

Management Review Report

Report No. MR/000001

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## Management Review Report

Period: 1 Jan 2023 to 30 Nov 2023

Report Number: MR/000001

Participants: QA/QC/RA/MFG Stakeholders

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[A] Internal Audit

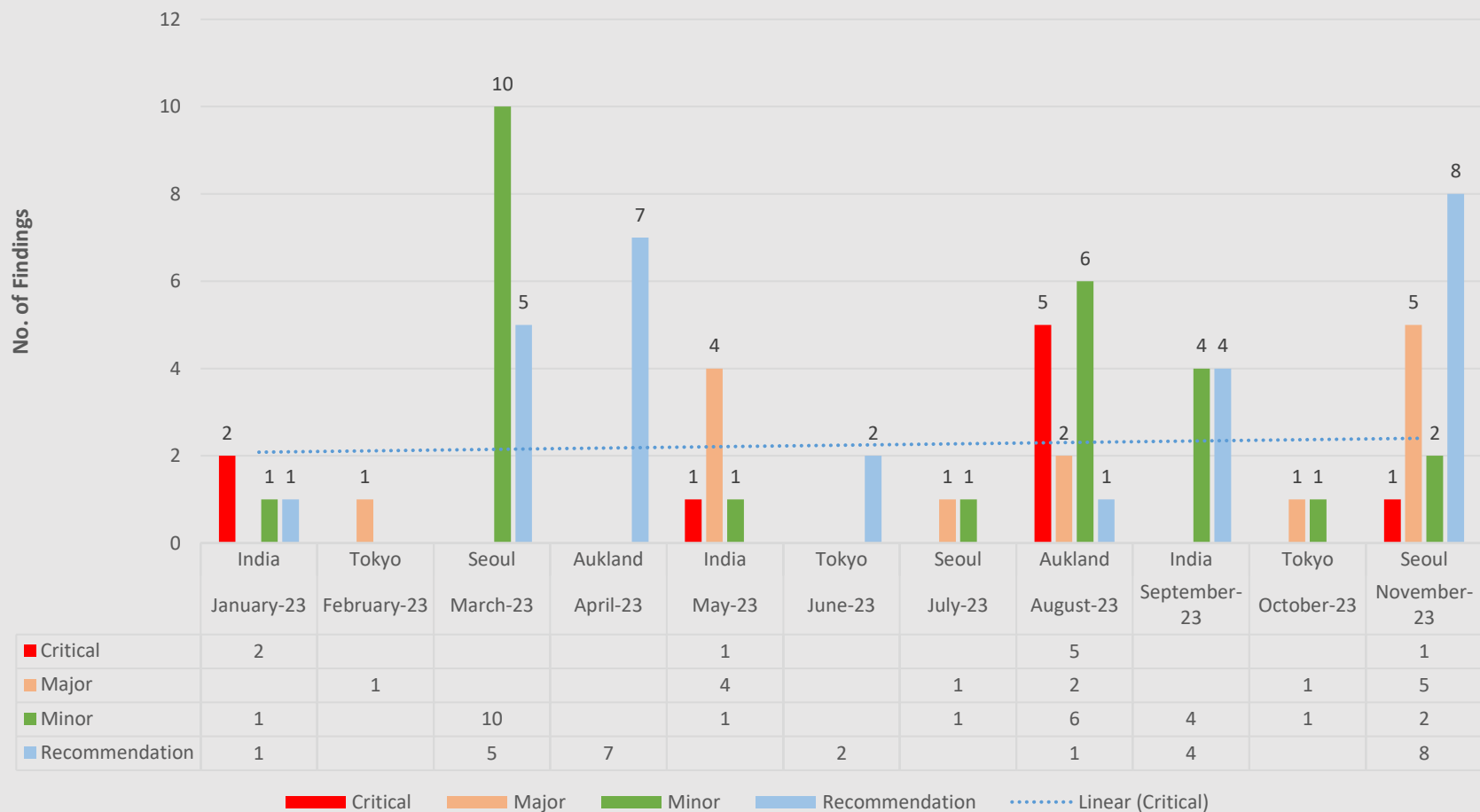
Month	Sites Audited	Critical	Major	Minor	Recommendation	CAPA Details	Closure Details
January-23	India	2		1	1	Yes	Closed
February-23	Tokyo		1			Yes	Work in Progress
March-23	Seoul			10	5	Yes	Closed
April-23	Auckland				7	Yes	Closed
May-23	India	1	4	1		Yes	Closed
June-23	Tokyo				2	Yes	Closed
July-23	Seoul		1	1		Yes	Closed
August-23	Auckland	5	2	6	1	Yes	Closed
September-23	India			4	4	Yes	Closed
October-23	Tokyo		1	1		Yes	Closed
November-23	Seoul	1	5	2	8	Yes	Work in Progress

