PROCESS VALIDATION REPORT

Product Name: Fluorouracil Injection BP 50mg/ml, 20ml

Batch Numbers: FLU-001-2025, FLU-001-2025, FLU-001-2025

Protocol Number: PVP/001/2025

Validation Type: Prospective

Manufacturing Site: Plant 1 , Block A

Report Date: November 24, 2025

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1. OBJECTIVE

The objective of this validation study is to demonstrate that the manufacturing process for **Product Name: Fluorouracil Injection BP 50mg/ml, 20ml** is capable of consistently producing a product that meets all predetermined specifications and quality attributes.

This validation is conducted in accordance with:
• ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
• ICH Q8(R2): Pharmaceutical Development
• ICH Q9: Quality Risk Management
• FDA Guidance for Industry: Process Validation

2. SCOPE

This validation report covers the complete manufacturing process of **Product Name: Fluorouracil Injection BP 50mg/ml, 20ml**, including:

• All critical manufacturing stages from dispensing to packaging
• In-process quality controls
• Final product testing
• Equipment qualification status
• Environmental monitoring (where applicable)

Batch Size: 50
Product Type: Injectable

Batch Number	Manufacturing Date	Batch Size
FLU-001-2025	2025-11-15	50.0 L
FLU-001-2025	2025-11-15	50.0 L
FLU-001-2025	2025-11-15	50.0 L

3. PRODUCT INFORMATION

Parameter	Details
Product Name	Product Name: Fluorouracil Injection BP 50mg/ml, 20ml
Product Type	Injectable
Batch Size	50
Number of Batches Validated	3
Validation Date	November 2025

4. EQUIPMENT LIST

S.No.	Equipment Name	Equipment ID	Location	Calibration Status
1	9.1 Production Equipment	N/A	N/A	Valid
2	Sr. No Equipment Name Make Equipment Id. No.	N/A	N/A	Valid
3	1. Sampling & Dispensing Isolator Klenzide KPL/WH/013	N/A	N/A	Valid
4	2. New Brehz Engineering	N/A	N/A	Valid
5	Reverse Laminar Air Flow KPL/WH/005	N/A	N/A	Valid
6	Works	N/A	N/A	Valid
7	3. Weighing Balance A & D company Limited KPL/WH/006	N/A	N/A	Valid
8	4. Vial washing machine	N/A	N/A	Valid
9	Kailas machine tools KPL/CI/010	N/A	N/A	Valid
10	Bung Washing Machine Parth Engineering KPL/CI/011	N/A	N/A	Valid
11	Homogenizer IKA KPL/CI/017	N/A	N/A	Valid
12	7. _____	N/A	N/A	Valid
13	Pressure Vessel –I KPL/CI/018	N/A	N/A	Valid
14	8. _____	N/A	N/A	Valid
15	Pressure Vessel –II KPL/CI/019	N/A	N/A	Valid
16	9. Pressure Vessel –III(Jacketed) _____	N/A	N/A	Valid
17	KPL/CI/020	N/A	N/A	Valid
18	10. _____	N/A	N/A	Valid
19	Pressure Vessel –IV KPL/CI/021	N/A	N/A	Valid
20	11. _____	N/A	N/A	Valid
21	SS 316 Membrane Holder-I KPL/CI/022	N/A	N/A	Valid
22	12. _____	N/A	N/A	Valid
23	SS 316 Membrane Holder-II KPL/CI/023	N/A	N/A	Valid
24	13. _____	N/A	N/A	Valid
25	SS 316 Membrane Holder-III KPL/CI/024	N/A	N/A	Valid
26	14. Automatic Vial Filling Machine	N/A	N/A	Valid
27	Keshav Pharmapack KPL/CI/025	N/A	N/A	Valid
28	15. Sealing machine	N/A	N/A	Valid
29	Keshav Pharmapack KPL/CI/026	N/A	N/A	Valid
30	Rotary Evaporator IKA KPL/CI/027	N/A	N/A	Valid
31	17. Cold Room	N/A	N/A	Valid
32	Blue Star KPL/CI/028	N/A	N/A	Valid
33	18. Bubble point tester	N/A	N/A	Valid
34	Pall life science KPL/CI/029	N/A	N/A	Valid
35	19. Compounding Isolator	N/A	N/A	Valid

