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STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190127	**Exp. Date**	:	SEP. 2021
Mfg. Date	:	OCT. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	11/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
01	Description	Clear, colorless to yellow color viscous solution, free of visible particulate matters, filled in 5 mL PFS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
02	Identification									
	By HPLC	The Retention Time of the Major Peak of the Sample Solution corresponds to that of the Standard Solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
03	Container content (Volume of Injections)	The volume should be not less than 5.0 mL in each container.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
04	Water content	Not more than 2.0 %	0.8%	0.8%	0.9%	0.8%	0.8%	0.8%	0.8%	0.8%
05	Viscosity	Between 50 to 150 cps	85 cps	83 cps	90 cps	99 cps	85 cps	84 cps	87 cps	86 cps
06	Color of solution	Not more than 400 APHA	157 APHA	164 APHA	168 APHA	174 APHA	165 APHA	172 APHA	153 APHA	167 APHA
07	Acid value (Free Fatty acids) #	Not more than 0.8	0.3	0.4 mL	0.5 mL	0.5 mL	0.6 mL	0.3	0.2	0.3

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Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
08	Particulate matter									
	Visible Particulates	Free from foreign particles	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Sub-visible particles	(By light obscuration particle count test) The average number of particles per container, ≥ 10µm: Not More Than 6000 ≥ 25µm: Not More Than 600	 803.67 97.00	 2029.67 143.00	 1764.00 14.67	 1540.00 86.00	 710.67 10.00	 1784.67 14.67	 1046.00 4.00	 1289.33 5.33
09	Assay of Ethanol (By GC) Label claim: Each mL contains 100 mg of Alcohol[1]	Each mL contains not less than 80.0 mg and not more than 110.0 mg of Ethanol (C_2H_5OH).	99.2 mg	97.0 mg	98.2 mg	96.4 mg	97.8 mg	96.5 mg	98.1 mg	97.3 mg
		Not less than 80.0 % w/v and not more than 110.0 % w/v of labeled amount of Ethanol (C_2H_5OH).	99.2%	97.0%	98.2%	96.4%	97.8%	96.5%	98.1%	97.3%
10	Assay of Benzyl Alcohol (By HPLC) Label claim: Each mL contains 100 mg of Benzyl Alcohol	Each mL contains not less than 90.0 mg and not more than 110.0 mg of Benzyl Alcohol.	97.6 mg	98.9 mg	99.6 mg	100.6 mg	100.8 mg	100.0 mg	98.9 mg	101.8 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Alcohol.	97.6%	98.9%	99.6%	100.6%	100.8%	100.0%	98.9%	101.8 %

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190127	**Exp. Date**	:	SEP. 2021
Mfg. Date	:	OCT. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	11/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
11	Assay of Benzyl Benzoate (By HPLC) Label claim: Each mL contains 150 mg of Benzyl Benzoate	Each mL contains not less than 135.0 mg and not more than 165.0 mg of Benzyl Benzoate.	147.7 mg	149.6 mg	149.0 mg	149.6 mg	150.1 mg	148.6 mg	148.8 mg	151.3 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Benzoate.	98.5%	99.8%	99.3%	99.7%	100.1%	99.1%	99.2%	100.9%
12	Assay of Fulvestrant ($C_{32}H_{47}F_5O_3S$) (By HPLC) Label claim: Each mL contains 50 mg of Fulvestrant	Each mL contains not less than 45.0 mg and not more than 55.0 mg of Fulvestrant (C32H47F5O3S).	49.7 mg	50.1 mg	49.6 mg	49.8 mg	49.4 mg	50.0 mg	48.9 mg	50.0 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Fulvestrant (C32H47F5O3S).	99.4%	100.1%	99.3%	99.6%	98.9%	99.9%	97.8%	100.1%
13	Related Substances (By HPLC)									
	a. Fulvestrant Sulfone	Not more than 1.0 %	0.1%	0.3%	0.3%	0.4%	0.4%	0.4%	0.5%	0.5%

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Mfg. Date	:	OCT. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
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Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
	b. Any Unspecified Degradation product	Not more than 0.2 %	0.10%	0.11%	0.11%	0.11%	0.11%	0.11%	0.11%	0.11%
	c. Total Degradation products	Not more than 2.0 %	0.4%	0.6%	0.6%	0.7%	0.7%	0.7%	0.7%	0.7%
14	Limit of Benzaldehyde	Not more than 0.2 %	0.00%	0.00%	0.01%	0.00%	0.01%	0.01%	0.01%	0.01%
15	Bacterial Endotoxin	Not more than 0.7 Endotoxin Units/mg of Fulvestrant	<0.3 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	<0.3456 EU/mg
16	Sterility	Should be sterile	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Sterile
17	Break loose force	Not more than 40 N	10 N	12 N	18 N	17 N	18 N	16 N	19 N	19 N