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### Internal Audit Dashboard



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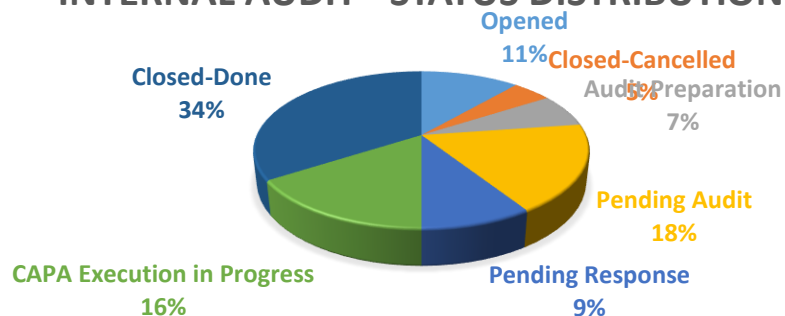
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## INTERNAL AUDIT - STATUS DISTRIBUTION



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[B] External Audit

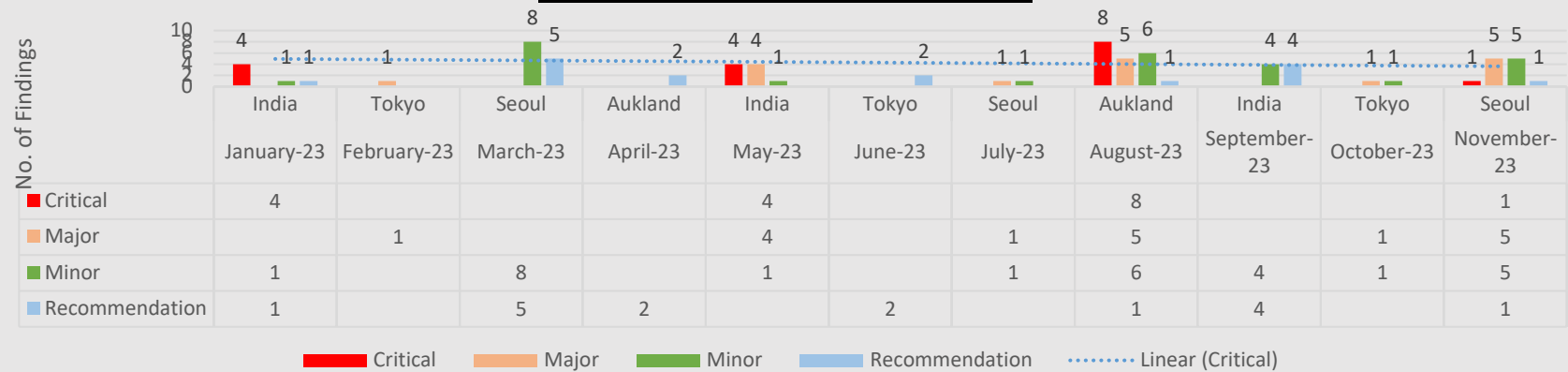
Month	Sites Audited	Critical	Major	Minor	Recommendation	CAPA Details	Closure Details
January-23	India	4		1	1	Yes	Closed
February-23	Tokyo		1			Yes	Closed
March-23	Seoul			8	5	Yes	Closed
April-23	Auckland				2	Yes	Closed
May-23	India	4	4	1		Yes	Closed
June-23	Tokyo				2	Yes	Closed
July-23	Seoul		1	1		Yes	Closed
August-23	Auckland	8	5	6	1	Yes	Closed
September-23	India			4	4	Yes	Closed
October-23	Tokyo		1	1		Yes	Closed
November-23	Seoul	1	5	5	1	Yes	Work in Progress