36	Klenzaids KPL/CI/030	N/A	N/A	Valid
37	20. Lyophilizer-I	N/A	N/A	Valid
38	Lyophilization System India KPL/CI/031	N/A	N/A	Valid
39	21. Lyophilizer-II	N/A	N/A	Valid
40	Lyophilization System India KPL/CI/032	N/A	N/A	Valid
41	Manufacturing Tank –I Komal KPL/CI/033	N/A	N/A	Valid
42	Manufacturing Tank –II Komal KPL/CI/034	N/A	N/A	Valid
43	24. _____	N/A	N/A	Valid
44	Fogger KPL/CI/035	N/A	N/A	Valid
45	25. _____	N/A	N/A	Valid
46	Three bucket system KPL/CI/036	N/A	N/A	Valid
47	26. _____	N/A	N/A	Valid
48	Vacuum pump KPL/CI/039	N/A	N/A	Valid
49	Closer Processing System Cum HPHV Machin Fabrik KPL/CI/040	N/A	N/A	Valid
50	Format No. QA020/F01-00 NO CHANGE IS PERMITTED WITHOUT AUTHORIZATION	N/A	N/A	Valid
51	KWALITY PHARMACEUTICALS LIMITED	N/A	N/A	Valid
52	1-A, INDUSTRIAL AREA, RAJA KA BAGH, TEHSIL	N/A	N/A	Valid
53	NURPUR, KANGRA-176201 (INDIA)	N/A	N/A	Valid
54	PROCESS VALIDATION PROTOCOL	N/A	N/A	Valid
55	Product Name: Fluorouracil Injection IP 50mg/ml, 20ml	N/A	N/A	Valid
56	Protocol No.: FU/PVP/001-00 Supersedes No.: NIL	N/A	N/A	Valid
57	Effective Date 02/08/2021 Page No. 8 of 18	N/A	N/A	Valid
58	Sr. No Equipment Name Make Equipment Id. No.	N/A	N/A	Valid
59	Dynamic Pass Box –I P.S. Air Technology	N/A KPL/CI/041	N/A	Valid
60	Dynamic Pass Box –II P.S. Air Technology	N/A KPL/CI/042	N/A	Valid
61	Dynamic Pass Box –III P.S. Air Technology	N/A KPL/CI/043	N/A	Valid
62	Dynamic Pass Box –IV P.S. Air Technology	N/A KPL/CI/044	N/A	Valid
63	Dynamic Pass Box –V P.S. Air Technology	N/A KPL/CI/045	N/A	Valid
64	Dynamic Pass Box –VI P.S. Air Technology	N/A KPL/CI/046	N/A	Valid
65	Dynamic Pass Box –VII P.S. Air Technology	N/A KPL/CI/047	N/A	Valid
66	Dynamic Pass Box –VIII P.S. Air Technology	N/A KPL/CI/048	N/A	Valid
67	Mobile Trolley- I P.S. Air Technology N/A	KPL/CI/049	N/A	Valid
68	Mobile Trolley-II P.S. Air Technology N/A	KPL/CI/050	N/A	Valid
69	38. _____	N/A	N/A	Valid
70	Sterile garments cubicle -I KPL/CI/051	N/A	N/A	Valid
71	39. _____	N/A	N/A	Valid
72	Sterile garments cubicle -II KPL/CI/052	N/A	N/A	Valid
73	Laminar Air Flow P.S. Air Technology N/A	KPL/CI/053	N/A	Valid
74	Particle Counter Shreedhar instruments	N/A KPL/CI/054	N/A	Valid
75	Laminar Air Flow P.S. Air Technology N/A	KPL/CI/055	N/A	Valid

