradation of vildagliptin with excipients mixture, (1 M NaOH at 80 °C) for 1hr

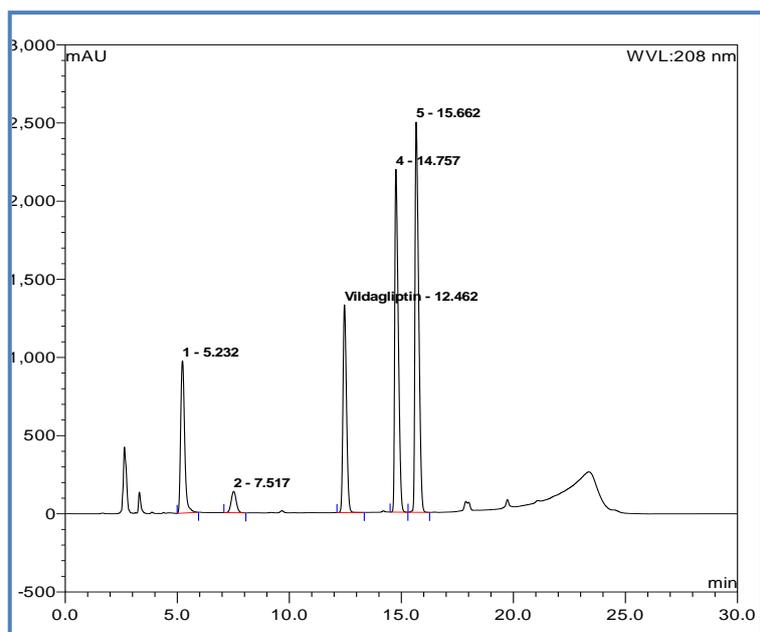


Figure S17 HPLC Chromatogram of basic degradation of vildagliptin with excipients mixture, (0.1 M NaOH at room temperature) for 3 hrs

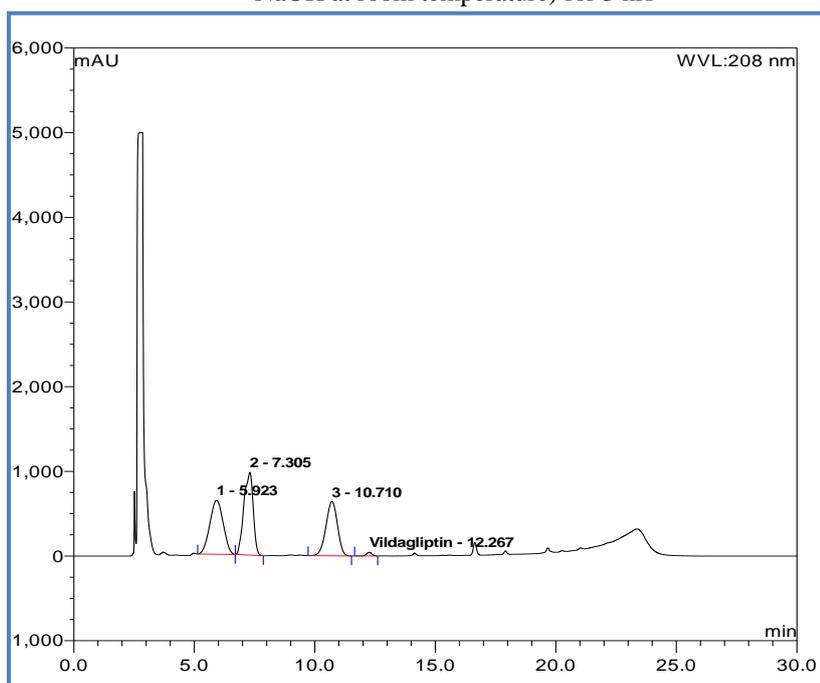


Figure S18 HPLC Chromatogram of oxidative degradation of vildagliptin with excipients mixture, 3% H₂O₂ at room temperature for 7 hrs