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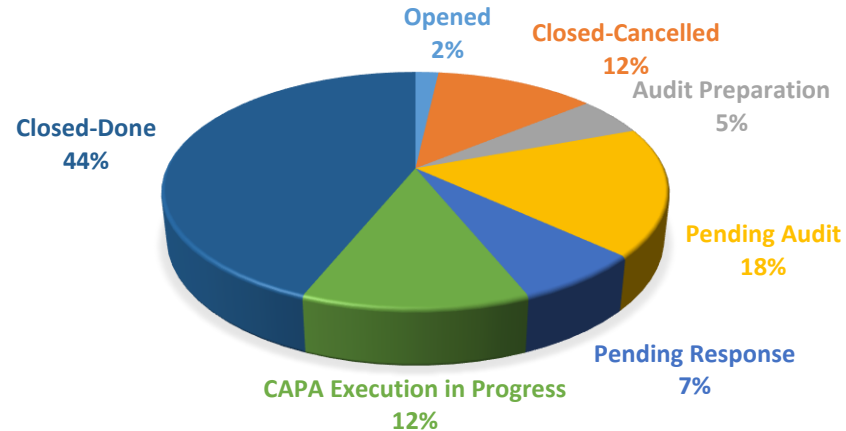
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### External Audit Dashboard



### EXTERNAL AUDIT - STATUS DISTRIBUTION



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#### [C] Action Item Details

Record Number	Short Description	CAPA Type (Corrective Action/Preventive Action)	Date Opened	Site/Division	Date Due	Current Status	Person Responsible	Date Closed
AI001	Equipment Qualification	PA	01/Mar/2023	Site 1	20/Apr/2023	Closed	John	19/Apr/2023

#### [D] Suitability of Policies & Procedures

Efficiency should also be evaluated to ensure best use of allocated resources. There are, therefore, four key parameters that are considered during management review in ISO/IEC 17025:

**Suitability.** Are the correct processes and operations included to enable/support the activities of the laboratory?

**Adequacy.** Evaluate if all the mandatory ISO 17025 contractual, organizational, and regulatory requirements are met.

**Effectiveness.** Evaluate the extent to which the management system is capable of accomplishing the purpose of producing the intended or expected result, i.e., **doing the right things**.

**Efficiency.** Evaluate the best use of resources – the relationship between the results achieved and the resources used, i.e., **doing things right**.

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[E] Status of Actions from Previous Management Reviews

Action Item Details	Owner	Due Date	Status	Remarks
Closure of overdue CAPA	Advin	25/Apr/2023	Closed	NA
Procurement of FTIR in Lab	Donald	19/Jul/2023	Closed	NA

[F] Outcome of Recent Internal Audits

Month	Sites Audited	Critical	Major	Minor	Recommendation	CAPA Details	Closure Details
January-23	India	2		1	1	Yes	Closed
February-23	Tokyo		1			Yes	Work in Progress
March-23	Seoul			10	5	Yes	Closed
April-23	Auckland				7	Yes	Closed
May-23	India	1	4	1		Yes	Closed
June-23	Tokyo				2	Yes	Closed
July-23	Seoul		1	1		Yes	Closed
August-23	Auckland	5	2	6	1	Yes	Closed
September-23	India			4	4	Yes	Closed
October-23	Tokyo		1	1		Yes	Closed
November-23	Seoul	1	5	2	8	Yes	Work in Progress



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[G] Outcome of Recent External Audits

Month	Sites Audited	Critical	Major	Minor	Recommendation	CAPA Details	Closure Details
January-23	India	4		1	1	Yes	Closed
February-23	Tokyo		1			Yes	Closed
March-23	Seoul			8	5	Yes	Closed
April-23	Auckland				2	Yes	Closed
May-23	India	4	4	1		Yes	Closed
June-23	Tokyo				2	Yes	Closed
July-23	Seoul		1	1		Yes	Closed
August-23	Auckland	8	5	6	1	Yes	Closed
September-23	India			4	4	Yes	Closed
October-23	Tokyo		1	1		Yes	Closed
November-23	Seoul	1	5	5	1	Yes	Work in Progress

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[H] CAPA Details

Record Number	Short Description	CAPA Type (Corrective Action/Preventive Action)	Date Opened	Site/Division	Date Due	Current Status	Person Responsible	Date Closed
CAPA-008	Update in GLP SOP	PA	08/Jan/2023	India	30/Mar/2023	Closed	John	28/Mar/2023