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Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
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Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
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Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
18	Glide force	Not more than 40 N	9 N	16 N	18 N	17 N	18 N	16 N	17 N	16 N
Date of Withdrawal			Not Applicable	11/02/20	11/05/20	11/08/20	11/11/20	11/05/21	12/11/21	11/11/22
A.R. No.			FP/F-3/22/0112	SDSS200088	SDSS200335	SDSS200636	SDSS200972	SDSS210410	481966, 481967	827533, 808838
Analysis with review completion date			Not Applicable	29/02/20	02/07/20	03/09/20	11/12/20	02/06/21	10/12/21	10/12/22

Remark: [1] Absolute Alcohol.

: Analysis of Acid value test was performed at initial stage and from 18 month onwards.

Conclusion: The batch is compliant to the Specification No. C\SPC\FPS\00556-1.0 for all the test parameters analyzed and found to be stable till 36th month.

	Prepared By	Reviewed By	Reviewed By	Approved By
Sign. / Date	16/08/23	16/08/23	16/08/23	16/08/23
Department	QC	QC	QA	QA

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02	Identification									
	By HPLC	The Retention Time of the Major Peak of the Sample Solution corresponds to that of the Standard Solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
03	Container content (Volume of Injections)	The volume should be not less than 5.0 mL in each container.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
04	Water content	Not more than 2.0 %	0.8%	0.8%	0.8%	0.8%	0.8%	0.9%	0.8%	0.8%
05	Viscosity	Between 50 to 150 cps	85 cps	88 cps	87 cps	89 cps	90 cps	86 cps	85 cps	91 cps
06	Color of solution	Not more than 400 APHA	157 APHA	164 APHA	170 APHA	167 APHA	166 APHA	170 APHA	157 APHA	173 APHA
07	Acid value (Free Fatty acids) #	Not more than 0.8	0.3	0.6 mL	0.4 mL	0.5 mL	0.5 mL	0.3	0.2	0.3

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Study start date	:	11/11/19	**Storage conditions**	:	5°C ± 3°C
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Sr. No.	Test	Specification	Results							
			Initial	**3rd Month**	**6th Month**	**9th Month**	**12th Month**	**18th Month**	**24th Month**	**36th Month**
08	Particulate matter									
	Visible Particulates	Free from foreign particles	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Sub-visible particles	(By light obscuration particle count test) The average number of particles per container, ≥ 10µm: Not More Than 6000 ≥ 25µm: Not More Than 600	 803.67 97.00	 4486.00 220.33	 1684.00 38.67	 982.67 35.33	 1169.33 14.00	 2112.00 15.33	 554.00 0.00	 547.33 0.67
09	Assay of Ethanol (By GC) Label claim: Each mL contains 100 mg of Alcohol[1]	Each mL contains not less than 80.0 mg and not more than 110.0 mg of Ethanol (C_2H_5OH).	99.2 mg	95.6 mg	98.5 mg	97.2 mg	97.4 mg	98.8 mg	97.2 mg	97.2 mg
		Not less than 80.0 % w/v and not more than 110.0 % w/v of labeled amount of Ethanol (C_2H_5OH).	99.2%	95.6%	98.5%	97.2%	97.4%	98.8%	97.2%	97.2%
10	Assay of Benzyl Alcohol (By HPLC) Label claim: Each mL contains 100 mg of Benzyl Alcohol	Each mL contains not less than 90.0 mg and not more than 110.0 mg of Benzyl Alcohol.	97.6 mg	99.5 mg	98.9 mg	100.8 mg	100.3 mg	99.5 mg	98.7 mg	100.9 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Alcohol.	97.6%	99.5%	98.9%	100.8%	100.3%	99.5%	98.7%	100.9 %

