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PHARMA QC

TOOLKIT

Essential Templates & Checklists for QC/QA Professionals

WHAT'S INSIDE

ICH Q1 · ICH Q2 · ICH Q6 · ICH Q8 · ICH Q9 · ICH Q10 · WHO GMP · USP · FDA 21 CFR · ALCOA+

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HOW TO USE THIS PHARMA QC TOOLKIT

Guidance for QC Analysts, QA Professionals & Students

How to Use This Pharma QC Toolkit

This toolkit is designed for:	• QC Analysts and Microbiologists • QA Professionals and GMP Auditors • Pharmaceutical Students and Trainees • Regulatory Affairs Personnel

Step-by-Step Usage Guide

Step	Action	Details
Step 1	**Select Template**	Choose the relevant template based on your situation: OOS, CAPA, QC Checklist, or Stability Study.
Step 2	**Fill All Fields**	Complete all required fields clearly and accurately. Do not leave blank fields. Use permanent ink for paper copies.
Step 3	**Follow Your SOP**	All actions must comply with your organisation's current approved SOPs before use in a GMP environment.
Step 4	**Scientific Justification**	Use scientifically justified decisions -- especially for OOS, CAPA root cause, and retesting decisions.
Step 5	**Maintain Data Integrity**	Apply ALCOA+ principles at all times. Enable audit trail for all electronic records (FDA 21 CFR Part 11).
Step 6	**QA Approval**	Always obtain QA approval before finalising any investigation, CAPA, or stability report.

Important: This toolkit must be reviewed, validated, and approved against your site-specific SOPs before use in any GMP-regulated environment. Always refer to current official versions of referenced guidelines.

TEMPLATE 01 — OUT-OF-SPECIFICATION (OOS) INVESTIGATION

FDA Guidance 2006 · ICH Q6A · USP <1010> · FDA 21 CFR 211.192

Out-of-Specification (OOS) Investigation Report

Reference: FDA Guidance for Industry — Investigating OOS Test Results (2006) · ICH Q6A · USP <1010>

1.1 Document Identification

SOP Reference	
OOS Report No.	
Product Name	
Batch / Lot No.	
Dosage Form	
Test Parameter	
Specification Limit	
Observed Result	
Date of OOS Detection	
Reported by (Analyst)	
Instrument ID / Method Ref.	

1.2 Phase I — Laboratory Investigation

Phase I must be completed within 5 business days. Determine whether OOS is attributable to laboratory error.

#	Check Item	Guideline Ref	Status	Initials
1	Review analyst training records & competency for the test method performed	FDA OOS Guidance IV.A	☐ Pass ☐ Fail ☐ N/A	
2	Verify instrument calibration status and qualification records (IQ/OQ/PQ)	FDA 21 CFR 211.68 · USP <1058>	☐ Pass ☐ Fail ☐ N/A	
3	Check reagent / reference standard lot numbers, COA, expiry dates	USP <11> · ICH Q6A	☐ Pass ☐ Fail ☐ N/A	
4	Confirm correct SOP / method revision was used for the analysis	FDA 21 CFR 211.194	☐ Pass ☐ Fail ☐ N/A	
5	Review calculation worksheet for arithmetic or transcription errors	FDA OOS Guidance IV.A.2	☐ Pass ☐ Fail ☐ N/A	
6	Inspect sample preparation records (dilution, weighing accuracy)	USP <1210>	☐ Pass ☐ Fail ☐ N/A	
7	Check HPLC system suitability parameters (tailing factor, plate count, %RSD)	USP <621> · ICH Q2(R1)	☐ Pass ☐ Fail ☐ N/A	

#	Check Item	Guideline Ref	Status	Initials
8	Review chromatogram / raw data for anomalies, extra peaks, baseline drift	FDA 21 CFR Part 11	☐ Pass ☐ Fail ☐ N/A	
9	Assess whether laboratory error can be definitively identified and documented	FDA OOS Guidance IV.A.3	☐ Pass ☐ Fail ☐ N/A	

Phase I Conclusion:

☐ Laboratory error identified — result invalidated (document fully below)

☐ No laboratory error found — proceed to Phase II full-scale investigation

1.3 Phase II — Full-Scale OOS Investigation

Initiate Phase II ONLY if Phase I finds NO laboratory error. Notify QA Manager immediately before proceeding.