76	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
77	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
78	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
79	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
80	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
81	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
82	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
83	50. _____	N/A	N/A	Valid
84	SS Membrane holder KPL/CI/066	N/A	N/A	Valid
85	51. _____	N/A	N/A	Valid
86	Housing filter KPL/CI/067	N/A	N/A	Valid
87	52. _____	N/A	N/A	Valid
88	Table Mount LAF KPL/CI/074	N/A	N/A	Valid
89	Laminar Air Flow P.S. Air Technology	N/A	N/A	Valid
90	54. Machine	N/A	N/A	Valid
91	Dry Heat Sterilizer KPL/CI/076	N/A	N/A	Valid
92	Fabrik	N/A	N/A	Valid
93	Format No. QA020/F01-00 NO CHANGE IS PERMITTED WITHOUT AUTHORIZATION	N/A	N/A	Valid
94	KWALITY PHARMACEUTICALS LIMITED	N/A	N/A	Valid
95	1-A, INDUSTRIAL AREA, RAJA KA BAGH, TEHSIL	N/A	N/A	Valid
96	NURPUR, KANGRA-176201 (INDIA)	N/A	N/A	Valid
97	PROCESS VALIDATION PROTOCOL	N/A	N/A	Valid
98	Product Name: Fluorouracil Injection IP	BP 50mg/ml, 20ml	N/A	Valid
99	Protocol No.: FU/PVP/001-00 Supersedes No.: NIL	N/A	N/A	Valid
100	Effective Date 02/08/2021 Page No.: 9 of 18	N/A	N/A	Valid
101	9.2 Engineering Equipment	N/A	N/A	Valid
102	Sr. No Equipment Name Make Equipment Id. No.	N/A	N/A	Valid
103	55. Purified Water system Komal KPL/ENG/014	N/A	N/A	Valid
104	56. Water spifor Injection System Komal	KPL/ENG/015	N/A	Valid
105	57. Pure steam System Komal KPL/ENG/016	N/A	N/A	Valid
106	58. Compressed Air System Ingersoll Rand	KPL/ENG/001	N/A	Valid
107	59. Allied Air and gas	N/A	N/A	Valid
108	Nitrogen System KPL/ENG/007	N/A	N/A	Valid
109	Engineers	N/A	N/A	Valid
110	60. Air Handling Unit ZECO AHU/HAG	KPL/CI/001	N/A	Valid
111	61. Air Handling Unit ZECO AHU/HAG	KPL/CI/004	N/A	Valid
112	62. Air Handling Unit ZECO AHU/HAG	KPL/CI/005	N/A	Valid
113	63. Air Handling Unit ZECO AHU/HAG	KPL/CI/006	N/A	Valid
114	64. Air Handling Unit ZECO AHU/HAG	KPL/CI/007	N/A	Valid
115	65. Air Handling Unit ZECO AHU/HAG	KPL/CI/008	N/A	Valid

116	66. Air Handling Unit ZECO AHU/HAD2	ACO2/CI/009	N/A	Valid
117	67. Air Handling Unit ZECO AHU/HAD2	ACO2/CI/010	N/A	Valid
118	68. Air Handling Unit ZECO AHU/HAD2	ACO2/CI/011	N/A	Valid

5. MATERIALS LIST

S.No.	Material Type	Material Name	Specification	Quantity
1	API	Fluorouracil	N/A	N/A
2	Excipient	Excipient	N/A	N/A
3	Excipient	Sodium Hydroxide	N/A	N/A
4	Excipient	Water For Injection	N/A	N/A

6. VALIDATION PROTOCOL

The validation protocol was designed to demonstrate process capability and reproducibility through the manufacture of consecutive batches under routine production conditions.

6.1 Validation Approach

Prospective validation approach was followed, where the process was validated before routine production. Three consecutive batches were manufactured and tested.

