厦门广信隆技术服务有限公司

Al-Baqara Certification

清真药品/医药产品认证方案

Halal Pharmaceutical / Medicinal Products Certification Scheme

文件编号：（Document No.）	ABC-CS-013
版本号：（Version No.）	A2
编制：（Compiled by）	技术委员会 Technical Committee
审核：（Reviewed by）	评审组 Review Group
批准：（Approved by）	沙忠虎
修订日期：（Revision Date）	2026.5.26

发布日期（Issuance Date）：

2022.8.1

实施日期（Implementation Date）：

2022.8.1

修订次数（Revision Times）	修订日期（Revision Date）	修改内容/原因 （Modification Content/Reason）	更改人（Modifier）	批准人（Approver）
1	2026.4.5（A1）	1）原名称BQR-FA-14 A/0，修改公司简称为ABC-CS-013. Original name: BQR-FA-14 A/0. Revised company abbreviation to ABC-CS-013. 2)文件由副总经理审核，修改为评审组审核。 The document shall be reviewed by the review team.	韩锐	沙忠虎
2	2026.5.26（A2）	1）3 引用文件中的6.加入印度尼西亚清真法规。 3 References, Item 6: Add Indonesian Halal Regulations. 2) 增加附录，提供一份矩阵表，内容包括贵机构所申请的认证范围、产品类型，以及对应的清真关键控制点。 Add an appendix containing a matrix table covering the applied certification scope, product categories and corresponding halal critical control points of your organization.	安娜	沙忠虎

清真药品/医药产品认证方案

Halal Pharmaceutical / Medicinal Products Certification Scheme

1 目的 / Purpose

为规范清真药品/医药产品认证活动，统一认证程序、审核标准与管理要求，确保认证过程符合国际标准、目标国法规及伊斯兰教法要求，依据公司《认证申请受理控制程序》《认证审核工作操作规范》《认证决定控制程序》制定本方案。

This scheme is formulated to standardize Halal certification activities for pharmaceutical/medicinal products, unify certification procedures, audit standards and management requirements, ensure the certification process complies with international standards, target country regulations and Islamic Shariah, in accordance with the company's Certification Application Acceptance Control Procedure, Operating Specification for Certification Audit Activities and Certification Decision Control Procedure.

2 适用范围 / Scope

本方案适用于各类药品、医药产品、药用原料、制剂、胶囊、片剂、颗粒剂、口服液、外用药品、药用辅料、膳食补充剂、健康产品等产品的清真认证。覆盖初次认证、监督审核、再认证、范围扩项、范围缩减、转让/变更、短通知审核、专项审核、暂停、恢复、撤销和终止等活动。

This scheme applies to the halal certification of various pharmaceuticals, medicinal products, medicinal raw materials, preparations, capsules, tablets, granules, oral liquids, topical medicines, pharmaceutical excipients, dietary supplements, health products and other related products. It covers activities including initial certification, surveillance audit, recertification, scope expansion, scope reduction, transfer/change, short-notice audit, special

audit, suspension, reinstatement, revocation and termination.

3 引用文件 / References

1.ISO/IEC 17065 产品、过程和服务认证机构要求

ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services

2. ISO/IEC 17021-1 合格评定 管理体系审核认证机构要求 第 1 部分：要求

ISO/IEC 17021-1,Conformity assessment-Requirements for bodies providing audit and certification of management systems--Part 1.Requirements.

在采用管理体系审核原则作为支持性指南时，参考 ISO/IEC 17021-1。

Refer to ISO/IEC 17021-1 when applying the principles for management system audits as supporting guidelines.

3. ISO/IEC 17025 检测和校准实验室能力的通用要求

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

当检测活动被分包或作为支持性证据使用时，参考 ISO/IEC 17025。

Refer to ISO/IEC 17025 when testing activities are subcontracted or used as supporting evidence.

