

**STABILITY STUDY RESULTS IN BULK- LES LABORATOIRES SERVIER INDUSTRIE (LSI)
S 6490**

Green film-coated tablet containing 10 mg of drug substance

1. INTRODUCTION

Details	Batch No.		
	6020356	6020357	6020358
Strength (mg)	10	10	10
Storage conditions	25 °C/60 % RH	25 °C/60 % RH	25 °C/60 % RH
Start of stability study	April 2021	April 2021	April 2021
Manufacturing site	LES LABORATOIRES SERVIER INDUSTRIE 45520 Gidy - France		
Date of manufacture	January 2021	January 2021	January 2021
Batch size (tablets)	2,000,000	2,000,000	2,000,000
Drug substance batch No.	40030386	40030386	40030386 40030387
Packaging	MINIBAG		

RH: relative humidity

Minibag : outer bag of Polypropylene bag containing an inner bag of opaque polyethylene

The stability study technique used is coded [DTC_S06490_PF_T_STA_1101_EN](#).

2.RESULTS


Product: S 6490

Batch No.: **6020356**

Strength: 10 mg

Packaging: Minibag

Parameters tested	Storage period at 25 °C/60 % RH			
	Initial	3 months	6 months	9 months
Appearance	N1	N1	N1	N1
Average mass (mg)	183.4	184,2	184,3	184,8
Disintegration time (min)	6	7	6	9
Identification of drug substance	Positive	Positive	Positive	Positive
Drug substance content (mg/tablet)	9.97	9.93	9,87	9,72
Degradation products content (%):				
. S 9780-1	0.12	0,18	0,28	0,37
. Y32	nq	nq	nq	nq
. Y33	nq	nq	nq	nq
. Y31	0.10	0.17	0,24	0,26
. Others degradation products	nq	nq	nq	nq
. Sum of degradation products	0.22	0,35	0,52	0,63
Uniformity of content	Complies	-	-	Complies
Microbiological quality	N2	-	-	N2

N1 : green, round, biconvex, film-coated tablet engraved with a heart on one face and *  on the other face

N2: complies with the European Pharmacopoeia (5.1.4.)

nq : not quantified (equal to or below the reporting threshold: $\leq 0.1\%$)

- : test not scheduled


Product: S 6490

Batch No.: 6020357

Strength: 10 mg

Packaging: Minibag

Parameters tested	Storage period at 25 °C/60 % RH			
	Initial	3 months	6 months	9 months
Appearance	N1	N1	N1	N1
Average mass (mg)	184.4	184,7	184,3	184,4
Disintegration time (min)	10	7	6	7
Identification of drug substance	Positive	Positive	Positive	Positive
Drug substance content (mg/tablet)	10.02	9.86	9,84	9,80
Degradation products content (%):				
. S 9780-1	0.11	0,19	0,28	0,39
. Y32	nq	nq	nq	nq
. Y33	nq	nq	nq	nq
. Y31	0.11	0.16	0,24	0,26
. Others degradation products	nq	nq	nq	nq
. Sum of degradation products	0.22	0,35	0,52	0,65
Uniformity of content	Complies	-	-	Complies
Microbiological quality	N2	-	-	N2

N1 : green, round, biconvex, film-coated tablet engraved with a heart on one face and *  on the other face

N2: complies with the European Pharmacopoeia (5.1.4.)

nq : not quantified (equal to or below the reporting threshold: $\leq 0.1\%$)

- : test not scheduled


Product: S 6490

Batch No.: 6020358

Strength: 10 mg

Packaging: Minibag

Parameters tested	Storage period at 25 °C/60 % RH			
	Initial	3 months	6 months	9 months
Appearance	N1	N1	N1	N1
Average mass (mg)	184.8	184.8	185,3	185.1
Disintegration time (min)	10	8	5	8
Identification of drug substance	Positive	Positive	Positive	Positive
Drug substance content (mg/tablet)	10.10	9.88	9,85	9.88
Degradation products content (%):				
. S 9780-1	0.12	0,19	0,33	0.44
. Y32	nq	nq	nq	nq
. Y33	nq	nq	nq	nq
. Y31	0.13	0.20	0,28	0.30
. Others degradation products	nq	nq	nq	nq
. Sum of degradation products	0.25	0,39	0,61	0.74
Uniformity of content	Complies	-	-	Complies
Microbiological quality	N2	-	-	N2

N1 : green, round, biconvex, film-coated tablet engraved with a heart on one face and *  on the other face

N2: complies with the European Pharmacopoeia (5.1.4.)

nq : not quantified (equal to or below the reporting threshold: $\leq 0.1\%$)

- : test not scheduled

3.CONCLUSION

The results obtained after 9 months of storage at 25 °C / 60 % RH show no significant modification of the tested parameters in comparison to those obtained at the initial control.

The S 6490 tablets are stable in the minibag (outer bag of Polypropylene bag containing an inner bag of opaque polyethylene.).