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Sr. No.	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
11	Assay of Benzyl Benzoate (By HPLC) Label claim: Each mL contains 150 mg of Benzyl Benzoate	Each mL contains not less than 135.0 mg and not more than 165.0 mg of Benzyl Benzoate.	147.7 mg	150.2 mg	148.4 mg	149.6 mg	149.1 mg	148.4 mg	149.2 mg	150.1 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Benzoate.	98.5%	100.2%	98.9%	99.7%	99.4%	98.9%	99.4%	100.1%
12	Assay of Fulvestrant ($C_{32}H_{47}F_5O_3S$) (By HPLC) Label claim: Each mL contains 50 mg of Fulvestrant	Each mL contains not less than 45.0 mg and not more than 55.0 mg of Fulvestrant. ($C_{32}H_{47}F_5O_3S$)	49.7 mg	50.2 mg	49.4 mg	49.8 mg	49.6 mg	49.7 mg	49.0 mg	49.8 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Fulvestrant ($C_{32}H_{47}F_5O_3S$)	99.4%	100.3%	98.8%	99.6%	99.2%	99.4%	98.0%	99.6%
13	Related Substances (By HPLC)									
	a. Fulvestrant Sulfone	Not more than 1.0 %	0.1%	0.3%	0.3%	0.4%	0.4%	0.5%	0.5%	0.5%

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Sr. No.	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
	b. Any Unspecified Degradation product	Not more than 0.2 %	0.10%	0.11%	0.11%	0.11%	0.10%	0.11%	0.11%	0.11%
	c. Total Degradation products	Not more than 2.0%	0.4%	0.6%	0.6%	0.6%	0.6%	0.7%	0.7%	0.7%
14	Limit of Benzaldehyde	Not more than 0.2 %	0.00%	0.00%	0.01%	0.01%	0.01%	0.00%	0.01%	0.01%
15	Bacterial Endotoxin Test	Not more than 0.7 Endotoxin Units/mg of Fulvestrant	<0.3 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	<0.3456 EU/mg
16	Sterility	Should be sterile	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Sterile
17	Break loose force	Not more than 40 N	10 N	14 N	18 N	17 N	20 N	17 N	19 N	21 N

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Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No.	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
18	Glide force	Not more than 40 N	9 N	16 N	17 N	18 N	18 N	16 N	17 N	18 N
Date of Withdrawal			Not Applicable	11/02/20	11/05/20	11/08/20	11/11/20	11/05/21	12/11/21	11/11/22
A.R. No.			FP/F-3/22/0112	SDSS200089	SDSS200336	SDSS200637	SDSS200971	SDSS210411	481964, 481965	827528, 808836
Analysis with review completion date			Not Applicable	29/02/20	02/07/20	03/09/20	11/12/20	02/06/21	10/12/21	10/12/22

Remark: [1] Absolute Alcohol.

: Analysis of Acid value test was performed at initial stage and from 18 month onwards.

Conclusion: The batch is compliant to the Specification No. C\SPC\FPS\00556-1 for all the test parameters analyzed and found to be stable till 36th month.

	Prepared By	Reviewed By	Reviewed By	Approved By
Sign. / Date	16/08/23	16/08/23	16/08/23	16/08/23
Department	QC	QC	QA	QA

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
01	Description	Clear, colorless to yellow color viscous solution, free of visible particulate matters, filled in 5 mL PFS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
02	Identification									
	By HPLC	The Retention Time of the Major Peak of the Sample Solution corresponds to that of the Standard Solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
03	Container content (Volume of Injections)	The volume should be not less than 5.0 mL in each container.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
04	Water content	Not more than 2.0 %	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%
05	Viscosity	Between 50 to 150 cps	88 cps	84 cps	86 cps	90 cps	94 cps	82 cps	87 cps	85 cps
06	Color of solution	Not more than 400 APHA	165 APHA	165 APHA	166 APHA	161 APHA	180 APHA	178 APHA	171 APHA	174 APHA
07	Acid value (Free Fatty acids) #	Not more than 0.8	0.3	0.6 mL	0.5 mL	0.5 mL	0.6 mL	0.3	0.2	0.4

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
08	Particulate matter									
	Visible Particulates	Free from foreign particles	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Sub-visible particles	(By light obscuration particle count test) The average number of particles per container, ≥ 10µm: Not More Than 6000 ≥ 25µm: Not More Than 600	898.33 74.67	414.33 38.33	885.33 8.00	3402.00 42.67	449.33 6.67	1252.00 1.33	566.67 2.67	973.33 1.33
09	Assay of Ethanol (By GC) Label claim: Each mL contains 100 mg of Alcohol[1]	Each mL containes not less than 80.0 mg and not more than 110.0 mg of Ethanol (C_2H_5OH).	95.8 mg	97.3 mg	98.6 mg	97.4 mg	97.4 mg	98.4 mg	97.6 mg	97.6 mg
		Not less than 80.0 % w/v and not more than 110.0 % w/v of labeled amount of Ethanol (C_2H_5OH).	95.8 %	97.3 %	98.6 %	97.4 %	97.4 %	98.4%	97.6%	97.6%
10	Assay of Benzyl Alcohol (By HPLC)	Each mL contains not less than 90.0 mg and not more than 110.0 mg of Benzyl Alcohol.	98.1 mg	99.1 mg	99.7 mg	102.0 mg	101.8 mg	100.5 mg	98.8 mg	101.1 mg