#	Check Item	Guideline Ref	Status	Initials
1	Notify QA Manager and initiate formal Phase II investigation	FDA OOS Guidance IV.B · ICH Q10	☐ Pass ☐ Fail ☐ N/A	
2	Review batch manufacturing records (BMR) for deviations	FDA 21 CFR 211.192	☐ Pass ☐ Fail ☐ N/A	
3	Examine raw material / excipient test records and COAs	ICH Q6A · USP <1>	☐ Pass ☐ Fail ☐ N/A	
4	Review environmental monitoring data for the manufacturing period	FDA 21 CFR 211.42	☐ Pass ☐ Fail ☐ N/A	
5	Evaluate process parameters — mixing, blending, compression, fill weight	ICH Q8(R2)	☐ Pass ☐ Fail ☐ N/A	
6	Review water system (WFI/PW) test data for the manufacturing period	USP <1231> · WHO TRS 970	☐ Pass ☐ Fail ☐ N/A	
7	Check retained samples — visual inspection and retest if justified	FDA OOS Guidance IV.B.2	☐ Pass ☐ Fail ☐ N/A	
8	Conduct additional retesting per pre-defined protocol (n=6, full sample)	USP <1010> 4	☐ Pass ☐ Fail ☐ N/A	
9	Statistical evaluation of all results (mean, SD, %RSD)	ICH Q9 · USP <1010>	☐ Pass ☐ Fail ☐ N/A	
10	Assess impact on other batches from same campaign / material lot	ICH Q10 3.2	☐ Pass ☐ Fail ☐ N/A	

1.4 Root Cause Analysis & Scientific Justification

Based on FDA OOS Guidance (2006) IV.B and ICH Q10. Root cause must be scientifically justified.

Assignable Cause Identified?	☐ Yes ☐ No
Root Cause Category	☐ Laboratory Error ☐ Manufacturing Process ☐ Material Issue ☐ Method Issue ☐ Environmental Factor ☐ Other: _____

Impact Assessment	☐ Limited to this batch ☐ Potential impact on other batches ☐ Market impact assessment required

Detailed Root Cause Description

Provide scientific explanation supported by investigation data...

Supporting Evidence

List data, chromatograms, batch records, audit trails referenced...

1.5 Data Integrity Verification

#	Check Item	Guideline Ref	Status	Initials
1	Audit trail reviewed — no unauthorised changes observed	FDA 21 CFR Part 11 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
2	User access control verified — only authorised personnel accessed data	EU GMP Annex 11 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
3	System date/time settings verified — no manipulation detected	FDA Data Integrity Guidance 2018	☐ Pass ☐ Fail ☐ N/A	
4	Backup/original records available and match working copy	FDA 21 CFR 211.68 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
5	Any data integrity concern? ☐ Yes (escalate to QA immediately) ☐ No	ALCOA+ · ICH Q10	☐ Pass ☐ Fail ☐ N/A	

Scientific Conclusion

Justify final conclusion with scientific rationale...

1.6 Retest / Resample Justification Control

WARNING: Unjustified retesting is a critical GMP violation. The FDA considers retesting without assignable cause an attempt to override a confirmed OOS result (FDA OOS Guidance 2006, V.B).

Retest Required?	☐ Yes ☐ No
Number of Retests Planned	
Sampling Plan	☐ Same sample ☐ New sample ☐ Retained sample
Approved By (QA)	_____ Date: _____

Scientific Justification for Retest
Scientific justification only -- not based on desire to obtain a passing result...

1.7 OOS Result Disposition

Disposition	Criteria	Action Required
Release	All retests pass and Phase I error documented	Document investigation; obtain QA approval for release
Reject Batch	Confirmed OOS — no assignable cause identified	Initiate CAPA; quarantine batch; regulatory notification if needed
Retest / Resample	Phase I laboratory error identified and documented	Invalidate original result; retest per pre-approved protocol
Further Investigation	Inconclusive — mixed OOS and passing results	Expand investigation; regulatory notification if market impact

Final Disposition	☐ Release ☐ Reject ☐ Retest ☐ Further Investigation
Related CAPA No.	
Regulatory Notification Required?	☐ Yes (attach documentation) ☐ No

1.8 Approvals & Sign-off

Role	Name (Print)	Signature	Date
QC Analyst			
QC Supervisor / Section Head			
QA Manager			
Regulatory Affairs (if applicable)			

** Based on FDA Guidance for Industry: Investigating OOS Test Results (2006), ICH Q6A, and USP General Chapter <1010>.*

TEMPLATE 02 — CAPA REPORT
ICH Q10 · ISO 9001:2015 10.2 · FDA 21 CFR 820.100 · WHO TRS 986

Corrective and Preventive Action (CAPA) Report

ICH Q10 Pharmaceutical Quality System · ISO 9001:2015 10.2 · FDA 21 CFR 820.100 · WHO TRS 986 Annex 4