[I] Root Cause Analysis Details

Record Number	Short Description	Date Opened	Site/Division	Date Due	Current Status	Person Responsible	Date Closed
RCA-015	Investigation for spillage of material in warehouse	22/Mar/2023	India	22/Apr/2023	Closed	Rakesh	22/Apr/2023

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[J] Lab Incident Details

Record Number	Short Description	Date Opened	Site/Division	Date Due	Current Status	Person Responsible	Date Closed
LI-025	System Suitability failure	08/Jan/2023	India	30/Mar/2023	Closed	John	28/Mar/2023
LI-048	HPLC outage	19/Feb/2023	India	28/Apr/2023	Closed	Meghna	28/Apr/2023

[K] Risk Assessment Details

Record Number	Short Description	Risk Category	Date Opened	Site/Division	Date Due	Current Status	Person Responsible	Date Closed
RA-008	Environment Safety Risk	Major	25/Jan/2023	India	30/Apr/2023	Closed	John	30/Apr/2023

[L] Change Control Details

Record Number	Short Description	Change Type	Date Opened	Site/Division	Date Due	Current Status	Person Responsible	Date Closed
CC-009	Change in Equipment	PC	24/Jul/2023	India	30/Oct/2023	Closed	Ajit	30/Oct/2023
CC-098	Change in HPLC Column	TC	18/Aug/2023	India	30/Nov/2023	Closed	Federic	30/Nov/2023

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[M] Assessment by External Bodies

External Body	Short Description	Type	Site/ Division	Assessment Date	Assessment Details	Date Due	Current Status	Person Responsible	Date Closed	Related Documents
MHRA	Audit	GLP	India	5/Mar/2023	As per MHRA Eudra Vol 4	10/Oct/2023	All observations closed	Om	5/Oct/2023	Refer Attachment

[N] Issues other than Audits

Short Description	Severity (Critical/Major/Minor)	Site/Division	Issue Reporting Date	CAPA Details if any	Due Date	Current Status	Person Responsible	Date Closed	Related Documents
NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

[O] Customer/Personnel Feedback

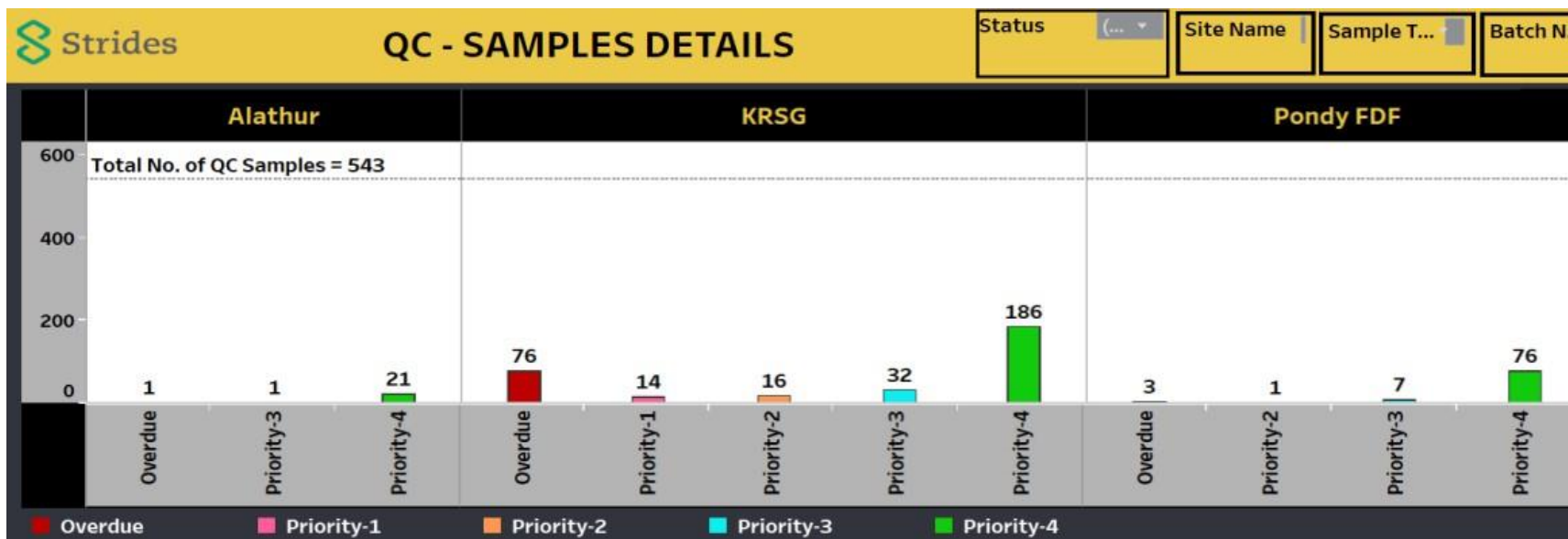
Feedback From (Customer/Personnel)	Feedback Reporting Date	Site/Division	Short Description	Due Date	Current Status	Person Responsible	Date Closed	Related Documents
Customer	5/Jun/2023	India	Update in cleaning validation SOP	5/Aug/2023	Closed	John	5/Aug/2023	Refer Attachment