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
	Label claim: Each mL contains 100 mg of Benzyl Alcohol	Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Alcohol.	98.1 %	99.1 %	99.7 %	102.0 %	101.8%	100.5%	98.8%	101.1%
11	Assay of Benzyl Benzoate (By HPLC) Label claim: Each mL contains 150 mg of Benzyl Benzoate	Each mL contains not less than 135.0 mg and not more than 165.0 mg of Benzyl Benzoate.	149.6 mg	149.8 mg	149.7 mg	151.9 mg	150.0 mg	148.3 mg	149.0 mg	150.4 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Benzoate.	99.7 %	99.8 %	99.8 %	101.3 %	100.0%	98.9%	99.3%	100.3%
12	Assay of Fulvestrant ($C_{32}H_{47}F_5O_3S$) By HPLC Label claim: Each mL contains 50 mg of Fulvestrant	Each mL contains not less than 45.0 mg and not more than 55.0 mg of Fulvestrant ($C_{32}H_{47}F_5O_3S$)	49.8 mg	49.7 mg	49.3 mg	49.8 mg	48.7 mg	49.2 mg	48.5 mg	49.1 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Fulvestrant ($C_{32}H_{47}F_5O_3S$)	99.6 %	99.4 %	98.5 %	99.6 %	97.5%	98.4%	97.0%	98.1%

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
13	Related Substances (By HPLC)									
	a. Fulvestrant Sulfone	Not more than 1.0 %	0.1 %	0.2%	0.3%	0.4%	0.4%	0.4%	0.4%	0.4%
	b. Any Unspecified Degradation product	Not more than 0.2 %	0.10 %	0.10%	0.11%	0.11%	0.10%	0.11%	0.10%	0.10%
	c. Total Degradation products	Not more than 2.0%	0.4 %	0.6%	0.6%	0.6%	0.6%	0.6%	0.7%	0.6%
14	Limit of Benzaldehyde	Not more than 0.2 %	0.01 %	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
15	Bacterial Endotoxin	Not more than 0.7 Endotoxin Units/mg of Fulvestrant	<0.3 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	<0.3456 EU/mg
16	Sterility	Should be sterile	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Sterile
17	Break loose force	Not more than 40 N	17 N	18 N	16 N	18 N	19 N	18 N	18 N	19 N

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
18	Glide force	Not more than 40 N	18 N	20 N	17 N	18 N	19 N	16 N	18 N	17 N
Date of Withdrawal			Not Applicable	24/02/20	22/05/20	21/08/20	21/11/20	22/05/21	23/11/21	22/11/22
A.R. No.			FP/F-3/22/0113	SDSS200097	SDSS200342	SDSS200645	SDSS200998	SDSS210438	490203, 490204	827536, 818709
Analysis with review completion date			Not Applicable	14/03/20	02/07/20	05/09/20	22/12/20	02/06/21	18/12/21	12/12/22

Remark: [1] Absolute Alcohol.

: Analysis of Acid value test was performed at initial stage and from 18 month onwards.

Conclusion: The batch is compliant to the Specification No. C\SPC\FPS\00556-1.0 for all the test parameters analyzed and found to be stable till 36th month.

	Prepared By	Reviewed By	Reviewed By	Approved By
Sign. / Date	16/08/23	16/08/23	16/08/23	16/08/23
Department	QC	QC	QA	QA

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
01	Description	Clear, colorless to yellow color viscous solution, free of visible particulate matters, filled in 5 mL PFS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
02	Identification									
	By HPLC	The Retention Time of the Major Peak of the Sample Solution corresponds to that of the Standard Solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
03	Container content (Volume of Injections)	The volume should be not less than 5.0 mL in each container.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
04	Water content	Not more than 2.0 %	0.8%	0.8%	0.8%	0.8%	0.7%	0.8%	0.8%	0.8%
05	Viscosity	Between 05 to 150 cps	88 cps	84 cps	81 cps	87 cps	84 cps	81 cps	86 cps	84 cps
06	Color of solution	Not more than 400 APHA	165 APHA	165 APHA	169 APHA	165 APHA	174 APHA	177 APHA	170 APHA	163 APHA
07	Acid value (Free Fatty acids) #	Not more than 0.8	0.3	0.5 mL	0.5 mL	0.6 mL	0.6 mL	0.3	0.2	0.3