2.1 Document Identification & Classification

CAPA No.	
Initiated By	
Department / Area	
Date Initiated	
CAPA Source	☐ OOS Result ☐ Deviation ☐ Audit Finding ☐ Complaint ☐ Change Control ☐ Other: ___
CAPA Type	☐ Corrective Action Only ☐ Preventive Action Only ☐ Both CA & PA
Risk Classification	☐ Critical (immediate) ☐ Major (within 15 days) ☐ Minor (within 30 days)
Related OOS / Deviation No.	
Product / Process Affected	
Target Completion Date	

2.2 Problem Description

Problem Description
Describe the non-conformance in detail: What happened? Where? When? How was it detected? Who was involved?

2.3 Root Cause Analysis — 6M Ishikawa

Analyse each category below. Mark contributing factors and document findings.

Category (6M)	Potential Factor	Contributing?	Evidence / Notes
Man (Personnel)	*Training, awareness, human error*	☐ Yes ☐ No	
Machine	*Calibration,*	☐ Yes ☐ No	

Category (6M)	Potential Factor	Contributing?	Evidence / Notes
(Equipment)	*maintenance, qualification*		
Method (Process/SOP)	*Procedure gap, ambiguity, revision needed*	☐ Yes ☐ No	
Material (Raw/Excipient)	*Supplier, specification, handling issue*	☐ Yes ☐ No	
Measurement (QC/Lab)	*Instrument, analyst, method error*	☐ Yes ☐ No	
Environment	*Temperature, humidity, contamination*	☐ Yes ☐ No	

Root Cause Statement (Verified)
State the verified root cause with scientific justification…

2.4 Corrective Action Plan

Actions taken to eliminate the root cause of the identified non-conformance (ICH Q10 3.2.3).

#	Action Description	Responsible	Target Date	Status	Evidence
1					
2					
3					
4					
5					

2.5 Preventive Action Plan

Actions taken to prevent recurrence and eliminate potential causes (ICH Q10 3.2.3 · ISO 9001:2015 10.2.1(f)).

#	Action Description	Responsible	Target Date	Status	Evidence
1					
2					

#	Action Description	Responsible	Target Date	Status	Evidence
3					
4					

2.6 Data Integrity Verification

#	Check Item	Guideline Ref	Status	Initials
1	Audit trail reviewed — no unauthorised changes observed	FDA 21 CFR Part 11 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
2	User access control verified — only authorised personnel accessed data	EU GMP Annex 11 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
3	System date/time settings verified — no manipulation detected	FDA Data Integrity Guidance 2018	☐ Pass ☐ Fail ☐ N/A	
4	Backup/original records available and match working copy	FDA 21 CFR 211.68 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
5	Any data integrity concern? ☐ Yes (escalate to QA immediately) ☐ No	ALCOA+ · ICH Q10	☐ Pass ☐ Fail ☐ N/A	

2.7 Effectiveness Check & CAPA Closure

ICH Q10 3.2.3 — Effectiveness must be verified through measurable evidence before CAPA closure.

Effectiveness Check Method	☐ Re-audit ☐ Re-test ☐ Trend monitoring ☐ Training effectiveness evaluation ☐ Other: ___
Defined Effectiveness Timeline	☐ 30 Days ☐ 60 Days ☐ 90 Days ☐ Other: _____
Effectiveness Check Date	
Effectiveness Check Result	☐ Effective — CAPA Closed ☐ Not Effective — CAPA Extended / Revised
CAPA Closed Date	

Key Performance Indicator (KPI)
Define measurable success criteria (e.g. no recurrence within 90 days, ≥X% deviation reduction)...

Closure Justification
Provide evidence-based conclusion demonstrating CAPA effectiveness...