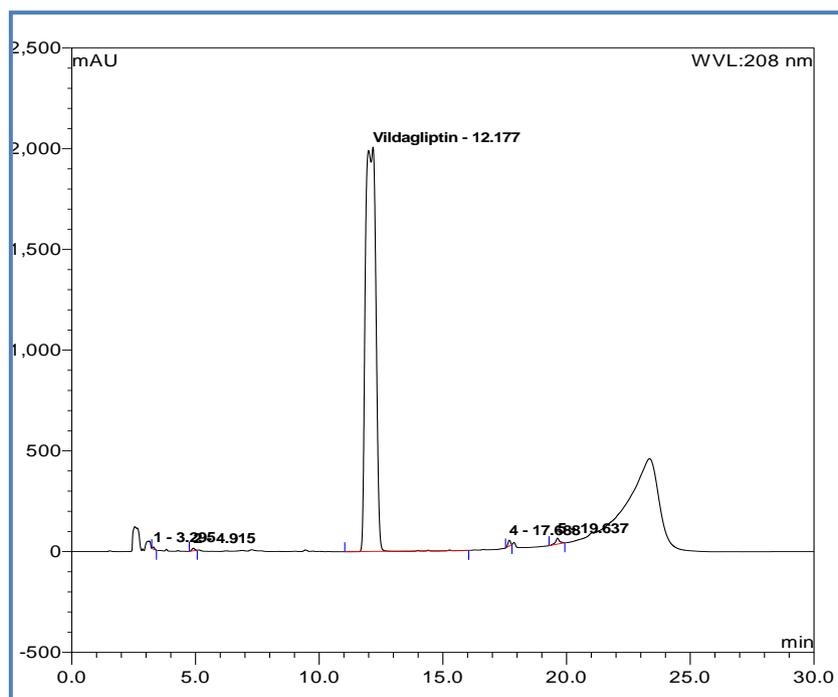


Figure S19 HPLC Chromatogram of thermal degradation of vildagliptin with excipients mixture, at 150 °C for 7 hrs

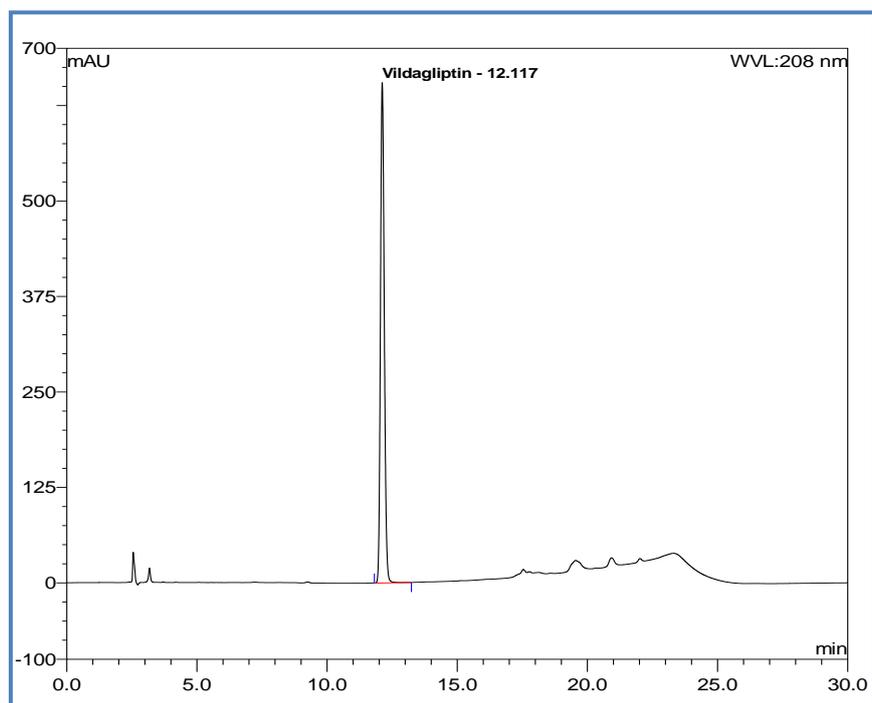


Figure S20 HPLC Chromatogram of UV at 254 nm degradation of vildagliptin with excipients mixture in solid state for 1 day