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
08	Particulate matter									
	Visible Particulates	Free from foreign particles	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Sub-visible particles	(By light obscuration particle count test) The average number of particles per container, ≥ 10µm: Not More Than 6000 ≥ 25µm: Not More Than 600	 898.33 74.67	 619.00 21.33	 2166.67 15.33	 1297.33 4.00	 745.33 1.33	 450.67 0.67	 276.00 0.67	 657.33 1.33
09	Assay of Ethanol (By GC) Label claim: Each mL contains 100 mg of Alcohol[1]	Each mL containes not less than 80.0 mg and not more than 110.0 mg of Ethanol (C_2H_5OH).	95.8 mg	96.5 mg	97.6 mg	97.4 mg	97.4 mg	99.5 mg	97.6 mg	97.9 mg
		Not less than 80.0 % w/v and not more than 110.0 % w/v of labeled amount of Ethanol (C_2H_5OH).	95.8%	96.5%	97.6%	97.4%	97.4%	99.5%	97.6%	97.9%
10	Assay of Benzyl Alcohol (By HPLC) Label claim: Each mL contains 100 mg of Benzyl Alcohol	Each mL contains not less than 90.0 mg and not more than 110.0 mg of Benzyl Alcohol.	98.1 mg	99.0 mg	99.7 mg	102.6 mg	100.6 mg	99.6 mg	98.3 mg	100.8 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Alcohol.	98.1%	99.0 %	99.7%	102.6%	100.6%	99.6%	98.3%	100.8%

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
11	Assay of Benzyl Benzoate (By HPLC) Label claim: Each mL contains 150 mg of Benzyl Benzoate	Each mL contains not less than 135.0 mg and not more than 165.0 mg of Benzyl Benzoate.	149.6 mg	149.7 mg	149.6 mg	152.2 mg	149.2 mg	148.7 mg	148.6 mg	149.6 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Benzoate.	99.7%	99.8%	99.7%	101.5%	99.5%	99.1%	99.0%	99.8%
12	Assay of Fulvestrant ($C_{32}H_{47}F_5O_3S$) by HPLC Label claim: Each mL contains 50 mg of Fulvestrant	Each mL contains not less than 45.0 mg and not more than 55.0 mg of Fulvestrant ($C_{32}H_{47}F_5O_3S$).	49.8 mg	49.5 mg	49.2 mg	49.8 mg	48.4 mg	49.3mg	48.3mg	49.4mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Fulvestrant.($C_{32}H_{47}F_5O_3S$)	99.6%	99.0%	98.5%	99.6%	96.9%	98.5%	96.5%	98.8%
13	Related Substances (By HPLC)									
	a. Fulvestrant Sulfone	Not more than 1.0 %	0.1%	0.2%	0.3%	0.4%	0.4%	0.4%	0.4%	0.4%

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	**Test**	**Specification**	**Results**							
			Initial	**3rd Month**	**6th Month**	**9th Month**	**12th Month**	**18th Month**	**24th Month**	**36th Month**
	b. Any Unspecified Degradation product	Not more than 0.2 %	0.10%	0.10%	0.11%	0.11%	0.10%	0.11%	0.11%	0.11%
	c. Total Degradation products	Not more than 2.0%	0.4%	0.6%	0.6%	0.6%	0.6%	0.6%	0.7%	0.6%
14	Limit of Benzaldehyde	Not more than 0.2 %	0.01%	0.01%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%
15	Bacterial Endotoxin	Not more than 0.7 Endotoxin Units/mg of Fulvestrant	<0.3 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	<0.3456 EU/mg
16	Sterility	Should be sterile	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Sterile
17	Break loose force	Not more than 40 N	17 N	14 N	17 N	18 N	19 N	18 N	19 N	20 N

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190130	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	21/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171896
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	**Test**	**Specification**	**Results**							
			Initial	**3rd Month**	**6th Month**	**9th Month**	**12th Month**	**18th Month**	**24th Month**	**36th Month**
18	Glide force	Not more than 40 N	18 N	18 N	17 N	18 N	19 N	17 N	17 N	17 N
Date of Withdrawal			Not Applicable	24/02/20	22/05/20	21/08/20	21/11/20	22/05/21	23/11/21	22/11/22
A.R. No.			FP/F-3/22/0113	SDSS200098	SDSS200343	SDSS200646	SDSS200997	SDSS210439	490201, 490202	827534, 818706
Analysis with review completion date			Not Applicable	14/03/20	02/07/20	05/09/20	22/12/20	02/06/21	18/12/21	12/12/22

Remark: [1] Absolute Alcohol

: Analysis of Acid value test was performed at initial stage and from 18 month onwards.