Role	Name (Print)	Signature	Date
Initiated By			
QA Review			
QA Manager Approval			

** Based on ICH Q10 Pharmaceutical Quality System, ISO 9001:2015 10.2, FDA 21 CFR 820.100, and WHO TRS 986 Annex 4.*

TEMPLATE 03 — QC LABORATORY COMPLIANCE CHECKLIST
WHO GMP TRS 986 · FDA 21 CFR 211 · USP <1058> · ICH Q10 · ALCOA+

QC Laboratory Compliance Checklist

WHO GMP TRS 986 Annex 2 · FDA 21 CFR Parts 211 & 212 · USP <1058> AIQ · ICH Q10 · EU GMP Annex 11

Laboratory Name / Area	
Checklist Date	
Shift	☐ Morning ☐ Afternoon ☐ Night
Checklist Type	☐ Daily ☐ Weekly ☐ Monthly ☐ Pre-campaign
Completed By	
Reviewed By (Supervisor)	

3.1 Equipment & Instrument Checks

#	Check Item	Guideline Ref	Status	Initials
1	All balances calibrated; within calibration due date; stickers visible	USP <41> · FDA 21 CFR 211.68	☐ Pass ☐ Fail ☐ N/A	
2	Balance daily performance check performed with certified weights	USP <41> · WHO TRS 986	☐ Pass ☐ Fail ☐ N/A	
3	HPLC/UPLC system suitability performed and results acceptable per SOP	USP <621> · ICH Q2(R1)	☐ Pass ☐ Fail ☐ N/A	
4	pH meter calibrated with ≥2 buffer solutions; electrode condition acceptable	USP <791>	☐ Pass ☐ Fail ☐ N/A	
5	Karl Fischer titrator standardized; water standard result within ±2%	USP <921>	☐ Pass ☐ Fail ☐ N/A	
6	Refrigerators / freezers: temperature logs reviewed; within specified range	FDA 21 CFR 211.68	☐ Pass ☐ Fail ☐ N/A	
7	UV-Vis spectrophotometer: wavelength and photometric accuracy verified	USP <857>	☐ Pass ☐ Fail ☐ N/A	
8	IQ/OQ/PQ qualification status current for all analytical instruments in use	USP <1058> · FDA Guidance	☐ Pass ☐ Fail ☐ N/A	
9	Instrument logbooks updated with maintenance, use, and any anomalies	FDA 21 CFR 211.68	☐ Pass ☐ Fail ☐ N/A	

3.2 Reagents, Standards & Reference Materials

#	Check Item	Guideline Ref	Status	Initials
1	All reagents labelled: name, concentration, prep date, expiry, analyst initials	FDA 21 CFR 211.194 · USP <1>	☐ Pass ☐ Fail ☐ N/A	

#	Check Item	Guideline Ref	Status	Initials
2	Reference standards within expiry; stored per COA conditions	USP <11> · ICH Q6A	☐ Pass ☐ Fail ☐ N/A	
3	Working standard potency calculated from primary standard; traceability documented	USP <11>	☐ Pass ☐ Fail ☐ N/A	
4	HPLC mobile phase prepared, labelled and expiry date assigned per SOP	ICH Q2(R1)	☐ Pass ☐ Fail ☐ N/A	
5	Hazardous reagents: SDS accessible; storage segregated per chemical compatibility	OSHA / local regulation	☐ Pass ☐ Fail ☐ N/A	

3.3 Documentation & Data Integrity (ALCOA+)

#	Check Item	Guideline Ref	Status	Initials
1	All raw data recorded in real-time in permanent ink; no pencil entries	FDA 21 CFR 211.68 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
2	No correction fluid used; errors corrected with single line, initialled, dated	ALCOA+ · EU GMP Annex 11	☐ Pass ☐ Fail ☐ N/A	
3	Electronic data: audit trail enabled; access control verified; no clock changes	FDA 21 CFR Part 11	☐ Pass ☐ Fail ☐ N/A	
4	All test methods are current approved versions; no obsolete methods in use	ICH Q10 · FDA 21 CFR 211.194	☐ Pass ☐ Fail ☐ N/A	
5	OOS/OOT log reviewed; all events have open or closed investigation records	FDA OOS Guidance 2006	☐ Pass ☐ Fail ☐ N/A	

3.4 Environmental Monitoring

#	Check Item	Guideline Ref	Status	Initials
1	Temperature & humidity in analytical lab within validated range; recorders functional	WHO GMP · FDA 21 CFR 211.42	☐ Pass ☐ Fail ☐ N/A	
2	Differential pressure readings within specifications (cleanroom)	ISO 14644-1 · EU GMP Annex 1	☐ Pass ☐ Fail ☐ N/A	
3	Microbial settle plates / active air sampling: results within alert/action limits	USP <1116> · EU GMP Annex 1	☐ Pass ☐ Fail ☐ N/A	
4	Fume hoods / biosafety cabinets: last certification within 12-month interval	NSF/ANSI 49 · WHO GMP	☐ Pass ☐ Fail ☐ N/A	