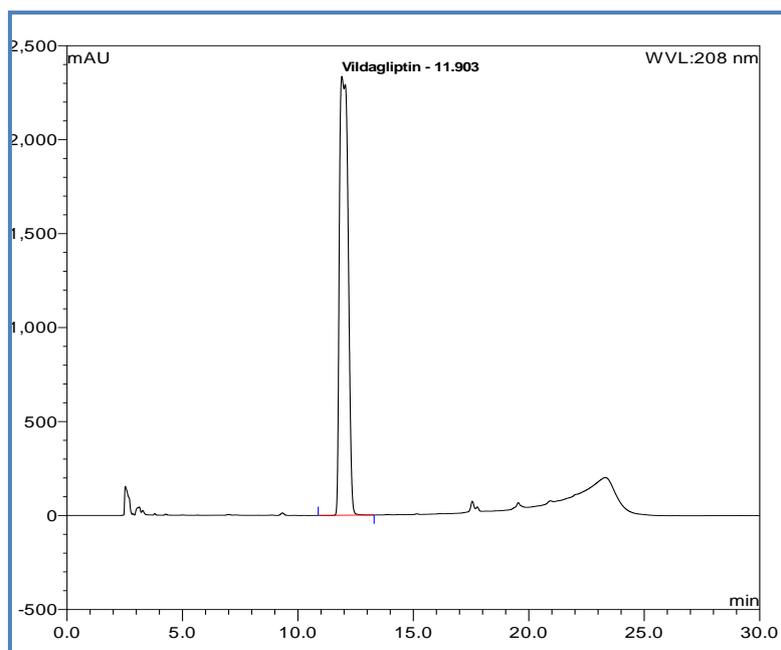


Figure S21 HPLC Chromatogram of UV degradation of vildagliptin with excipients mixture in liquid state at 254 nm for 1 day

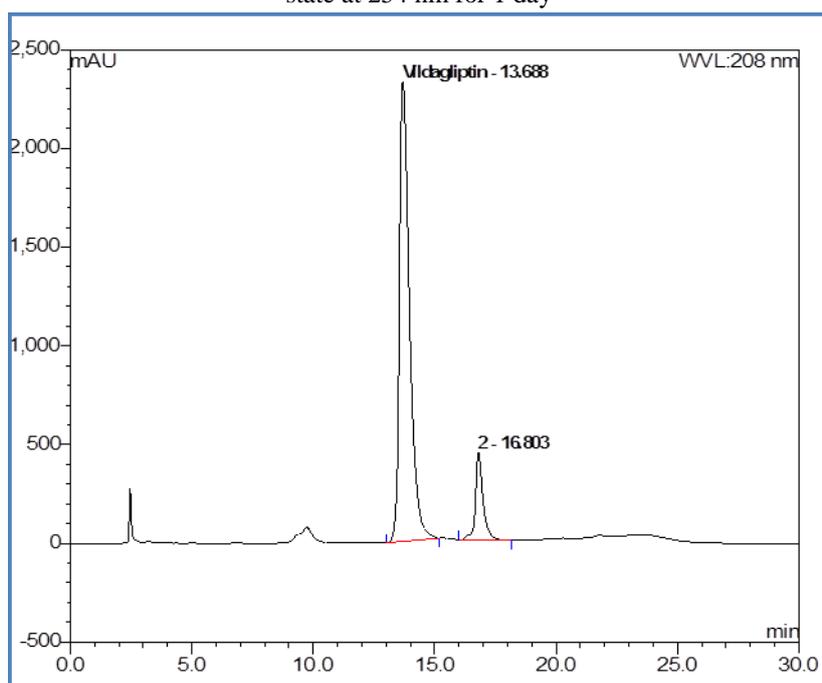


Figure S22 HPLC Chromatogram of neutral hydrolysis degradation of vildagliptin with excipients mixture, at 80 °C for 1hr