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[P] Effectiveness Check Details

Record Number	Short Description	Date Opened	Site/Division	Date Due	Current Status	Person Responsible	Date Closed
NA	NA	NA	NA	NA	NA	NA	NA

[Q] QC Sample Details



Tracking of the quality samples from the date of receipt in QC Lab till the completion of analysis and QA release.

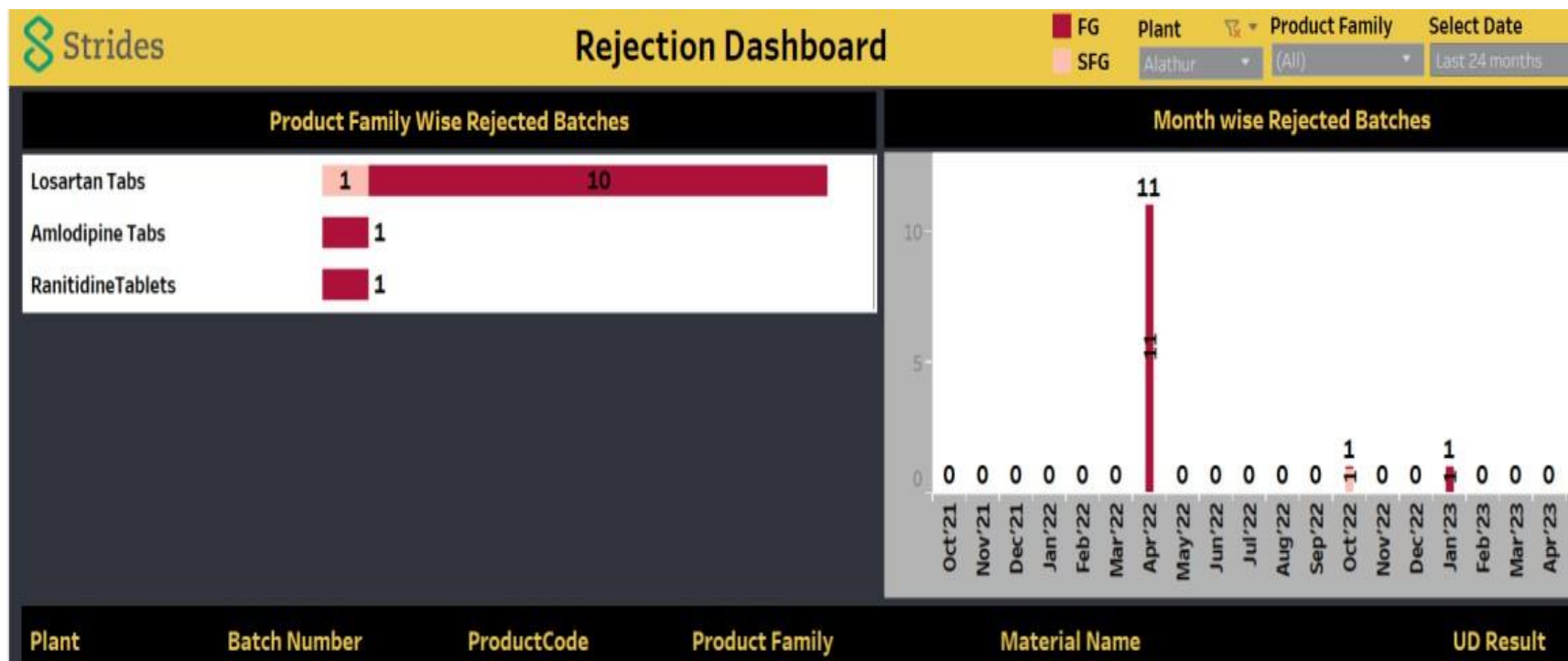
The total number of samples shown in the area bifurcated into 5 categories.