4.GSO 2055-1, GSO 2055-2 海湾国家清真产品标准

GCC GSO 2055-1, GSO 2055-2 Halal product standards

5.MS 1500:2019 马来西亚清真食品标准

Malaysia MS 1500:2019 Halal food standard

6.印度尼西亚 2023 年第 20 号、2014 年第 33 号法、2021 年第 39 号、2024 年第 42 号、2021 年第 748 号、2024 年第 944 号、2021 年第 1360 号等。

Indonesia: Law No.33 of 2014, Government Regulation No.39 of 2021, Government Regulation No.42 of 2024, Decree of Head of BPJPH No.20 of 2023, Decree of Minister of Religious Affairs No.748 of 2021, Decree of Minister of Religious Affairs No.944 of 2024, Decree of Minister of Religious Affairs No.1360 of 2021, etc.

1）清真产品保障管理机构负责人法令 2023 年第 20 号关于修订清真产品保障管理机构负责人 2021 年第 57 号关于清真产品保障体系标准的决定

Decree of the Head of Halal Product Assurance Organizing Agency (BPJPH) Number 20 of 2023 Concerning Criteria for Halal Product Assurance System

2）印度尼西亚共和国 2014 年第 33 号《清真产品保障法》，及其适用的修订或补充法规。

Law of the Republic of Indonesia No. 33 of 2014 concerning Halal Product Assurance, as amended and/or supplemented by applicable laws.

3）2021 年第 39 号政府法规《清真产品保障实施条例》，以及任何最新适用的替代或修订法规。

Government Regulation No. 39 of 2021 concerning the Implementation of Halal Product Assurance, and any latest applicable replacement/amendment.

4）印度尼西亚共和国 2024 年第 42 号政府条例关于清真产品保障领域的实施

Government Regulation of the Republic of Indonesia Number 42 of 2024 Concerning the Implementation of Halal Product Assurance

5）宗教事务部长 2021 年第 748 号关于必须取得清真认证的产品类型的决定

Decree of the Minister of Religious Affairs Number 748 of 2021 concerning Types of Products That Must Be Halal Certified

6）印度尼西亚清真产品类别和关键点参考文件，包括适用于食品和饮料产品的 KMA 2024 年第 944 号

Indonesian halal product category and critical-point references, including KMA No. 944 of 2024 for Food and Beverages Products.

7)2021 年第 1360 号宗教部长令《豁免清真认证义务的原料清单（正面清单）》

Decree of the Minister of Religious Affairs Number 1360 of 2021 Concerning Materials Exempted from Halal- Certification Obligation

8）印度尼西亚共和国 2023 年第 6 号总统令，关于药品、生物制品和医疗器

械清真认证

Presidential Regulation No. 6 of 2023 concerning Halal Certification of Medicines, Biological Products, and Medical Devices

9）BPJPH 关于外国清真认证机构、清真认证认可、清真产品类别、注册、监督和报告的法规及指南。

BPJPH regulations and guidelines concerning Foreign Halal Certification Bodies, halal certification recognition, halal product categories, registration, surveillance, and reporting.

7.SMIIC1:2019 清真食品的一般要求（土耳其 / 伊斯兰合作组织）

SMIIC 1:2019 General Requirements for Halal Food (Turkey / Standards and Metrology Institute for Islamic Countries)

8.伊斯兰教法及清真通用准则 Islamic Shariah and general Halal guidelines

9.药品生产质量管理、辅料、标签、卫生及安全相关法规

Relevant laws and regulations on pharmaceutical GMP, excipients, labeling, hygiene and safety.