3.5 Personnel & Training

#	Check Item	Guideline Ref	Status	Initials
1	Analyst training records current for all methods being performed today	ICH Q10 · FDA 21 CFR 211.68	☐ Pass ☐ Fail ☐ N/A	
2	All personnel wearing correct PPE per chemical / biological risk assessment	OSHA 29 CFR 1910	☐ Pass ☐ Fail ☐ N/A	
3	No unauthorised personnel in restricted laboratory areas	FDA 21 CFR 211.42	☐ Pass ☐ Fail ☐ N/A	

#	Check Item	Guideline Ref	Status	Initials
4	Annual SOP re-read and acknowledgement records up to date	ICH Q10 2.2	☐ Pass ☐ Fail ☐ N/A	

3.6 Data Integrity Verification

#	Check Item	Guideline Ref	Status	Initials
1	Audit trail reviewed — no unauthorised changes observed	FDA 21 CFR Part 11 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
2	User access control verified — only authorised personnel accessed data	EU GMP Annex 11 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
3	System date/time settings verified — no manipulation detected	FDA Data Integrity Guidance 2018	☐ Pass ☐ Fail ☐ N/A	
4	Backup/original records available and match working copy	FDA 21 CFR 211.68 · ALCOA+	☐ Pass ☐ Fail ☐ N/A	
5	Any data integrity concern? ☐ Yes (escalate to QA immediately) ☐ No	ALCOA+ · ICH Q10	☐ Pass ☐ Fail ☐ N/A	

Checklist Summary

Total Items	Pass	Fail	N/A	Overall Status
37				☐ Acceptable ☐ Conditional ☐ Not Acceptable

CAPA Required?	☐ Yes — CAPA No.: _____ ☐ No
Comments / Observations	

Role	Name (Print)	Signature	Date
QC Analyst / Lab Technician			
QC Supervisor			

TEMPLATE 04 — STABILITY STUDY DESIGN & REPORTING

ICH Q1A(R2) · ICH Q1B · ICH Q1D · ICH Q1E · WHO TRS 953 · FDA Stability Guidance

Stability Study Design & Data Recording Template

ICH Q1A(R2) · ICH Q1B Photostability · ICH Q1D Bracketing & Matrixing · ICH Q1E Statistical Evaluation · WHO TRS 953

4.1 Product & Study Identification

Product Name (INN)	
Dosage Form & Strength	
Batch No.	
Batch Size	
Manufacturing Date	
Container Closure System	
Study Type	☐ Long-term ☐ Accelerated ☐ Intermediate ☐ Stress (Forced Degradation)
Protocol No. / Version	
Regulatory Zone	☐ ICH Zone I/II ☐ ICH Zone III ☐ ICH Zone IVa ☐ ICH Zone IVb
Primary Packaging Material	
Study Start Date	
Proposed End Date	

4.2 Storage Conditions (ICH Q1A(R2))

Condition Type	Temperature	Humidity / RH	Duration	Purpose
Long-term (Zone I/II)	25°C ± 2°C	60% RH ± 5%	12 months min.	Proposed shelf life (ICH Q1A(R2))
Accelerated	40°C ± 2°C	75% RH ± 5%	6 months min.	Early shelf-life prediction
Intermediate	30°C ± 2°C	65% RH ± 5%	6 months min.	If significant change at accelerated
Long-term Zone IVb	30°C ± 2°C	75% RH ± 5%	12 months min.	Tropical climate markets
Photostability (ICH Q1B)	Visible: ≥1.2M lux·hr	UV: ≥200 W·hr/m²	Single exposure	Photodegradation assessment
Stress — Thermal	50°C / 60°C	Open dish	2–4 weeks	Forced degradation (dev only)
Stress — Humidity	25°C	90% RH	2–4 weeks	Hygroscopic products (dev only)
Stress — Acid/Base	0.1N HCl / NaOH	Ambient	2–24 hours	Hydrolysis pathways (dev only)
Stress — Oxidation	3–5% H2O2	Ambient	2–24 hours	Oxidative degradation (dev only)

4.3 Study Design Optimization — Bracketing & Matrixing (ICH Q1D)

Bracketing and matrixing are acceptable design approaches to reduce samples tested when scientifically justified per ICH Q1D.

