KWALITY PHARMACEUTICALS LIMITED

1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Kangra-176201 (India)

PROCESS VALIDATION REPORT

Product Name:
Fluorouracil Injection BP

Strength: 50mg/ml, 20ml

Report No: FU/PVR/001-00

Batch Size: 50.0 Litres (2500 vials)

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1. OBJECTIVE

The purpose of this report is to provide the documented evidence for the batch manufacturing process of Fluorouracil Injection BP that was manufactured at the facility. This validation summary report provides an overview of the entire validation process and documents the process results and process parameters obtained during the manufacturing of three batches.

2. SCOPE

This report is applicable for three consecutive batches manufactured with specific batch size (50.0 Litres (2500 vials)) and equipment for Fluorouracil Injection BP.

3. RESPONSIBILITY

3.1 QA Personnel: Responsible for preparation and approval of process validation summary report and review of data compiled.

3.2 Production Personnel: Responsible for review of process validation summary report.

3.3 Quality Control Personnel: Responsible for review of process validation summary report and compiled data.

4. PRODUCT & BATCH DETAILS

Product/Generic Name	Fluorouracil Injection BP
Strength	50mg/ml, 20ml
Report Number	FU/PVR/001-00
Batch Size	50.0 Litres (2500 vials)
Dosage Form	Liquid Injection
Storage Conditions	Store at temperature below 25°C

Batch Details for Validation:

Sr. No	Batch No	Batch Size	Mfg. Date	Exp. Date
1	OI0330	50.0 Litres (2500 vials)	10/2025	07/2029
2	OI0331	50.0 Litres (2500 vials)	10/2025	07/2029
3	OI0332	50.0 Litres (2500 vials)	10/2025	07/2029

5. EQUIPMENT & MACHINERY LIST

Sr. No	Equipment Name	Make	Equipment ID
1	Sampling & Dispensing Isolator	Klenzide	KPL/WH/013
2	Reverse Laminar Air Flow	New Brehz Engineering Works	KPL/WH/005
3	Weighing Balance	A & D company Limited	KPL/WH/006
4	Vial washing machine	Kailas machine tools	KPL/CI/010
5	Bung Washing Machine	Parth Engineering	KPL/CI/011
6	Homogenizer	IKA	KPL/CI/017
7	Pressure Vessel –I	-	KPL/CI/018
8	Pressure Vessel –II	-	KPL/CI/019
9	Pressure Vessel –III(Jacketed)	-	KPL/CI/020
10	Pressure Vessel –IV	-	KPL/CI/021
11	SS 316 Membrane Holder-I	-	KPL/CI/022
12	SS 316 Membrane Holder-II	-	KPL/CI/023
13	SS 316 Membrane Holder-III	-	KPL/CI/024
14	Automatic Vial Filling Machine	Keshav Pharmapack	KPL/CI/025
15	Sealing machine	Keshav Pharmapack	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	Fogger	-	KPL/CI/035
25	Three bucket system	-	KPL/CI/036

Sr. No	Equipment Name	Make	Equipment ID
26	Vacuum pump	-	KPL/CI/039
27	Closer Processing System Cum HPHV	Machin Fabrik	KPL/CI/040
28	Dynamic Pass Box –I	P.S. Air Technology	KPL/CI/041
29	Dynamic Pass Box –II	P.S. Air Technology	KPL/CI/042
30	Dynamic Pass Box –III	P.S. Air Technology	KPL/CI/043
31	Dynamic Pass Box –IV	P.S. Air Technology	KPL/CI/044
32	Dynamic Pass Box –V	P.S. Air Technology	KPL/CI/045
33	Dynamic Pass Box –VI	P.S. Air Technology	KPL/CI/046
34	Dynamic Pass Box –VII	P.S. Air Technology	KPL/CI/047
35	Dynamic Pass Box –VIII	P.S. Air Technology	KPL/CI/048
36	Mobile Trolley- I	P.S. Air Technology	KPL/CI/049
37	Mobile Trolley-II	P.S. Air Technology	KPL/CI/050
38	Sterile garments cubicle -I	-	KPL/CI/051
39	Sterile garments cubicle -II	-	KPL/CI/052
40	Laminar Air Flow	P.S. Air Technology	KPL/CI/053
41	Particle Counter	Shreedhar instruments	KPL/CI/054
42	Laminar Air Flow	P.S. Air Technology	KPL/CI/055
43	Laminar Air Flow	P.S. Air Technology	KPL/CI/056
44	Laminar Air Flow	P.S. Air Technology	KPL/CI/057
45	Laminar Air Flow	P.S. Air Technology	KPL/CI/058
46	Laminar Air Flow	P.S. Air Technology	KPL/CI/059
47	Laminar Air Flow	P.S. Air Technology	KPL/CI/060
48	Laminar Air Flow	P.S. Air Technology	KPL/CI/061
49	Laminar Air Flow	P.S. Air Technology	KPL/CI/062
50	SS Membrane holder	-	KPL/CI/066