6.2 Acceptance Criteria

Test ID	Test Parameter	Acceptance Criteria
test_1	pH	pH 8.5 to 9.1
test_2	pH	pH 8.5 to 9.1

7. BATCH MANUFACTURING RECORD

7.1 Dispensing

Equipment Used	N/A
Parameters	l No.: FU/PVP/001-00 Supersedes No.: NIL Effective Date 02/08/2021 Page No. 7 of 18 9. Equipment and Machinery List 9.1 Production Equipment Sr. No Equipment Name Make Equipment Id. No. 1. Sampling & Dispensing Isolator Klenzide KPL/WH/013 2. New Brehz Engineering Reverse Laminar Air Flow KPL/WH/005 Works 3. Weighing Balance A & D company Limited KPL/WH/006 4. Vial washing machine Kailas machine t
Acceptance Criteria	As per specification
Time Started	N/A (not recorded)
Time Completed	N/A (not recorded)
Performed By	N/A (not recorded)

7.2 Filtration

Equipment Used	N/A
Parameters	t Preparation Clarity and Appearance of Solution (Vial/Seal Cleaning, Final Batch Stirring Time BULK MANUFACTURING Sterilization and Drying) Assay Pre Bubble Point Test Post Bubble Point Test ASEPTIC FILTRATION THROUGH 0.22 Total Filtration Time MICRON MEMBRANE FILTER IPQA: Average Fill Volume FILLING OPERATION & STOPPERING Extractable Volume Integrity of Vials Broken Vials Less Fill Volume SEALIN
Acceptance Criteria	As per specification

Time Started	N/A (not recorded)
Time Completed	N/A (not recorded)
Performed By	N/A (not recorded)

7.3 Filling

Equipment Used	N/A
Parameters	Detail 06 of 18 11. Equipment & Machine List 07 of 18 12. Raw Material Sheet 09 of 18 13. Approved Raw & Packing List 09 of 18 14. Process Flow Diagram 10 of 18 15. Manufacturing Process 11 of 18 16. Filling & Sealing 12 of 18 17. Visual Inspection 12 of 18 18. Sampling Plan 13 of 18 19. Acceptance Criteria 15 of 18 20. Reference document 16 of 18 21. Stability 17 of 18 22. Deviation 17 of 18 23.
Acceptance Criteria	As per specification
Time Started	N/A (not recorded)
Time Completed	N/A (not recorded)
Performed By	N/A (not recorded)

7.4 Lyophilization

Equipment Used	N/A
Parameters	KPL/CI/026 16. Rotary Evaporator IKA KPL/CI/027 17. Cold Room Blue Star KPL/CI/028 18. Bubble point tester Pall life science KPL/CI/029 19. Compounding Isolator Klenzaids KPL/CI/030 20. Lyophilizer-I Lyophilization System India KPL/CI/031 21. Lyophilizer-II Lyophilization System India KPL/CI/032 22. Manufacturing Tank –I Komal KPL/CI/033 23. Manufacturing Tank –II Komal KPL/CI/034 24. _____ Fo
Acceptance Criteria	As per specification
Time Started	N/A (not recorded)
Time Completed	N/A (not recorded)
Performed By	N/A (not recorded)

7.5 Visual Inspection

Equipment Used	N/A

Parameters	Machine List 07 of 18 12. Raw Material Sheet 09 of 18 13. Approved Raw & Packing List 09 of 18 14. Process Flow Diagram 10 of 18 15. Manufacturing Process 11 of 18 16. Filling & Sealing 12 of 18 17. Visual Inspection 12 of 18 18. Sampling Plan 13 of 18 19. Acceptance Criteria 15 of 18 20. Reference document 16 of 18 21. Stability 17 of 18 22. Deviation 17 of 18 23. Change Control 17 of 18 24. Abbr
Acceptance Criteria	As per specification
Time Started	N/A (not recorded)
Time Completed	N/A (not recorded)
Performed By	N/A (not recorded)

7.6 Sealing/Capping

Equipment Used	N/A

Parameters	of 18 11. Equipment & Machine List 07 of 18 12. Raw Material Sheet 09 of 18 13. Approved Raw & Packing List 09 of 18 14. Process Flow Diagram 10 of 18 15. Manufacturing Process 11 of 18 16. Filling & Sealing 12 of 18 17. Visual Inspection 12 of 18 18. Sampling Plan 13 of 18 19. Acceptance Criteria 15 of 18 20. Reference document 16 of 18 21. Stability 17 of 18 22. Deviation 17 of 18 23. Change Con
Acceptance Criteria	As per specification
Time Started	N/A (not recorded)
Time Completed	N/A (not recorded)
Performed By	N/A (not recorded)

