Manual 052

6.1 Appendix A Reference Samples

Sample	Quantity	Retention Period
Raw Materials	N/A	N/A
Intermediates	N/A	N/A
API	2X quantity to perform release testing (excluding sterility/pyrogen testing where 1X is required)	11 years after release
Excipients	2X quantity to perform release testing (excluding sterility and/or microbial tests where 1X is required)	5 years after release
Primary Packaging and Printed Packaging Components	At least one sample	5 years after release
Bulk IMP including manipulated comparators and diluents	2X quantity to perform release testing (excluding sterility/pyrogen testing where 1X is required)	10 years after release
Packaged IMP	2X quantity to perform release testing (excluding sterility/pyrogen testing where 1X is required)	10 years after release
Comparators	N/A	N/A
Drug Delivery Systems[++]	50 (for multiple dose delivery systems)	2 years after end of trial or 7 years maximum
Packaged Product (BA/BE)	5X quantity to perform release testing for drug product (test article) and reference standard	5 years after approval of NDA or 5 years after completion of study if NDA is withdrawn or not approved
	(An upper limit of 300 units for oral solid dosage forms and at least 50 units for multi-dose inhalant articles.)	
Analytical Method Validation[##]	4 samples equivalent to 3X quantity to perform release testing	One year after a successful PAI, or if no PAI one year after product approval

6.2 Appendix B Retention Samples

Sample	Quantity	Retention Period
Packaged IMP	At least one sample	10 years after release