Sr. No	Equipment Name	Make	Equipment ID
51	Housing filter	-	KPL/CI/067
52	Table Mount LAF	-	KPL/CI/074
53	Laminar Air Flow	P.S. Air Technology	KPL/CI/075
54	Dry Heat Sterilizer	Machine Fabrik	KPL/CI/076
55	Purified Water system	Komal	KPL/ENG/014
56	Water for Injection System	Komal	KPL/ENG/015
57	Pure steam System	Komal	KPL/ENG/016
58	Compressed Air System	Ingersoll Rand	KPL/ENG/001
59	Nitrogen System	Allied Air and gas Engineers	KPL/ENG/007
60	Air Handling Unit	ZECO	AHU/HAC02/CI/001
61	Air Handling Unit	ZECO	AHU/HAC02/CI/004
62	Air Handling Unit	ZECO	AHU/HAC02/CI/005
63	Air Handling Unit	ZECO	AHU/HAC02/CI/006
64	Air Handling Unit	ZECO	AHU/HAC02/CI/007
65	Air Handling Unit	ZECO	AHU/HAC02/CI/008
66	Air Handling Unit	ZECO	AHU/HAC02/CI/009
67	Air Handling Unit	ZECO	AHU/HAC02/CI/010
68	Air Handling Unit	ZECO	AHU/HAC02/CI/011
69	HPLC	Shimadzu LC	KPL/QC/117
70	HPLC	Shimadzu	KPL/QC/118
71	Weighing Balance	Shimadzu	KPL/QC/054

6. OBSERVATIONS/RESULTS

6.1 Stage: Manufacturing - During Mixing

Batch No: OI0330

Time Point	pH	Assay (%)	Description
10 minutes	9.012	98.5	Clear Colourless solution
15 minutes	9.034	99.2	Clear Colourless solution
20 minutes	9.011	98.8	Clear Colourless solution

Batch No: OI0331

Time Point	pH	Assay (%)	Description
10 minutes	9.043	99.6	Clear Colourless solution
15 minutes	8.944	99.8	Clear Colourless solution
20 minutes	8.811	99.4	Clear Colourless solution

Batch No: OI0332

Time Point	pH	Assay (%)	Description
10 minutes	9.033	99.7	Clear Colourless solution
15 minutes	8.915	99.9	Clear Colourless solution
20 minutes	8.943	99.4	Clear Colourless solution

6.2 Stage: Filling & Sealing

Batch No: OI0330

Stage	pH	Assay (%)	Leak Test
Initial	9.043	99.6	Pass
Middle	8.914	99.4	Pass
End	8.963	99.9	Pass

Batch No: OI0331

Stage	pH	Assay (%)	Leak Test
Initial	8.913	99.8	Pass
Middle	8.943	99.3	Pass
End	8.972	99.5	Pass

Batch No: OI0332

Stage	pH	Assay (%)	Leak Test
Initial	9.012	100.3	Pass
Middle	9.045	99.9	Pass
End	8.965	99.8	Pass

7. QUALITY CONTROL RESULTS OF FINISHED PRODUCT

Quality Attribute	Specification	Batch 1	Batch 2	Batch 3
pH	8.5 to 9.1	9.024	9.045	9.037
Extractable Volume (ml)	NLT 20 ml	20.1	20.1	20.1
Assay (mg)	900-1100 mg (90-110%)	996	1008	994
Particulate Matter 10-25 µm	NMT 6000	834	11454	454
Particulate Matter ≥25 µm	NMT 600	10	11	21

8. CONCLUSION

Based on the compilation of all three batches data, it is concluded that Fluorouracil Injection BP was challenged against various parameters at different time intervals and the results found were within the acceptance criteria. All quality control attributes meet their predetermined specifications.

9. SUMMARY

From the observed data of process validation of Fluorouracil Injection BP, it has been found that the process consistently produces a product meeting predetermined specifications and quality characteristics. The process is validated and can be used for commercial batch production.

APPROVAL SIGNATURES

Prepared By:		Date:
Name:		
Reviewed By:		Date:
Name:		
Approved By:		Date:
Name:		