4 认证模式 / Certification Mode

申请受理 + 文件审查 + 第一阶段审核 + 第二阶段现场审核 + 抽样检测（必要时）+ 复核与认证决定 + 获证后监督 + 再认证

Application Acceptance + Document Review + Stage 1 Audit + Stage 2 On-site Audit + Sampling Testing (if necessary) + Review and Certification Decision + Post-certification Surveillance + Recertification

5 认证单元划分 / Certification Unit Classification

- 化学药品 / Chemical pharmaceuticals
- 中成药/传统药品 / Traditional Chinese medicines / traditional medicinal products

- 药用胶囊、片剂、颗粒剂 / Capsules, tablets, granules
- 口服液、糖浆剂 / Oral liquids, syrups
- 外用药品/消毒剂（医药用）/ Topical medicines / disinfectants (medicinal)
- 药用辅料、原料 / Pharmaceutical excipients and raw materials
- 膳食补充剂、保健食品 / Dietary supplements, health foods

6 认证程序 / Certification Procedure

1. 认证申请与受理（按《认证申请受理控制程序》执行）

Certification application and acceptance (Implemented in accordance with the Certification Application Acceptance Control Procedure)

2. 合同评审与签订 Contract review and signing

3. 第一阶段审核（文件审核） Stage 1 Audit (Document Review)

4. 第二阶段现场审核 Stage 2 On-site Audit

5. 抽样检测（必要时） Sampling Testing (if necessary)

6. 技术复核与认证决定（按《认证决定控制程序》执行）

Technical review and certification decision (Implemented in accordance with the Certification Decision Control Procedure)

7. 批准发证 Approval and certification

8. 获证后监督 Post-certification surveillance

9. 再认证、扩项/缩项、暂停/恢复/撤销

Recertification, scope expansion/reduction, suspension/restoration/withdrawal

7 申请资料要求 / Documentation Required

按《认证申请受理控制程序》执行，包括：

Implemented in accordance with the Certification Application Acceptance Control Procedure, including:

- 申请表、企业资质、生产许可

Application form, enterprise qualification, production license

- 药品注册/备案证明 Pharmaceutical registration/filing certificate

- 配方、工艺流程、厂区布局图

Formula, process flow chart, factory layout

- 原辅料/药用辅料清单及清真证明

Raw material / pharmaceutical excipient list and Halal certificates

- 清真保障体系与 GMP 管理文件

Halal assurance system and GMP documents

- 标签、包装、说明书 Label, packaging, instructions

- 检测报告、生产用水报告 Test reports, production water reports

- 目标国专项要求资料 Country-specific requirement documents

8 审核策划与审核组要求 / Audit Planning & Audit Team

按《认证审核工作操作规范》执行：

Implemented in accordance with the Operating Specification for Certification Audit Activities:

1.审核项目管理人员策划审核，确定目的、范围、方案、时间。

Audit project manager plans audit, defines objectives, scope, scheme, time.

2.审核组设组长，成员专业能力匹配

The audit team has a leader, and members have matching professional competence

3.审核组中至少有一名伊斯兰事务专家

At least one member of the audit team shall be an expert in Islamic affairs

4.审核组组成须经受审核方确认

The composition of the audit team shall be confirmed by the auditee

5.审核组长编制《审核计划》并报批

The audit team leader develops the Audit Plan and submits for approval

9 审核实施 / Audit Implementation

9.1 第一阶段审核 / Stage 1 Audit

评审清真管理体系、原料风险、生产条件、认证范围。

Review the Halal management system, raw material risks, production conditions, and certification scope.

出具《第一阶段审核报告》，确认是否具备二阶段条件。

Issue the **Phase 1 Audit Report** to confirm whether the conditions for Phase 2 audit are met.

9.2 第二阶段现场审核 / Stage 2 On-site Audit

重点审核：人员、设备、工艺、原料、仓储、清洁、防虫、追溯、标签、混产隔离、敏感原辅料管控、GMP 合规、药用辅料清真合规。

Key audit points: Personnel, equipment, process, raw materials, warehousing, cleaning, pest control, traceability, labeling, mixed-production isolation, control of sensitive raw materials, GMP compliance, Halal compliance of pharmaceutical excipients.

流程：首次会议 → 现场审核 → 审核发现 → 不符合报告 → 末次会议。

Process: Opening meeting → On-site audit → Audit findings → Non-conformity report → Closing meeting.

