# Washing-machine FAT record

Vial, ampoule and bottle projects: prepare the agreed samples, configuration, conditions and observations before the factory trial.

> BLANK WORKSHEET - not an approved FAT protocol, trial result or acceptance approval. Use the approved order, URS, drawings and project-specific test protocol. Every result and disposition remains blank.

**Project / site:** _____ **Project date:** _____

**Record owner:** _____ **Model / equipment ID:** _____

**Order / URS reference:** _____ **Drawing revision:** _____

| Prepare before FAT | Record during FAT |
|---|---|
| **Approved order, URS, layout, drawings and machine configuration** | **Model, revision, options tested and any excluded scope** |
| | |
| | |
| | |

| Prepare before FAT | Record during FAT |
|---|---|
| **Approved samples, format list and representative/worst-case formats** | **Sample identity, format, change parts and observed handling** |
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| | |

Use production-representative empty, unfilled containers and approved drawings. Include agreed minimum, maximum and representative/worst-case formats. Do not substitute a similar-volume vial/ampoule or assume one smooth run proves every changeover.

# Utilities and coverage

**Project / model:** _____ **FAT protocol reference:** _____

| Prepare before FAT | Record during FAT |
|---|---|
| **Wash recipe, utilities and project-defined operating conditions** | **Connected media, actual readings where required and test conditions** |

## Utility / wash-stage record

| Service / wash stage | Approved condition / reference | Actual reading / instrument | Temporary supply / limitation |
|---|---|---|---|
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## Format-and-process coverage

| Container drawing / sample | Installed format parts | Media arrangement | Acceptance observations / evidence | Coverage status |
|---|---|---|---|---|
| | | | | |
| | | | | |

| Representative selection / boundary | Agreed rationale, untested combinations and later-review owner |
|---|---|

Mark untested combinations separately from completed or failed checks. Record which evidence remains for later review and who agrees that boundary. Run the documented wash/media order; washing alone does not sterilize or depyrogenate containers.

# Run, controls and inspection

**Project / model:** _____ **Sample / format reference:** _____

| Prepare before FAT | Record during FAT |
|---|---|
| Output, quality, alarm and interlock acceptance criteria | Run duration, accepted/rejected counts, stops, alarms and observations |

| | |
|---|---|
| Format / options tested | |
| Run duration (state units) | |
| Accepted units | |
| Rejected units | |
| Stops / jams | |
| Operator interventions | |
| Operating pattern / conditions | |

| | |
|---|---|
| Control / alarm / interlock scenario | |
| Response / message / recovery | |
| Upstream / downstream stop | |
| Inspection method / sample basis | |
| Criteria / observations / rejects | |

Trained personnel must use the approved safe test procedure. Do not bypass guards or protective functions. Record only the tested conditions; published model ratings do not guarantee every format, recipe, change part or connected line.

# Documents and open actions

**Project / model:** _____ **Protocol / record reference:** _____

| Prepare before FAT | Record during FAT |
|---|---|
| FAT protocol, document list and release route | Signatures, deviations, punch-list owner, retest and dispatch disposition |

## Document status

| Document / revision / scope reference | Supplied / pending / correction | Action / owner |
|---|---|---|
| | | |
| | | |

## Deviation / punch-list record

| Deviation / substitution / limitation | Owner | Retest / evidence required | Disposition / dispatch restriction |
|---|---|---|---|
| | | | |
| | | | |

| | |
|---|---|
| **Dispatch authority / release route** | |

Use the agreed contract/protocol release process. A signature does not erase open scope or deviations. Carry unresolved items into the site plan. FAT evidence covers only the configuration, samples and conditions tested; it does not replace SAT, commissioning, IQ/OQ/PQ, process qualification, or separate sterilization/depyrogenation validation. Keep microbiological and endotoxin work in the approved qualification/laboratory plan unless the FAT protocol expressly assigns a test.