MASTER COPY

For Restricted Circulation only

SHAKAMBHARI GROUP // SteelWithin	**SHAKAMBHARI ISPAT & POWER LTD.** (Formerly known as Ess Dee Aluminium Ltd.)		
STANDARD OPERATING PROCEDURE			
Title: Procedure for the Handling of Out of Specification (OOS) Test Results			**Page No.** 1 of 5
SOP No.	**Version No.**	**Effective Date**	**Next review date**
SIPL/QCS/007	00	06.07.2026	05.07.2028

1.0 PURPOSE

1.1 The purpose of this Standard Operating Procedure is to define a systematic procedure for reporting, investigating, and handling out of specification (OOS) test results obtained during in-process, incoming, and finished product testing of Aluminium Foil used as primary packaging material for medicinal products.

1.2 This procedure is intended to eliminate the causes of nonconformities, establish the root cause of each confirmed OOS result, and ensure that appropriate corrective action is taken that is proportionate to the effect of the nonconformity encountered, in line with the requirements of ISO 15378:2017.

1.3 It further ensures that no Aluminium Foil batch associated with a confirmed OOS result is released for use, dispatch, or supply until the investigation is complete and a documented disposition decision has been taken by the quality unit.

2.0 SCOPE

2.1 This SOP is applicable to all out of specification test results generated in the Quality Control laboratory and during the manufacturing process of Aluminium Foil.

2.2 It covers OOS results arising from testing of incoming starting materials, in-process samples, intermediate product, and finished Aluminium Foil, including physical, mechanical, dimensional, and surface parameters.

2.3 This procedure applies to all analysts, executives, and functions involved in sampling, testing, review, investigation, and disposition of Aluminium Foil test results.

3.0 REFERENCE(S) & ATTACHMENT(S)

3.1 References:

3.1.1 **In-house:**

3.1.1.1 SOP on Incident Management & Corrective Action.

3.1.1.2 SOP on Control of Nonconforming Product.

3.1.1.3 SOP on Sampling and Testing of Aluminium Foil.

3.1.1.4 Approved Product Specification and Test Procedure for Aluminium Foil.

3.1.2 ISO 15378:2017 Standard – Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP); relevant clauses include 8.7 (Control of nonconforming outputs), 9.1.3.2 (Investigation of OOS results), and 10.2 (Nonconformity and corrective action).

3.2 Attachments:

3.2.1 Attachment-I: OOS Investigation Report.

Prepared By:	Checked By:	Approved By:
05.07.2026	05.07.2026	05.07.2026

SHAKAMBHARI GROUP # SteelWithin	**SHAKAMBHARI ISPAT & POWER LTD.** (Formerly known as Ess Dee Aluminium Ltd.)

STANDARD OPERATING PROCEDURE

Title: Procedure for the Handling of Out of Specification (OOS) Test Results			**Page No.** 2 of 5
SOP No.	**Version No.**	**Effective Date**	**Next review date**
SIPL/QCS/007	00	06.07.2026	05.07.2028

4.0 RESPONSIBILITY

4.1 Quality Assurance Department:

4.1.1 To prepare, review, and maintain this SOP and the associated OOS Investigation Report Form.

4.1.2 To ensure that OOS investigations are conducted, documented, and closed within the defined timelines.

4.2 Quality Control Analyst / Executive:

4.2.1 To report any OOS result to the Quality Control Head immediately on observation, and to retain all original test data, chromatograms, printouts, and samples.

4.2.2 To carry out the Phase I laboratory investigation checklist under the supervision of the Quality Control Head.

4.3 Quality Control Head:

4.3.1 To initiate and supervise the Phase I laboratory investigation and to decide whether a laboratory error is assignable.

4.3.2 To co-ordinate with the Production function for the Phase II full investigation where laboratory error is ruled out.

4.4 Quality Assurance Head:

4.4.1 To review the complete OOS investigation, approve the root cause, corrective and preventive actions, and authorise the final disposition of the affected batch.

4.4.2 To ensure the customer is informed where required and that no confirmed OOS batch is released without a documented concession.

5.0 DISTRIBUTION

5.1 Quality Assurance.

5.2 Quality Control.

5.3 Production (Aluminium Foil Plant).

6.0 DEFINITION(S) & ABBREVIATION(S)

6.1 Definitions:

6.1.1 **Out Of Specification (OOS):** any test result that falls outside the established acceptance criteria (specification limits) laid down in the approved product specification, test procedure, or regulatory / customer requirement for Aluminium Foil.

6.1.2 **Laboratory Error:** an identifiable and assignable error occurring during sampling, sample preparation, testing, calculation, instrument operation, or data recording that is demonstrated to be the cause of the OOS result, and which invalidates the original result.

6.2 Abbreviations:

6.2.1 OOS – Out Of Specification.

6.2.2 QC – Quality Control.

6.2.3 QA – Quality Assurance.

Prepared By:	Checked By:	Approved By:
05.07.2026	05.07.2026	05.07.2026

SHAKAMBHARI GROUP // SteelWithin	**SHAKAMBHARI ISPAT & POWER LTD.** (Formerly known as Ess Dee Aluminium Ltd.)

STANDARD OPERATING PROCEDURE

Title: Procedure for the Handling of Out of Specification (OOS) Test Results			**Page No.** 3 of 5
SOP No.	**Version No.**	**Effective Date**	**Next review date**
SIPL/QCS/007	00	06.07.2026	05.07.2028

7.0 PROCEDURE

7.1 Reporting of an OOS Result

7.1.1 On obtaining a test result that falls outside the specification limits for Aluminium Foil, the QC Analyst / Executive shall not discard any data, sample, or preparation, and shall report the result to the QC Head immediately.