- **Overdue-** If open days>30 Days.

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- Priority 1- If open days >27 days and <=30 days.
- Priority 2- If open days >23 days and <=27 days.
- Priority 3- If open days >15 days and <=23 days.
- Priority 4- If open days <=15 days.

[R] Rejection Analysis



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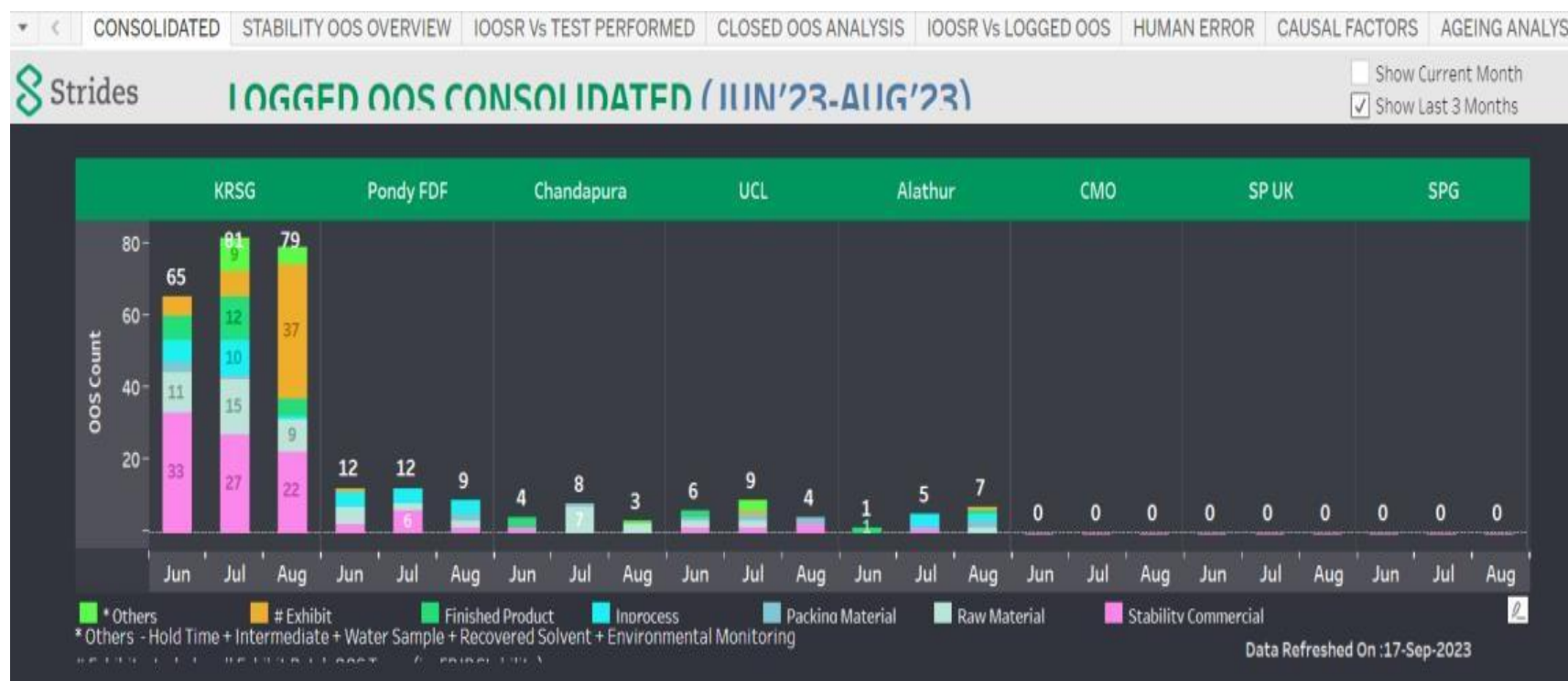
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- The Dashboard shows month-on-month or Q on Q RFT % based on the business formula as below.
- Formula-**  $\frac{\text{Sum of Batches with no OOS/OOT/Deviation (FG+SFG)}}{\text{Total Batches Released FG+SFG}} + \frac{\text{Total Batches Rejected (FG+SFG)}}{\text{Total Batches Released FG+SFG}} \times 100$

Only commercial batches will be considered which are identified by the data from ERP.