审核时间按 GSO 2055-2、MS1500、BPJPH、SMIIC 及风险等级计算。

The audit duration is calculated in accordance with GSO 2055-2, MS 1500, BPJPH, SMIIC and the risk level.

9.3 抽样检测（必要时）/ Sampling Testing (if necessary)

重点检测：动物源性成分、猪 DNA、乙醇含量、禁忌成分、明胶/硬脂酸/甘油等辅料来源；

Key testing: Animal-derived ingredients, porcine DNA, ethanol content, prohibited ingredients, sources of excipients (gelatin, stearic acid, glycerin, etc.).

实验室应符合 ISO/IEC 17025。

The laboratory shall comply with ISO/IEC 17025.

10 复核与认证决定 / Review and Certification Decision

按《认证决定控制程序》《认证审核工作操作规范》执行：

Implemented in accordance with the Certification Decision Control Procedure and Operating Specification for Certification Audit Activities:

1. 复核人员独立于审核活动

Reviewers are independent of audit activities

2. 认证决定组至少 3 人，至少 1 名伊斯兰事务专家

Certification decision panel has at least 3 members, including at least 1 Islamic affairs expert

3. 决定类型：授予、拒绝、扩大、缩小、暂停、恢复、撤销

Decision types: Grant, refuse, expand, reduce, suspend, restore, withdraw

4. 经高层领导批准生效 Effective upon approval by Top Management

11 证书与标志 / Certificate and Mark

1. 证书有效期 3 年 Certificate validity: 3 years

2. 标志仅限认证范围内产品及包装使用

Mark only used on certified products and packaging

3. 获证方建立使用台账，接受监督

Certified client maintains usage log and accepts surveillance

4. 违规使用将暂停/撤销证书

Violation leads to suspension/withdrawal of certificate

12 获证后监督 / Post-certification Surveillance

1. 周期：**每年至少 1 次**，间隔不超过 12 个月。

Cycle: **at least once a year**, interval ≤12 months.

2. 内容：体系持续运行、不符合整改、变更、标志使用、投诉、敏感原辅料。

Contents: system operation, correction, changes, mark use, complaints, sensitive materials.

3. 出现重大风险可增加**突击审核（短通知审核）**。

Unannounced/short-notice audit may be conducted for major risks.

13 再认证 / Recertification

证书到期前 3 个月申请，程序同初次认证；逾期自动失效。

Apply 3 months before expiration; same procedure as initial certification; overdue invalidation.

14 变更与范围调整 / Change and Scope Adjustment

1. 扩项：提交申请→专项审核→更新证书。

Scope expansion: Apply → Special audit → Update certificate.

2. 缩项：企业申请或机构核实→调整范围→换发证书。

Scope reduction: Client apply or verification → Adjust scope → Reissue certificate.

3. 重大变更（配方、工艺、场地、关键人员）须立即申报并验证

Major changes (formula, process, site, key personnel): declare immediately and verify

15 暂停、撤销、恢复、终止 / Suspension, Withdrawal, Restoration, Termination

按《认证决定控制程序》《认证审核工作操作规范》执行。

Implemented in accordance with the Certification Decision Control Procedure and Operating Specification for Certification Audit Activities.

暂停：整改不达标、违规用标、未监督、事故等；≤6 个月。

Suspension: Uncorrected non-conformity, mark violation, no surveillance, incident; ≤6 months.

撤销：暂停未整改、严重违规、虚假材料、丧失清真能力。

Withdrawal: No correction after suspension, serious violation, falsification, loss of Halal capability.

恢复：整改验证合格→申请→审核→批准恢复。

Restoration: Correction verified → Apply → Audit → Approve restoration.

终止：认证中发现严重不符合，终止流程。

Termination: Terminate if serious non-conformity found during certification.

16 申诉、投诉与争议 / Appeal, Complaint and Dispute

依据 ISO/IEC 17065、GSO 2055-2 等执行，处理人员独立于原审核与认证决定。

Handled in accordance with ISO/IEC 17065, GSO 2055-2, etc. Handlers are

independent of original audit and certification decision.