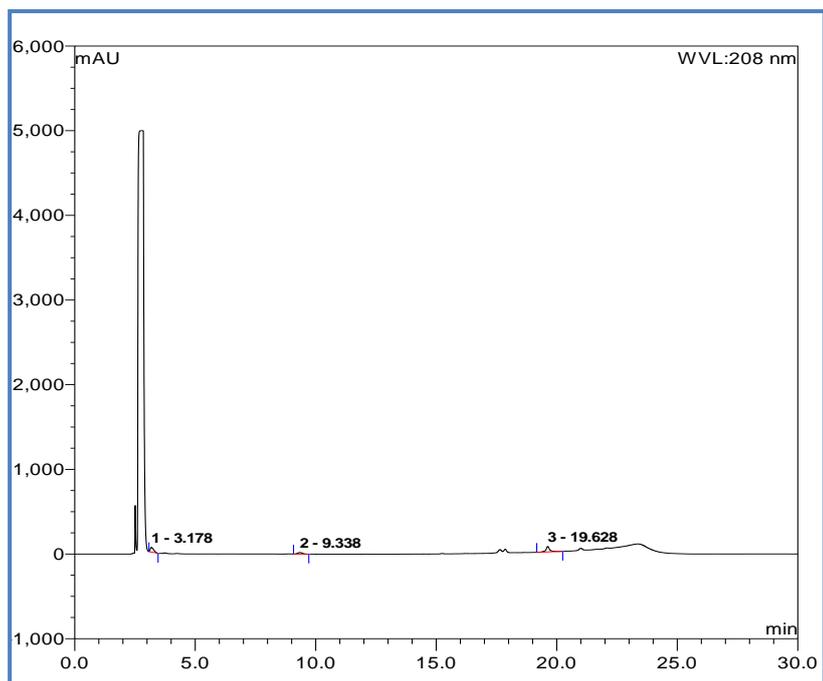


Figure S23 HPLC Chromatogram of oxidative degradation of excipients mixture, 3% H₂O₂ at room temperature for 7 hrs

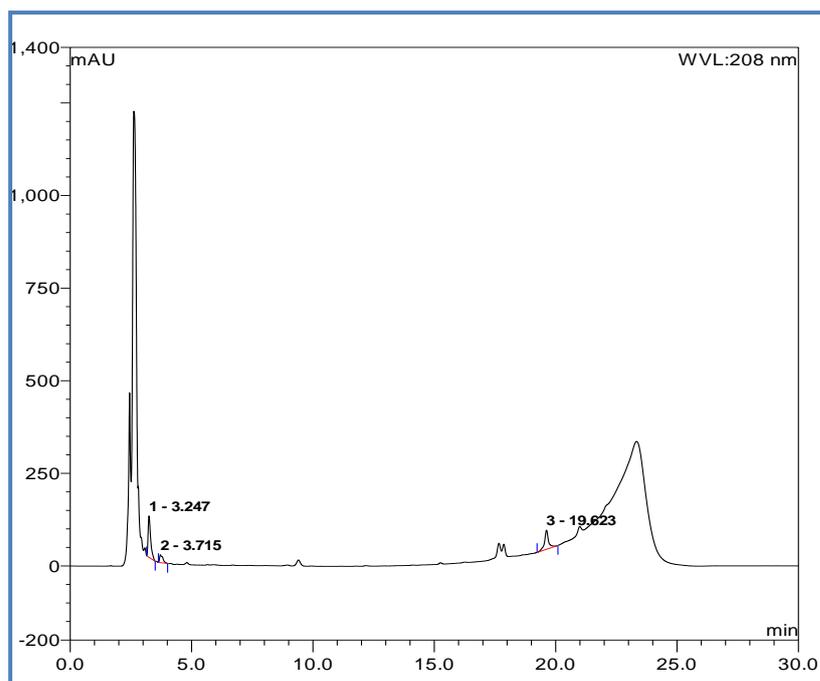


Figure S24 HPLC Chromatogram of basic degradation of excipients mixture, (0.1 M NaOH at room temperature) for 3 hrs

Table S1 Results of degradation under 1M HCl at 80 °C in 9 hrs

Condition	RRT	% Area of Impurity	% Assay of Vildagliptin after degradation
Degradation of vildagliptin raw material	1.3	15.7	73.60
Vildagliptin with excipients mixture	1.2	14.1	86.20
Vildagliptin with Microcrystalline Cellulose (Avicel PH112)	1.2	13.7	85.30
Vildagliptin with Magnesium stearate	-	-	99.28
Vildagliptin with Sodium Starch Glycolate	1.3	4.5	94.00
Vildagliptin with Sucrose	-	-	89.40
Vildagliptin with Povidone	-	-	98.58
Vildagliptin with Lactose	-	-	96.10

Table S2 Results of degradation under 1.0 M NaOH at 80 °C for 1 hr

Condition	RRT	% Area of Impurity	% Assay of Vildagliptin after degradation
Degradation of vildagliptin raw material	0.4	79.5	0.20
	0.7	20.3	
Vildagliptin with excipients mixture	0.4	78.9	0.00
	0.6	20.9	
Vildagliptin with Microcrystalline Cellulose (Avicel PH112)	0.4	71.4	0.00
	0.7	28.6	
Vildagliptin with Magnesium stearate	0.4	41.9	0.00
	0.7	57.9	
Vildagliptin with Sodium Starch Glycolate	0.4	77.5	0.00
	0.7	21.6	
Vildagliptin with Sucrose	0.4	54.1	0.00
	0.7	44.9	
Vildagliptin with Povidone	0.4	93.9	4.80
Vildagliptin with Lactose	0.4	63.4	0.00
	0.7	36.6	