Approach	Applied?	Regulatory Basis	Justification / Details
Bracketing: Testing only extreme strengths / pack sizes	☐ Yes ☐ No	*ICH Q1D 2.1*	*Describe bracketed strengths / container sizes:*
Matrixing: Reduced testing schedule across factor combinations	☐ Yes ☐ No	*ICH Q1D 2.2*	*Describe reduced schedule and factor combinations:*

Regulatory Acceptability	☐ As per ICH guidelines — no additional justification required ☐ Requires specific regulatory justification (attach)

4.4 Testing Schedule (ICH Q1A(R2) 2.2)

Test Parameter	Specification	T=0	3M	6M	9M	12M	18M	24M	36M
Appearance / Description	*Complies*								
Assay (% label claim)	*98.0 – 102.0%*								
Related Substances / Degradants	*≤0.50% total*								
Water Content (Karl Fischer)	*≤0.50%*								
Dissolution / Disintegration	*≥80% (Q)*								
pH (liquid / semi-solid)	*4.5 – 6.5*								
Particulate Matter (injectables)	*Complies USP <788>*								
Microbial Limits / Bioburden	*≤100 cfu/g*								

4.5 Significant Change Criteria (ICH Q1A(R2))

Parameter	Significant Change Definition
Assay	5% change from initial assay value
Degradation Products	Any individual degradant exceeds specification limit
Physical Attributes	Failure to meet criteria for colour, hardness, or dissolution
pH	Change of ≥1 unit outside defined specification
Dissolution	12-point drop (e.g. from ≥85% to ≤73%)

4.6 Conclusions & Shelf-life Estimate

Significant Change Observed?	☐ Yes — at Timepoint: ___ Condition: ___ ☐ No
Action Taken	☐ CAPA initiated ☐ Shelf-life revised ☐ Further testing ☐ N/A
Preliminary Shelf-life Estimate	
Statistical Method Used	☐ ICH Q1E regression ☐ Minimum batch method ☐ Other: _____

Role	Name (Print)	Signature	Date
Study Coordinator			
QC Manager			
Regulatory Affairs			
QA Approval			

** Based on ICH Q1A(R2), Q1B, Q1D, Q1E, WHO Technical Report Series 953, and FDA Guidance for Industry: Stability Testing.*

REGULATORY REFERENCE GUIDE

Guidelines applicable to all templates in this toolkit

Applicable Regulatory Guidelines & Standards

Reference	Title	Applied In
ICH Q1A(R2)	Stability Testing of New Drug Substances and Products	Stability Template 4
ICH Q1B	Photostability Testing of New Drug Substances and Products	Stability 4.2
ICH Q1D	Bracketing and Matrixing Designs for Stability Testing	Stability 4.3
ICH Q1E	Evaluation for Stability Data — Statistical Analysis	Stability 4.6
ICH Q2(R1)	Validation of Analytical Procedures: Text and Methodology	OOS 1.3 · Checklist 3.1
ICH Q6A	Specifications: Test Procedures — New Drug Substances	OOS 1.1 · Stability 4.4
ICH Q8(R2)	Pharmaceutical Development (Design Space)	OOS Phase II 1.3
ICH Q9	Quality Risk Management	CAPA 2.3 · Checklist general
ICH Q10	Pharmaceutical Quality System (PQS)	CAPA 2.7 throughout
FDA 21 CFR 211	Current GMP — Finished Pharmaceuticals	OOS · Checklist throughout
FDA 21 CFR Part 11	Electronic Records; Electronic Signatures	Checklist 3.3 · DI sections
FDA Guidance 2006	Investigating OOS Test Results for Pharmaceutical Production	OOS Template 1.2–1.6
WHO GMP TRS 986	WHO Good Manufacturing Practices for Pharmaceutical Products	Checklist 3.1–3.6
WHO TRS 953	Stability Testing of APIs and Finished Pharmaceutical Products	Stability Template 4
USP <11>	Reference Standards	Checklist 3.2
USP <41>	Balances	Checklist 3.1
USP <621>	Chromatography	OOS 1.2 · Checklist 3.1
USP <791>	pH	Checklist 3.1
USP <921>	Water Determination (Karl Fischer)	Checklist 3.1
USP <1010>	Analytical Data Interpretation and Treatment	OOS 1.3
USP <1058>	Analytical Instrument Qualification (AIQ)	Checklist 3.1
ALCOA+	Data Integrity Principles	All DI sections throughout
ISO 9001:2015	Quality Management Systems — Requirements 10.2	CAPA 2.7
EU GMP Annex 11	Computerised Systems — Data Integrity	Checklist 3.3 · DI sections

Disclaimer: This toolkit is provided by Ask PharmaTutor for educational and professional development purposes only. All templates must be reviewed, validated, and approved against your organisation's SOPs and applicable regulatory requirements before use in a GMP environment.