17 目标国专项要求 / Country-specific Requirements

1. **印尼（IND）**：执行适用于食品和饮料以外产品的 KMA 第 748 号

Indonesia (IND): Implement KMA No. 748 applicable to products other than food and beverages

2.马来西亚（JAKIM）：原料与配方符合 JAKIM 医药类要求

Malaysia (JAKIM): Raw materials and formula comply with JAKIM pharmaceutical requirements

3.海湾国家：执行 GSO 2055 系列，药品类清真要求严格

GCC countries: Implement GSO 2055 series with strict Halal rules for pharmaceuticals

4. **土耳其 / OIC（SMIIC）**：SMIIC 1:2019，强化成分溯源、动物源禁用、乙醇管控

Turkey/OIC (SMIIC): SMIIC 1:2019;strengthen traceability, animal-derived prohibition, alcohol control

5.所有认证必须满足**伊斯兰教法**与目标国官方要求。

All certification complies with **Islamic Shariah** & official target country rules.

18 药品行业专项控制点 / Special Controls for Pharmaceuticals

1. 明胶、硬脂酸、甘油、胶囊壳、乳糖、酶等药用辅料必须提供清真证书

Pharmaceutical excipients including gelatin, stearic acid, glycerin, capsule shells, lactose, enzymes must provide Halal certificates

2. 乙醇仅限工艺使用，来源非酿酒，残留符合目标国要求

Ethanol only for process use, non-wine origin, residue complies with target country requirements

3. 严禁使用猪源、血液、胎盘、猪油、非清真动物成分

Porcine ingredients, blood, placenta, lard and non-Halal animal ingredients are strictly prohibited

4. 生产线必须专用或有效隔离，清洁验证完整

Production line must be dedicated or effectively isolated with complete cleaning validation

5. GMP 与清真保障体系同步运行

GMP and Halal assurance system operate simultaneously

6. 标签与说明书不得违背伊斯兰教法

Labels and instructions shall not violate Islamic Shariah

7. 药品包材不得含非清真成分且无污染风险

Pharmaceutical packaging materials shall not contain non-Halal ingredients or contamination risks

19 质量记录表格 / Quality Record Forms

认证申请评审表 Certification Application Review Form

审核任务书 Audit Assignment Letter

审核计划 Audit Plan

现场审核表 On-site Audit Form

不符合项报告 Non-conformity Report

认证复核决定记录 Certification Review and Decision Record

Appendix - Proposed Scope, Product Type, and Halal Critical Point Matrix

附录 - 拟申请范围、产品类型和清真关键点矩阵

No.	Proposed Scope	Product / Service Category	Examples	Main Halal Critical Points	Evidence to Verify
序号	拟申请范围	产品 / 服务类别	示例	主要清真关键点	待核验证据
1	Medicine	Medicines and medicinal substances	Traditional medicines, health supplements, quasi medicines, OTC drugs, restricted OTC drugs, prescription drugs excluding narcotics/psychotropics, API/excipients; capsules/tablets/syrups/topicals as dosage forms	Gelatin capsule shell; magnesium stearate/stearic acid/glycerin/lactose; coating; ethanol solvent; animal-derived API/excipient; enzyme; microbial media; porcine DNA risk; GMP and batch traceability.	Formula, API/excipient specs, COA, halal certificates, GMP records, ethanol declaration/test, supplier declaration, batch record.
	药品	药品和药用物质	传统药品、健康补充剂、准药品、非处方/限制非处方/处方药（不含麻醉药和精神药品）、API/辅料；胶囊/片剂/糖浆/外用剂型。	明胶胶囊壳；硬脂酸镁/硬脂酸/甘油/乳糖；包衣；乙醇溶剂；动物源 API/辅料；酶；微生物培养基；猪源 DNA 风险；GMP 和批次追溯。	配方、API/辅料规格、COA、清真证书、GMP 记录、乙醇声明/检测、供应商声明、批记录。