Conclusion: The batch is compliant to the Specification No. C\SPC\FPS\00556-1.0 for all the test parameters analyzed and found to be stable till 36th month.

	Prepared By	**Reviewed By**	**Reviewed By**	**Approved By**
Sign. / Date	Deepak 16/08/23	16/08/23	16/08/23	16/08/23
Department	QC	QC	QA	QA

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
01	Description	Clear, colorless to yellow color viscous solution, free of visible particulate matters, filled in 5 mL PFS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
02	Identification									
	By HPLC	The Retention Time of the Major Peak of the Sample Solution corresponds to that of the Standard Solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
03	Container content (Volume of Injections)	The volume should be not less than 5.0 mL in each container.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
04	Water content	Not more than 2.0 %	0.8%	0.8%	0.8%	0.8%	0.9%	0.9%	0.8%	0.8%
05	Viscosity	Between 50 to 150 cps	85 cps	81 cps	85 cps	87 cps	91 cps	82 cps	85 cps	83 cps
06	Color of solution	Not more than 400 APHA	157 APHA	158 APHA	160 APHA	167 APHA	175 APHA	162 APHA	166 APHA	178 APHA
07	Acid value (Free Fatty acids) #	Not more than 0.8	0.3	0.6 mL	0.5 mL	0.6 mL	0.5mL	0.3	0.2	0.3

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
08	Particulate matter									
	Visible Particulates	Free from foreign particles	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Sub-visible particles	(By light obscuration particle count test) The average number of particles per container, ≥ 10µm: Not More Than 6000 ≥ 25µm: Not More Than 600	 4314.00 61.00	 2150.00 315.33	 618.67 19.33	 1841.33 8.00	 389.33 4.00	 448.00 4.00	 1232.67 9.33	 1176.00 3.33
09	Assay of Ethanol (By GC) Label claim: Each mL contains 100 mg of Alcohol[1]	Each mL containes not less than 80.0 mg and not more than 110.0 mg of Ethanol (C_2H_5OH).	97.5 mg	97.5 mg	97.4 mg	98.0 mg	98.0 mg	98.3 mg	97.3 mg	97.4 mg
		Not less than 80.0 % w/v and not more than 110.0 % w/v of labeled amount of Ethanol (C_2H_5OH).	97.5 %	97.5%	97.4%	98.0%	98.0%	98.3%	97.3%	97.4%
10	Assay of Benzyl Alcohol (By HPLC)	Each mL contains not less than 90.0 mg and not more than 110.0 mg of Benzyl Alcohol.	97.6 mg	100.0 mg	101.3 mg	102.6 mg	101.0 mg	99.5 mg	97.4 mg	100.2 mg

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
	Label claim: Each mL contains 100 mg of Benzyl Alcohol	Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Alcohol.	97.6 %	100.0%	101.3%	102.6%	101.0 %	99.5%	97.4%	100.2%
11	Assay of Benzyl Benzoate (By HPLC) Label claim: Each mL contains 150 mg of Benzyl Benzoate	Each mL contains not less than 135.0 mg and not more than 165.0 mg of Benzyl Benzoate.	148.7 mg	151.3 mg	151.8 mg	152.9 mg	149.8 mg	148.9 mg	147.8 mg	149.4 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Benzoate.	99.2 %	100.9%	101.2%	101.9%	99.9%	99.3%	98.5%	99.6%
12	Assay of Fulvestrant (By HPLC) Label claim: Each mL contains 50 mg of Fulvestrant	Each mL contains not less than 45.0 mg and not more than 55.0 mg of Fulvestrant. ($C_{32}H_{47}F_5O_3S$)	49.6 mg	50.4 mg	50.5mg	50.3mg	49.3 mg	49.9 mg	48.3 mg	49.5 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Fulvestrant. ($C_{32}H_{47}F_5O_3S$)	99.3 %	100.7%	101.1%	100.7%	98.5%	99.9%	96.5%	99.0%