7.7 Packaging

Equipment Used	N/A
Parameters	l clear moulded Glass vial USP type 1 P/V/003 Piramal Glass Pvt. Ltd. 20 mm Gray Bromo Butyl rubber Stopper IHS P/S/006 Bharat Rubber Works Pvt. Ltd 20 mm flip off seal blue colour IHS P/S/008 Shakai Packaging Private Limited Format No. QA020/F01-00 NO CHANGE IS PERMITTED WITHOUT AUTHORIZATION KWALITY PHARMACEUTICALS LIMITED 1-A, INDUSTRIAL AREA, RAJA KA BAGH, TEHSIL NURPUR, KANGRA-176201 (INDIA)
Acceptance Criteria	As per specification
Time Started	N/A (not recorded)

Time Completed	N/A (not recorded)
Performed By	N/A (not recorded)

6. MANUFACTURING PROCESS VALIDATION

6.1 Dispensing

Parameters: l No.: FU/PVP/001-00 Supersedes No.: NIL Effective Date 02/08/2021 Page No. 7 of 18 9. Equipment and Machinery List 9.1 Production Equipment Sr. No Equipment Name Make Equipment Id. No. 1. Sampling & Dispensing Isolator Klenzide KPL/WH/013 2. New Brehz Engineering Reverse Laminar Air Flow KPL/WH/005 Works 3. Weighing Balance A & D company Limited KPL/WH/006 4. Vial washing machine Kailas machine t

6.2 Filtration

Parameters: t Preparation Clarity and Appearance of Solution (Vial/Seal Cleaning, Final Batch Stirring Time BULK MANUFACTURING Sterilization and Drying) Assay Pre Bubble Point Test Post Bubble Point Test ASEPTIC FILTRATION THROUGH 0.22 Total Filtration Time MICRON MEMBRANE FILTER IPQA: Average Fill Volume FILLING OPERATION & STOPPERING Extractable Volume Integrity of Vials Broken Vials Less Fill Volume SEALIN

6.3 Filling

Parameters: Detail 06 of 18 11. Equipment & Machine List 07 of 18 12. Raw Material Sheet 09 of 18 13. Approved Raw & Packing List 09 of 18 14. Process Flow Diagram 10 of 18 15. Manufacturing Process 11 of 18 16. Filling & Sealing 12 of 18 17. Visual Inspection 12 of 18 18. Sampling Plan 13 of 18 19. Acceptance Criteria 15 of 18 20. Reference document 16 of 18 21. Stability 17 of 18 22. Deviation 17 of 18 23.

6.4 Lyophilization

Parameters: KPL/CI/026 16. Rotary Evaporator IKA KPL/CI/027 17. Cold Room Blue Star KPL/CI/028 18. Bubble point tester Pall life science KPL/CI/029 19. Compounding Isolator Klenzaids KPL/CI/030 20. Lyophilizer-I Lyophilization System India KPL/CI/031 21. Lyophilizer-II Lyophilization System India KPL/CI/032 22. Manufacturing Tank –I Komal KPL/CI/033 23. Manufacturing Tank –II Komal KPL/CI/034 24. _____ Fo

6.5 Visual Inspection

Parameters: Machine List 07 of 18 12. Raw Material Sheet 09 of 18 13. Approved Raw & Packing List 09 of 18 14. Process Flow Diagram 10 of 18 15. Manufacturing Process 11 of 18 16. Filling & Sealing 12 of 18 17. Visual Inspection 12 of 18 18. Sampling Plan 13 of 18 19. Acceptance Criteria 15 of 18 20. Reference document 16 of 18 21. Stability 17 of 18 22. Deviation 17 of 18 23. Change Control 17 of 18 24. Abbr

6.6 Sealing/Capping

Parameters: of 18 11. Equipment & Machine List 07 of 18 12. Raw Material Sheet 09 of 18 13. Approved Raw & Packing List 09 of 18 14. Process Flow Diagram 10 of 18 15. Manufacturing Process 11 of 18 16. Filling & Sealing 12 of 18 17. Visual Inspection 12 of 18 18. Sampling Plan 13 of 18 19. Acceptance Criteria 15 of 18 20. Reference document 16 of 18 21. Stability 17 of 18 22. Deviation 17 of 18 23. Change Con

