

Stability Test report of CAVERJECT S 20 MCG

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1. Study information

Study Number	Man Lotnumber	Storage Condition	Storage Period	Container	Closure	Lot Quantity	Start Date	Manufacturing Date	Manufacturing Place
ST09073LF	S01690	25°C ± 2°C – 60% RH ± 5% RH	24 MONTHS	Vial	Stopper Lyo	69723	15/06/2009	27/05/2009	PFIZER PUURS
ST10099LF	S11185	25°C ± 2°C – 60% RH ± 5% RH	24 MONTHS	Vial	Stopper Lyo	69179	20/04/2010	10/03/2010	PFIZER PUURS
ST11009LF	X09376	25°C ± 2°C – 60% RH ± 5% RH	24 MONTHS	Vial	Stopper Lyo	69352	15/02/2011	26/01/2011	PFIZER PUURS

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2. Schedule

		ALPROSTADIL TOTAL	CLARITY AND OPALESCENCE	DEGREE OF COLORATION	DESCRIPTION	PGA1	pH	RECONSTITUTION TIME	STERILITY	WATER
ST09073LF	00 MONTHS	X	X	X	X	X	X	X	X	X
	06 MONTHS	X	X	X	X	X	X	X		X
	12 MONTHS	X	X	X	X	X	X	X		X
	18 MONTHS	X	X	X	X	X	X	X		X
	24 MONTHS	X	X	X	X	X	X	X	X	X
ST10099LF	00 MONTHS	X	X	X	X	X	X	X	X	X
	06 MONTHS	X	X	X	X	X	X	X		X
	12 MONTHS	X	X	X	X	X	X	X		X
	18 MONTHS	X	X	X	X	X	X	X		X
	24 MONTHS	X	X	X	X	X	X	X	X	X
ST11009LF	00 MONTHS	X	X	X	X	X	X	X	X	X
	06 MONTHS	X	X	X	X	X	X	X		X
	12 MONTHS	X	X	X	X	X	X	X		X
	18 MONTHS	X	X	X	X	X	X	X		X
	24 MONTHS	X	X	X	X	X	X	X	X	X

3. Currently registered procedures and limits on stability

Test	Method	Limits
Description	Visual	A white to off-white powder
pH	Potentiometrically	3.5 to 6.0
Water	GP0366 - TA2617	Not More Than 1.0 %
Clarity and Opalescence	Ph. Eur.	Meets Ph. Eur. requirements for a clear solution
Degree of Coloration	Ph. Eur.	Meets Ph. Eur. requirements for a colorless solution
Alprostadil Deliverable	TA6268	18.0 to 22.0 mcg/ml at time of release, equivalent to 18.5 to 22.5 mcg/ml Alprostadil Total.
PGA1	TA6268	Not More Than 2.0 mcg/ml
Reconstitution Time	Time registration	Not More Than 60 seconds
Sterility	Ph. Eur.	Meets Ph. Eur. Requirements

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4. Stability Test results at 25°C ± 2°C – 60% RH ± 5% RH

DESCRIPTION

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
06 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
18 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

All results within limits up to testing period: no problems reported.

pH

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	4.5	4.6	4.8
06 MONTHS	4.4	4.7	4.6
12 MONTHS	4.4	4.9	4.8
18 MONTHS	4.5	4.9	4.6
24 MONTHS	4.4	4.7	4.8

All results within limits up to testing period: no problems reported.

WATER

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	0.1	0.1	0.1
06 MONTHS	0.3	0.2	0.2
12 MONTHS	0.2	0.3	0.4
18 MONTHS	0.3	0.4	0.3
24 MONTHS	0.5	0.4	0.4

All results within limits up to testing period: no problems reported.

CLARITY AND OPALESCENCE

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
06 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
18 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

All results within limits up to testing period: no problems reported.

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DEGREE OF COLORATION

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
06 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
18 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

All results within limits up to testing period: no problems reported.

ALPROSTADIL TOTAL

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	20.5	20.3	20.6
06 MONTHS	20.2	20.0	19.7
12 MONTHS	20.1	19.8	19.3
18 MONTHS	19.5	19.2	19.4
24 MONTHS	19.5	18.9	18.8

All results within limits up to testing period: no problems reported.

PGA1

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	0.1	0.2	0.1
06 MONTHS	0.5	0.5	0.7
12 MONTHS	0.8	0.7	0.9
18 MONTHS	0.9	1.0	0.8
24 MONTHS	0.8	1.3	1.4

All results within limits up to testing period: no problems reported.

RECONSTITUTION TIME

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	23	13	25
06 MONTHS	18	9	18
12 MONTHS	23	16	16
18 MONTHS	13	22	25
24 MONTHS	15	17	18

All results within limits up to testing period: no problems reported.

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STERILITY

	ST09073LF	ST10099LF	ST11009LF
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
24 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

All results within limits up to testing period: no problems reported.

5. Conclusion

The results show that CAVERJECT S 20 MCG is stable up to testing period when stored at 25°C ± 2°C – 60% RH ± 5% RH.

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