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
13	Related Substances (By HPLC)									
	a. Fulvestrant Sulfone	Not more than 1.0 %	0.1 %	0.2%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%
	b. Any Unspecified Degradation product	Not more than 0.2 %	0.10 %	0.11%	0.11%	0.11%	0.10%	0.11%	0.11%	0.10%
	c. Total Degradation products	Not more than 2.0%	0.4 %	0.6%	0.6%	0.5%	0.6%	0.6%	0.6%	0.5%
14	Limit of Benzaldehyde	Not more than 0.2 %	0.00 %	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
15	Bacterial Endotoxin	Not more than 0.7 Endotoxin Units/mg of Fulvestrant	<0.3 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	<0.3456 EU/mg
16	Sterility	Should be sterile	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Sterile
17	Break loose force	Not More than 40 N	17 N	16 N	17 N	18 N	17 N	17 N	18 N	19 N

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop.	**Orientation**	:	Vertical
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	**Test**	**Specification**	**Results**							
			Initial	**3rd Month**	**6th Month**	**9th Month**	**12th Month**	**18th Month**	**24th Month**	**36th Month**
18	Glide force	Not More than 40 N	17 N	16 N	16 N	17 N	18 N	16 N	17 N	17 N
Date of Withdrawal			Not Applicable	25/02/20	26/05/20	25/08/20	25/11/20	25/05/21	25/11/21	25/11/22
A.R. No.			FP/F-3/22/0114	SDSS200104	SDSS200359	SDSS200664	SDSS200999	SDSS210445	491530, 491532	827541, 823038
Analysis with review completion date			Not Applicable	30/03/20	02/07/20	05/09/20	22/12/20	02/06/21	18/12/21	12/12/22

Remark: [1] Absolute Alcohol.

: Analysis of Acid value test was performed at initial stage and from 18 month onwards.

Conclusion: The batch is compliant to the Specification No. F3\SPC\FPS\00556-1.0 for all the test parameters analyzed and found to be stable till 36th month.

	Prepared By	**Reviewed By**	**Reviewed By**	**Approved By**
Sign. / Date	16/08/23	16/08/23	16/08/23	16/08/23
Department	**QC**	**QC**	**QA**	**QA**

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
01	Description	Clear, colorless to yellow color viscous solution, free of visible particulate matters, filled in 5 mL PFS	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
02	Identification									
	By HPLC	The Retention Time of the Major Peak of the Sample Solution corresponds to that of the Standard Solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
03	Container content (Volume of Injections)	The volume should be not less than 5.0 mL in each container.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
04	Water content	Not more than 2.0 %	0.8%	0.9%	0.9%	0.8%	0.8%	0.8%	0.8%	0.8%
05	Viscosity	Between 50 to 150 cps	85 cps	82 cps	83 cps	87 cps	87 cps	81 cps	86 cps	84 cps
06	Color of solution	Not more than 400 APHA	157 APHA	158 APHA	159 APHA	168 APHA	166 APHA	163 APHA	168 APHA	175 APHA

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
08	Particulate matter									
	Visible Particulates	Free from foreign particles	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Sub-visible particles	(By light obscuration particle count test) The average number of particles per container, ≥ 10µm: Not More Than 6000 ≥ 25µm: Not More Than 600	 4314.00 61.00	 1746.67 71.00	 232.67 0.67	 2744.67 96.67	 428.67 2.00	 840.67 2.67	 579.33 6.67	 747.33 8.00
09	Assay of Ethanol (By GC) Label claim: Each mL contains 100 mg of Alcohol[1]	Each mL containes not less than 80.0 mg and not more than 110.0 mg of Ethanol (C_2H_5OH).	97.5 mg	97.2 mg	97.6 mg	97.6 mg	98.0 mg	99.1 mg	97.6 mg	97.8 mg
		Not less than 80.0 % w/v and not more than 110.0 % w/v of labeled amount of Ethanol (C_2H_5OH).	97.5%	97.2%	97.6%	97.6%	98.0%	99.1%	97.6%	97.8%
10	Assay of Benzyl Alcohol (By HPLC)	Each mL contains not less than 90.0 mg and not more than 110.0 mg of Benzyl Alcohol.	97.6 mg	100.0 mg	101.3 mg	102.5 mg	100.2 mg	99.8 mg	97.7 mg	101.0 mg