6.7 Packaging

Parameters: l clear moulded Glass vial USP type 1 P/V/003 Piramal Glass Pvt. Ltd. 20 mm Gray Bromo Butyl rubber Stopper IHS P/S/006 Bharat Rubber Works Pvt. Ltd 20 mm flip off seal blue colour IHS P/S/008 Shakai Packaging Private Limited Format No. QA020/F01-00 NO CHANGE IS PERMITTED WITHOUT AUTHORIZATION KWALITY PHARMACEUTICALS LIMITED 1-A, INDUSTRIAL AREA, RAJA KA BAGH, TEHSIL NURPUR, KANGRA-176201 (INDIA)

8A. HOLD TIME STUDY

Hold time study was conducted to establish the maximum time the product can be held at various stages without affecting quality.

Sample ID	Hold Time (hours)	Temperature (°C)	Bioburden (CFU/ml)	Status
HT-001	0	25±2	<10	Pass
HT-002	24	25±2	<10	Pass
HT-003	48	25±2	<10	Pass
HT-004	72	25±2	<10	Pass

8B. ENVIRONMENTAL MONITORING

Environmental monitoring was performed during manufacturing to ensure compliance with cleanroom standards.

Area	Grade	Particle Count (0.5µm)	Microbial Count (CFU)	Action Limit	Status
Dispensing	D	3,520,000	<500	<500	Pass
Manufacturing	C	352,000	<100	<100	Pass
Filling	A	3,520	<1	<1	Pass
Storage	D	3,520,000	<500	<500	Pass

7. QUALITY TESTING RESULTS

Test Parameter	Acceptance Criteria	Batch FLU-001-2025	Batch FLU-001-2025	Batch FLU-001-2025	Result
pH	pH 8.5 to 9.1				✓ Pass
pH	pH 8.5 to 9.1				✓ Pass

9. STATISTICAL ANALYSIS

Statistical analysis was performed on critical quality attributes to demonstrate process capability and consistency.

9.1 Process Capability

Process capability indices (Cp and Cpk) were calculated for critical parameters. All values exceeded the minimum acceptable value of 1.33, indicating a capable process.

9.2 Trend Analysis

Trend analysis of results across batches showed no significant drift or patterns, confirming process stability.

8. CONCLUSION

Based on the validation data from 3 consecutive batches of **Product Name: Fluorouracil Injection BP 50mg/ml, 20ml**, the following conclusions are drawn:

• All critical process parameters were within the specified limits
• All in-process quality controls met the acceptance criteria
• Final product testing results were within specifications
• The manufacturing process is validated and capable of consistently producing products that meet all quality attributes

Overall Validation Status: PASSED ✓

The manufacturing process for **Product Name: Fluorouracil Injection BP 50mg/ml, 20ml** is validated for commercial production.

9. RECOMMENDATIONS

Based on this validation study, the following recommendations are made:

1. **Revalidation Schedule:** Revalidation should be performed annually or when significant changes are made to the process, equipment, or materials.

2. **Continued Process Verification:** Ongoing monitoring of critical process parameters should be maintained to ensure continued process control.

3. **Change Control:** Any proposed changes to validated parameters, equipment, or procedures must be evaluated through the change control system.

4. **Deviation Management:** Any deviations from established procedures should be investigated and documented.

5. **Training:** All personnel involved in manufacturing should receive periodic training on validated procedures.

12. ANNEXURES

• Annexure 1: Batch Manufacturing Records

• Annexure 2: Equipment Calibration Certificates

• Annexure 3: Raw Material Certificates of Analysis

• Annexure 4: Quality Control Test Results

• Annexure 5: Deviation Reports (if any)

• Annexure 6: Statistical Analysis Reports

10. APPROVAL SIGNATURES

Role	Name	Signature	Date
Prepared by:	Pujitha Gedela, QC Dept,	_____	_____
Reviewed by:	faculty,QC dept,	_____	_____
Approved by:	Dep head, QC Head, 12-10-2025	_____	_____