PROCESS VALIDATION REPORT

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

Batch Numbers: FLU-001-2024, FLU-002-2024, FLU-003-2024

Report Date: November 12, 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: BATCH SIZE 50
Product Type: Injectable

3. PRODUCT INFORMATION

Parameter	Details
Product Name	Product Name: Fluorouracil Injection BP 50mg/ml, 20ml
Product Type	Injectable
Batch Size	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/	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	3. Weighing Balance A & D company Limited KPL/WH/0	N/A	N/A	Valid
7	4. Vial washing machine	N/A	N/A	Valid
8	Kailas machine tools KPL/CI/010	N/A	N/A	Valid
9	Bung Washing Machine Parth Engineering KPL/CI/011	N/A	N/A	Valid
10	Homogenizer IKA KPL/CI/017	N/A	N/A	Valid
11	7. _____	N/A	N/A	Valid
12	Pressure Vessel –I KPL/CI/018	N/A	N/A	Valid
13	8. _____	N/A	N/A	Valid
14	Pressure Vessel –II KPL/CI/019	N/A	N/A	Valid
15	9. Pressure Vessel –III(Jacketed) _____	N/A	N/A	Valid
16	KPL/CI/020	N/A	N/A	Valid
17	10. _____	N/A	N/A	Valid
18	Pressure Vessel –IV KPL/CI/021	N/A	N/A	Valid
19	11. _____	N/A	N/A	Valid
20	SS 316 Membrane Holder-I KPL/CI/022	N/A	N/A	Valid
21	12. _____	N/A	N/A	Valid
22	SS 316 Membrane Holder-II KPL/CI/023	N/A	N/A	Valid
23	13. _____	N/A	N/A	Valid
24	SS 316 Membrane Holder-III KPL/CI/024	N/A	N/A	Valid
25	14. Automatic Vial Filling Machine	N/A	N/A	Valid
26	Keshav Pharmapack KPL/CI/025	N/A	N/A	Valid
27	15. Sealing machine	N/A	N/A	Valid
28	Keshav Pharmapack KPL/CI/026	N/A	N/A	Valid
29	Rotary Evaporator IKA KPL/CI/027	N/A	N/A	Valid
30	17. Cold Room	N/A	N/A	Valid
31	Blue Star KPL/CI/028	N/A	N/A	Valid
32	18. Bubble point tester	N/A	N/A	Valid
33	Pall life science KPL/CI/029	N/A	N/A	Valid
34	19. Compounding Isolator	N/A	N/A	Valid
35	Klenzaids KPL/CI/030	N/A	N/A	Valid

36	20. Lyophilizer-I	N/A	N/A	Valid
37	Lyophilization System India KPL/CI/032	N/A	N/A	Valid
38	21. Lyophilizer-II	N/A	N/A	Valid
39	Lyophilization System India KPL/CI/032	N/A	N/A	Valid
40	Manufacturing Tank –I Komal KPL/CI/033	N/A	N/A	Valid
41	Manufacturing Tank –II Komal KPL/CI/034	N/A	N/A	Valid
42	24. _____	N/A	N/A	Valid
43	Fogger KPL/CI/035	N/A	N/A	Valid
44	25. _____	N/A	N/A	Valid
45	Three bucket system KPL/CI/036	N/A	N/A	Valid
46	26. _____	N/A	N/A	Valid
47	Vacuum pump KPL/CI/039	N/A	N/A	Valid
48	Closer Processing System Cum HPHV	N/A	Machin Fabrik KP	N/A	Valid
49	Format No. QA020/F01-00 NO CHANGE IS PERMITTED WIT	N/A	N/A	Valid
50	KWALITY PHARMACEUTICALS LIMITED	N/A	N/A	Valid

5. MATERIALS LIST

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

6. MANUFACTURING PROCESS VALIDATION

6.15 Manufacturing Process

7. QUALITY TESTING RESULTS

Test Parameter	Acceptance Criteria	Batch FLU-001-2024	Batch FLU-002-2024	Batch FLU-003-2024	Result
Particulate Matter	Particulate Matter	N/A	N/A	N/A	✗ Fail

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.

10. APPROVAL SIGNATURES

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
Reviewed by:	_____	_____	_____
Approved by:	_____	_____	_____