[S] OOS



OOS dashboard has the following sub dashboards:

- OOS Consolidated:** sidewise & section-wise no. of initiated OOS
- Stability OOS Overview:** Break-up of the stability OOS & its status.

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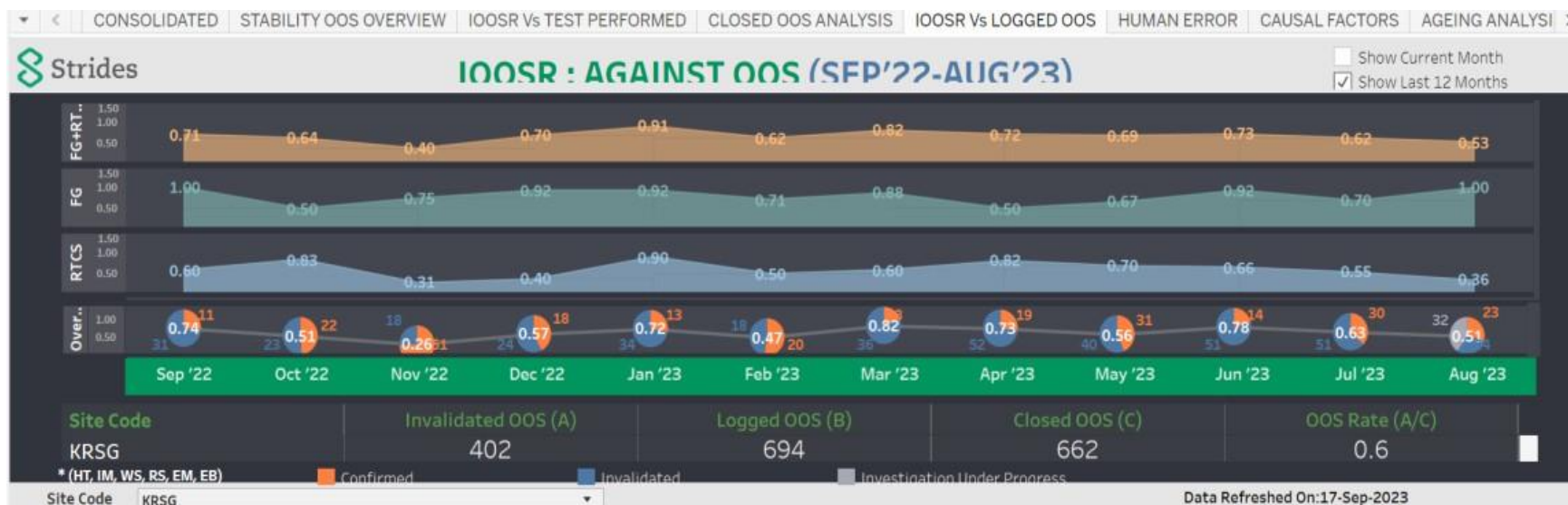
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- Real-time commercial stability failure
  - Upcoming submission (new prod. exhibit)
  - Post expiry
  - New Portfolio (for new product, pack, mkt)
- **IOOSR:** Invalid OOS/total no of OOS logged for
    - FG+RTCS
    - FG
    - RTCS
    - Overall

IOOSR Vs test performed



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#### [T] Summary & Recommendations

All the mandatory processes have been reviewed as mentioned below and found satisfactory.

- status of actions from previous management reviews;
- outcome of recent internal audits and assessments by external bodies;
- changes in internal and external issues that are relevant to the laboratory;
- changes in the volume and type of the work or in the range of laboratory activities;
- assurance of the validity of results;
- results of risk identification;
- corrective actions;
- complaints, customer and personnel feedback;
- other relevant factors, such as monitoring activities and training;
- policies and procedures and fulfillment of objectives;
- implemented improvements; and
- resources.