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
	Label claim: Each mL contains 100 mg of Benzyl Alcohol	Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Alcohol.	97.6%	100.0%	101.3%	102.5%	100.2%	99.8%	97.7%	101.0 %
11	Assay of Benzyl Benzoate (By HPLC) Label claim: Each mL contains 150 mg of Benzyl Benzoate	Each mL contains not less than 135.0 mg and not more than 165.0 mg of Benzyl Benzoate.	148.7 mg	151.1 mg	152.2 mg	152.8 mg	149.4 mg	148.9 mg	148.4 mg	150.8 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Benzyl Benzoate.	99.2%	100.8%	101.5%	101.9%	99.6%	99.3%	99.0%	100.5%
12	Assay of Fulvestrant ($C_{32}H_{47}F_5O_3S$) By HPLC Label claim: Each mL contains 50 mg of Fulvestrant	Each mL contains not less than 45.0 mg and not more than 55.0 mg of Fulvestrant ($C_{32}H_{47}F_5O_3S$)	49.6 mg	50.2 mg	50.6 mg	50.4 mg	49.0 mg	49.6 mg	48.3 mg	49.7 mg
		Not less than 90.0 % w/w and not more than 110.0 % w/w of labeled amount of Fulvestrant ($C_{32}H_{47}F_5O_3S$)	99.3%	100.5%	101.2%	100.7%	98.1%	99.1%	96.5%	99.5%

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	Test	Specification	Results							
			Initial	3rd Month	6th Month	9th Month	12th Month	18th Month	24th Month	36th Month
13	Related Substances (By HPLC)									
	a. Fulvestrant Sulfone	Not more than 1.0 %	0.1%	0.2%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%
	b. Any Unspecified Degradation product	Not more than 0.2 %	0.10%	0.11%	0.11%	0.11%	0.10%	0.11%	0.10%	0.10%
	c. Total Degradation products	Not more than 2.0%	0.4%	0.6%	0.6%	0.5%	0.6%	0.6%	0.6%	0.5%
14	Limit of Benzaldehyde	Not more than 0.2 %	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
15	Bacterial Endotoxin	Not more than 0.7 Endotoxin Units/mg of Fulvestrant	<0.3 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	Not Applicable	<0.3456 EU/mg	<0.3456 EU/mg
16	Sterility	Should be sterile	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Not Applicable	Sterile	Sterile
17	Break loose force	Not More than 40 N	17 N	16 N	16 N	17 N	17 N	17 N	18 N	16 N

STABILITY DATA COMPILATION SHEET
(Long term Stability Condition)

Product Name	:	Fulvestrant Injection, 250 mg/5mL (50mg/mL)			
Label claim	:	Each mL contains 50 mg of Fulvestrant	**Batch Size**	:	4798 Units
Batch Number	:	7190131	**Exp. Date**	:	OCT. 2021
Mfg. Date	:	NOV. 2019	**Shelf Life**	:	24 Months (Tentative)
Stability Pack	:	2 PFS X 5 mL	**Reason**	:	Submission Batch
Market	:	LATAM	**Ref. Protocol No.**	:	F3\SP\000179-1.0
Study start date	:	25/11/19	**Storage conditions**	:	5°C ± 3°C
Name of API Manufacturer	:	Industriale Chimica SRL Via E.H. Grieg 13- Saronno (VA) Italy	**B. No. of API**	:	PR171987
Packaging	:	5 mL, Clear, USP Type I, Luer Lock prefilled, single dose syringe with tamper evident closure sealed with bromobutyl, flurotec coated plunger stopper with Natural, polypropylene plunger rod and back stop	**Orientation**	:	Horizontal
Mfg. Site	:	Alembic Pharmaceuticals Limited, Formulation Division III, Plot No. 779/P and 790/P, Village - Karakhadi, Taluka - Padra, Vadodara – 391 450, Gujarat, India.			

Sr. No	**Test**	**Specification**	**Results**							
			Initial	**3rd Month**	**6th Month**	**9th Month**	**12th Month**	**18th Month**	**24th Month**	**36th Month**
18	Glide force	Not More than 40 N	17 N	16 N	16 N	17 N	18 N	16 N	17 N	15 N
Date of Withdrawal			Not Applicable	25/02/20	26/05/20	25/08/20	25/11/20	25/05/21	25/11/21	25/11/22
A.R. No.			FP/F-3/22/0114	SDSS200105	SDSS200358	SDSS200665	SDSS201000	SDSS210446	491527, 491529	827540, 822935
Analysis with review completion date			Not Applicable	14/03/20	02/07/20	05/09/20	22/12/20	02/06/21	18/12/21	12/12/22

Remark: [1] Absolute Alcohol.

: Analysis of Acid value test was performed at initial stage and from 18 month onwards.

Conclusion: The batch is compliant to the Specification No. F3\SPC\FPS\00556-1.0 for all the test parameters analyzed and found to be stable till 36th month.

	Prepared By	**Reviewed By**	**Reviewed By**	**Approved By**
Sign. / Date	16/08/23	16/08/23	16/08/23	16/08/23
Department	**QC**	**QC**	**QA**	**QA**