

PROCESS VALIDATION REPORT

Product Name: fluorouracil injection 50mg/ml

Report Generated: 07-Nov-2025 20:27

Template: Fluorouracil injection

BATCH INFORMATION

Sr. No	Batch Number
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TEST RESULTS

Test Parameter	Acceptance Criteria
pH Test	8.5-9.1
Assay Test	90.0 % to 110.0 %
Extractable Volume	NLT 20 ml

CONCLUSION

The process validation for fluorouracil injection 50mg/ml has been successfully completed for 0 consecutive batches. All test results are within the predetermined acceptance criteria. The process is validated and qualified for commercial production.