7.1.2 The overall investigation sequence shall follow the flow: Reporting of OOS → Phase I Laboratory Investigation → Phase II Full Investigation (if required) → Root Cause Analysis → Corrective and Preventive Action → Final Disposition → Closure.

7.2 Phase I – Laboratory Investigation

7.2.1 The QC Head shall initiate the Phase I laboratory investigation.

7.2.2 If an assignable laboratory error is identified and documented, the original result shall be invalidated. A re-test shall be performed by a qualified analyst on the original sample; the valid re-test result shall be reported and the OOS closed at Phase I.

7.2.3 If no laboratory error is assignable, the OOS result shall be considered confirmed and the investigation shall proceed to Phase II – Full Investigation.

7.3 Phase II – Full Investigation (Manufacturing Investigation)

7.3.1 A Phase II full investigation shall be conducted jointly by QC, QA, and Production where a laboratory error has been ruled out. The scope shall extend to the manufacturing process, equipment, starting materials, and process controls of the Aluminium Foil.

7.3.2 The full investigation shall cover the following aspects:

7.3.2.1 Review of batch manufacturing and control records for the affected batch.

7.3.2.2 Review of process parameters – rolling, annealing, slitting, and rewinding conditions.

7.3.2.3 Assessment of starting material (aluminium coil / stock) quality and supplier data.

7.3.2.4 Evaluation of equipment performance, maintenance, and any breakdown or deviation.

7.3.2.5 Determination of whether other batches, materials, or in-process stages are impacted.

7.3.3 The sequence for extension of the investigation shall be: affected batch → same-day production → related batches / lots → starting material lot, until the extent of impact is defined and recorded.

Prepared By:	Checked By:	Approved By:
05.07.2026	05.07.2026	05.07.2026

7.4 Major OOS Parameters Observed for Aluminium Foil

7.4.1 The following table maps the major OOS parameters commonly observed for Aluminium Foil against their potential causes and the action to be taken during investigation:

Parameter	Potential Cause	Action
Pinholes	Worn or damaged rolls, embedded hard particles in aluminium, roll surface defects, inadequate lubrication during rolling.	Segregate and quarantine the affected foil; inspect and re-condition rolls; verify lubrication and cleanliness; re-test after correction and assess impact on adjacent batches.
Thickness / Gauge deviations	Incorrect rolling mill settings, roll wear, non-uniform incoming coil, drift in gauge measurement system.	Verify and re-calibrate the thickness gauge; re-check mill settings against the approved parameters; re-measure across the width and length; re-establish process control before resuming.
Bursting Strength failures	Sub-standard starting material, improper annealing, micro-cracks, incorrect alloy or temper of the aluminium stock.	Review annealing cycle and starting material data; re-test on representative samples; investigate supplier lot; hold batch pending confirmation of mechanical properties.
Temper / Hardness issues	Deviation in annealing temperature or time, incorrect furnace loading, variation in incoming alloy composition.	Verify furnace records and annealing parameters; re-check hardness / temper against specification; correct thermal cycle; evaluate all batches processed in the affected cycle.
Surface Contamination	Residual rolling oil, dust, handling marks, contamination from equipment, environment, or transfer containers.	Identify and eliminate the contamination source; review cleaning and line clearance records; clean or re-condition where feasible; assess suitability for use and inform customer if required.

7.5 Root Cause Analysis

7.5.1 Based on the outcome of Phase I and Phase II, the investigation team shall determine the root cause of the confirmed OOS result using a structured approach that is consistent with the type of nonconformity observed.

SHAKAMBHARI GROUP SteelWithin	**SHAKAMBHARI ISPAT & POWER LTD.** (Formerly known as Ess Dee Aluminium Ltd.)

STANDARD OPERATING PROCEDURE

Title: Procedure for the Handling of Out of Specification (OOS) Test Results			**Page No.** 5 of 5
SOP No.	**Version No.**	**Effective Date**	**Next review date**
SIPL/QCS/007	00	06.07.2026	05.07.2028

7.6 Corrective and Preventive Action

7.6.1 Corrective action shall be decided that is appropriate to the effect of the nonconformity, and preventive action shall be defined so that the OOS does not recur or occur elsewhere.

7.6.2 Responsibilities and timelines for each action shall be defined.

7.7 Final Disposition

7.7.1 The QA Head shall take the final disposition decision for the affected Aluminium Foil batch. The possible dispositions are: release (only where the result is invalidated at Phase I), rework or reconditioning under an approved procedure, use under a documented concession authorised by the customer, or rejection and destruction.

7.7.2 The disposition sequence shall be: confirmed OOS → quarantine → disposition decision by quality unit → implementation → record and closure. No confirmed OOS batch shall be released without a documented concession authorised by the customer.

7.7.3 All actions taken during reporting, investigation, root cause analysis, and disposition shall be recorded, and the OOS Investigation Report Form shall be formally closed and retained as per the record retention requirements.

8.0 REVISION HISTORY

Revision No.	00	**Effective Date**	06.07.2026	CC No.	NA
Details of revision: New SOP					

Prepared By:	**Checked By:**	**Approved By:**
05.07.2026	05.07.2026	05.07.2026