NHASA

National Halal Accreditation Services Australia

Is Your Pharmaceutical Business Ready for Halal Certification?

PRE-CERTIFICATION READINESS CHECKLIST

HOW TO USE THIS CHECKLIST

Work through each section. A tick means you are on track. An X means action is needed before your audit.

1 INGREDIENTS & RAW MATERIALS

Core requirement — no halal cert without this

- ☐ CRITICAL **All active pharmaceutical ingredients (APIs) are from halal-permissible sources.**
- ☐ CRITICAL **No porcine-derived ingredients (gelatin, heparin, trypsin, pepsin) in any formulation.**
  Includes capsule shells, binders, and coating agents.
- ☐ All alcohol-based excipients have been reviewed — alternatives sourced where possible.
  Residual alcohol may be permissible under necessity provisions — document the justification.
- ☐ Animal-derived raw materials (stearic acid, lactose, glycerol) are verified halal.
  Supplier halal certificates must be on file.
- ☐ A complete ingredient inventory with supplier halal documentation exists.

2 MANUFACTURING & FACILITY

Contamination controls are audited on-site

- ☐ CRITICAL **Dedicated halal production lines or validated clean-down procedures are in place.**
- ☐ Storage areas for halal and non-halal materials are clearly separated and labelled.
- ☐ Equipment cleaning and sanitisation records are documented and available.
  Auditors will request the last 12 months of cleaning logs.
- ☐ Water used in production is potable and free of contamination.
- ☐ Pest control products used on-site do not contain haram substances.

YOUR READINESS SCORE GUIDE

90 - 100% ticked	Certification-ready. Contact NHASA to begin your application.
70 - 89% ticked	Minor gaps. Address flagged items then schedule a pre-audit consultation.
Below 70% ticked	Significant groundwork required. Our team can guide you step by step.

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3 DOCUMENTATION & TRACEABILITY

Paper trail is everything in a halal audit

- [ ] CRITICAL **Valid halal certificates are held for every ingredient supplier.**
  Certificates must be current — check expiry dates.
- [ ] Batch production records link each product to its specific raw material lots.
- [ ] A documented halal management system (HMS) or standard operating procedures exist.
  SMIIC OIC/SMIIC 1 and ESMA GSO 2055 require a formal HMS.
- [ ] Recall and traceability procedures are documented and tested.
- [ ] Label claims and halal logos currently used are from a recognised certifying body.
  Unauthorised use of halal logos can disqualify your application.

4 PERSONNEL & TRAINING

Staff awareness reduces contamination risk

- [ ] A designated Halal Coordinator or responsible officer has been appointed.
- [ ] Production and QA staff have received halal awareness training.
  Training records must be available for auditor review.
- [ ] Staff handling halal-certified materials understand cross-contamination protocols.
- [ ] Senior management is committed to maintaining halal compliance post-certification.
  Auditors assess culture, not just documentation.

5 EXPORT & INTERNATIONAL STANDARDS ALIGNMENT

For companies targeting Muslim-majority markets

- [ ] Target export markets (Malaysia, UAE, Saudi Arabia, Indonesia) have been identified.
  Different markets require different standard alignments — confirm with NHASA.
- [ ] CRITICAL **Compliance with OIC/SMIIC 1 halal pharmaceutical standard has been assessed.**
  Mandatory for OIC member-country market access.
- [ ] ESMA GSO 2055 requirements reviewed for UAE/GCC market entry.
- [ ] JAKIM Malaysia halal pharmaceutical guidelines reviewed if targeting Malaysian market.
- [ ] Export documentation procedures include halal certificate endorsement.

Ready to Take the Next Step?

Submit your application or book a free pre-audit consultation with our team.