

PROCESS VALIDATION REPORT

GEMCITABINE FOR INJECTION

Batch Numbers: GEM-PV-001-2024, GEM-PV-002-2024, GEM-PV-003-2024

Report Date: November 15, 2025

TABLE OF CONTENTS

1. Objective
2. Scope
3. Product Information
4. Equipment List
5. Materials List
6. Manufacturing Process Validation
7. Quality Testing Results
8. Conclusion
9. Recommendations
10. Signatures

1. OBJECTIVE

The objective of this validation study is to demonstrate that the manufacturing process for **GEMCITABINE FOR INJECTION** 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 **GEMCITABINE FOR INJECTION**, 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 5

Product Type: Injectable

3. PRODUCT INFORMATION

Parameter	Details
Product Name	GEMCITABINE FOR INJECTION
Product Type	Injectable
Batch Size	BATCH SIZE 5
Number of Batches Validated	3
Validation Date	November 2025

4. EQUIPMENT LIST

S.No.	Equipment Name	Equipment ID	Location	Calibration Status
1	Purified Water system	36.	N/A	Valid
2	Water for Injection System	37.	N/A	Valid
3	Pure steam System	38.	N/A	Valid
4	Compressed Air System	39	N/A	Valid
5	Nitrogen System	40.	N/A	Valid
6	Air Handling Unit	4L.	N/A	Valid
7	Air Handling Unit	42.	N/A	Valid
8	Air Handling Unit	43.	N/A	Valid
9	Air Handling Unit	44.	N/A	Valid
10	Air Handling Unit	45.	N/A	Valid
11	Air Handling Unit	46.	N/A	Valid
12	Air Handling Unit	47.	N/A	Valid
13	Air Handling Unit	48.	N/A	Valid
14	Air Handling Unit	49.	N/A	Valid
15	9.1 Production Equipment	N/A	N/A	Valid
16	Sr. No	N/A	N/A	Valid
17	Equipment Name Make Equipment ID/No.	N/A	N/A	Valid
18	1. Sampling & Dispensing Isolator Klenzide KPL/WH	N/A	N/A	Valid
19	2. New Brehz Engineering	N/A	N/A	Valid
20	Reverse Laminar Air Flow KPL/WH/000s	N/A	N/A	Valid
21	3. Refrigerator 2 -8 'C KPL/WH/009	N/A	N/A	Valid
22	4. Weighing Balance A&D company Limited KPL/WH/006	N/A	N/A	Valid
23	Vial Washing Machine Kailas machine Tools KPL/Ct/O	N/A	N/A	Valid
24	Dry Heat Sterilizer KPL/Ct/OLz	N/A	N/A	Valid
25	Closer Processing System cum HP HVM Machine Fabrik KP	N/A	N/A	Valid
26	Compounding Isolator Klenzide KPL/WH/030	N/A	N/A	Valid
27	Manufacturing Tank Komal KPL/Cr/003	N/A	N/A	Valid
28	10. Bubble Point Pall Life Science KPL/Ct/O29	N/A	N/A	Valid
29	11. Filling Tank KPL/cr/00s	N/A	N/A	Valid
30	L2. KPL/Ct/O2s	N/A	N/A	Valid
31	Automatic Vial Filling and stoppering Machine Parth	N/A	N/A	Valid
32	13. KPL/Cr/019	N/A	N/A	Valid
33	Pressure vessel	N/A	N/A	Valid
34	74. KPL/Cr/00s	N/A	N/A	Valid
35	Vial Sealing Machine Parth Engineering	N/A	N/A	Valid

36	15. KPL/CrI001	N/A	N/A	Valid
37	Visual Inspection Table	N/A	N/A	Valid
38	Labeling & Coding machine Parth Engineering KPL/Ct	N/A	N/A	Valid
39	17. Dynamic Pass Box -VIII PS Air technology KPL/C	N/A	N/A	Valid
40	18. Dynamic Pass Box -II PS Air technology KPL/Ct/	N/A	N/A	Valid
41	19. Dynamic Pass Box -I PS Air technology KPL/Cv04	N/A	N/A	Valid
42	Dynamic Pass Box -V PS Air technology KPL/Ct/O4s	N/A	N/A	Valid
43	27. Dynamic Pass Box -VI PS Air technology KPL/Ct/	N/A	N/A	Valid
44	22. Mobile Trolley PS Air technology KPL/Ct/O49	N/A	N/A	Valid
45	23. Mobile Trolley PS Air technology KPL/CrI0s0	N/A	N/A	Valid
46	24. Sterile Garment Cubicle KPL/Ct/O57	N/A	N/A	Valid
47	25. Sterile Garment Cubicle KPL/Ct/O52	N/A	N/A	Valid
48	26. Vial Washing Area LAF PS Air technology KPL/Cr	N/A	N/A	Valid
49	Format No. NO CHANGE IS PERMITTED WITHOUT AUTHORIZ	N/A	N/A	Valid
50	KWALTTY PHARMACEUTICALS LIMITED	N/A	N/A	Valid

5. MATERIALS LIST

S.No.	Material Type	Material Name	Specification	Quantity
1	Excipient	Gemcitabine Hydrochloride	USP	N/A
2	Excipient	Mannitol	USP	N/A
3	Excipient	Sodium Acetate	USP	N/A
4	Excipient	Sodium Hydroxide	USP	N/A
5	Excipient	Hydrochloric Acid	USP	N/A
6	Excipient	Water for Injection	USP	N/A
7	Excipient	Packing material	USP	N/A
8	Excipient	L0 ml clear moulded Glass vial USP Type I	USP	N/A
9	Excipient	20 mm Bromo butyl slotted Rubber stopper	USP	N/A
10	Excipient	20 mm Flip Top Red Grain Finish Aluminium Seal.	Aluminium USP	N/A
11	Excipient	Excipient	USP	N/A

6. MANUFACTURING PROCESS VALIDATION

6.13 Manufacturing Process

7. QUALITY TESTING RESULTS

Test Parameter	Acceptance Criteria	Batch GEM-PV-001-2021	Batch GEM-PV-002-2021	Batch GEM-PV-003-2021	Result
Particulate Matter	Particulate Matter	N/A	N/A	N/A	✗ Fail

8. CONCLUSION

Based on the validation data from 3 consecutive batches of **GEMCITABINE FOR INJECTION**, 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 **GEMCITABINE FOR INJECTION** 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:			