Table S3 Results of degradation under 0.1 M NaOH at RT for 3 hrs

Condition	RRT	% Area of Impurity	% Assay of Vildagliptin after degradation
Degradation of vildagliptin raw material	0.7	3.1	11.10
	1.2	85.9	
Vildagliptin with excipients mixture	0.4	14.6	17.60
	1.17	29.2	
	1.2	34.7	
Vildagliptin with Microcrystalline Cellulose (Avicel PH112)	0.7	16.9	17.30
	1.2	64.6	
Vildagliptin with Magnesium stearate	0.4	41.8	16.50
	1.2	64.7	
Vildagliptin with Sodium Starch Glycolate	0.7	13.2	19.60
	1.2	66.5	
Vildagliptin with Sucrose	0.7	9.3	16.60
	1.2	73.6	
Vildagliptin with Povidone	1.2	86.5	10.60
Vildagliptin with Lactose	0.7	15.9	13.50
	1.2	70.6	

Table S4 Results of degradation under hydrolytic degradation, at 80 °C in 7 hrs

Condition	RRT	% Area of Impurity	% Assay of Vildagliptin after degradation
Degradation of vildagliptin raw material	0.4	7.7	56.90
	0.7	22.9	
	1.1	3.0	
	1.2	7.4	
Vildagliptin with excipients mixture	0.6	30.4	9.50
Vildagliptin with Microcrystalline Cellulose (Avicel PH112)	0.7	20.7	62.00
	1.2	10.3	
Vildagliptin with Magnesium stearate	0.7	19.2	57.90
	1.2	12.4	
Vildagliptin with Sodium Starch Glycolate	0.7	27.4	50.70
	1.2	13.9	
Vildagliptin with Sucrose	0.7	75.9	57.70
	1.2	13.9	
Vildagliptin with Povidone	0.7	18.1	76.40
Vildagliptin with Lactose	0.7	22.7	57.30
	1.2	11.2	

Table S5 Results of degradation under 3% H₂O₂ at room temperature for 7 hrs

Condition	RRT	% Area of Impurity	% Assay of Vildagliptin after degradation
Degradation of vildagliptin raw material	0.5	38.9	0.00
	0.6	12.6	
	0.7	32.2	
	0.8	11.2	
Vildagliptin with excipients mixture	0.5	32.3	0.90
	0.6	34.6	
	0.9	28.0	
Vildagliptin with Microcrystalline Cellulose (Avicel PH112)	0.7	20.2	0.60
	1.2	10.0	
Vildagliptin with Magnesium stearate	0.7	41.8	0.70
	1.2	57.7	
Vildagliptin with Sodium Starch Glycolate	0.7	26.1	0.12
	1.2	13.2	
Vildagliptin with Sucrose	0.7	19.1	0.84
	1.2	17.3	
Vildagliptin with Povidone	0.7	16.5	0.60
Vildagliptin with Lactose	0.7	22.6	0.10
	1.2	11.1	

Table S6 Results of degradation under 30% H₂O₂ at room temperature for 3 hrs

Condition	RRT	% Area of Impurity	% Assay of Vildagliptin after degradation
Degradation of vildagliptin Raw Material	0.7	9.1	0.00
	1.2	88.6	
Vildagliptin with Excipients Mixture	0.5	2.3	0.00
	0.6	82.7	
	1.3	3.5	
Vildagliptin with Microcrystalline Cellulose (Avicel PH112)	0.65	15.9	0.00
	0.69	23.8	
	1.3	24.5	
Vildagliptin with Magnesium Stearate	0.5	42.9	0.00
	0.7	23.2	
	0.8	27.7	
Vildagliptin with Sodium Starch Glycolate	0.7	41.9	0.00
	0.8	42.8	
Vildagliptin with Sucrose	0.5	11.5	0.00
	0.7	37.5	
Vildagliptin with Povidone	0.5	10.7	0.00
	0.7	57.2	
	0.8	23.6	
Vildagliptin with Lactose	-	-	0.00