DEVIATION REPORT

Deviation Number: 3863

Product(s) / Items(s) Affected: M23-071BRU (23/153)

Batches Affected: M23-071BRU (23/153)

Reference(s): SOP-281, PI-232-08

Date(s) of Occurrence: 02-Nov-23 **Date of Discovery:** 02-Nov-23

A) Description of Deviation Attachment No.(s): _____ N/A☐

While secondary packaging, it was noticed that there was an issue with the Checkweigher as per EBM1562.
It was decided that while this issue was being investigated, the batch was to continue as follows:
1) Blisters come into secondary packaging from blisterpacking and is to put into cartons, along with leaflets & inhalers.
2) These cartons are to be put into grey trays (bypassing the checkweigher and the printer) and to be stored in secondary packaging until the checkweigher is fixed. Each tray will contain 8 cartons and will be numbered and recorded on a sheet for traceability in addition to the normal steps of the process instructions.
3) Once the checkweigher is fixed, the cartons will be put through the checkweigher in the same order as collected. The packaging leader will ensure that 8 cartons are transferred from each tray into the line, signing the sheet in Step2.

As per SOP/PI, the steps will be followed as required to capture critical elements/checks.
In process inspections occur while putting cartons into the trays as well as before putting printed kits into the shippers. However, as this is not normal procedure as per SOP-281, this deviation has been raised.

Signed: _____ Date: 07-Nov-23

B) Investigation / Root Cause(s) Attachment No.(s): _____ N/A☐

The cause is that the checkweigher doesn't work. The root cause is to be investigated by Engineering department and Mettler Toledo. Refer to EBM1562.

Signed: _____ Date: 07-Nov-23

C) Immediate Action Taken Attachment No.(s): _____ N/A☐

Batch was immediately stopped upon discovery of issue.

Discussion with Production, Quality and Engineering.

Contacted Mettler Toledo to ask them to come on site to investigate the issue.

Steps undertaken as per Section A.

Signed: _____ Date: 07-Nov-23

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D) Risk Assessment Attachment No.(s): _____ N/A ☐

RAN Reference (if applicable): N/A

Justification of Risk Level Assigned

Assigned Severity: C

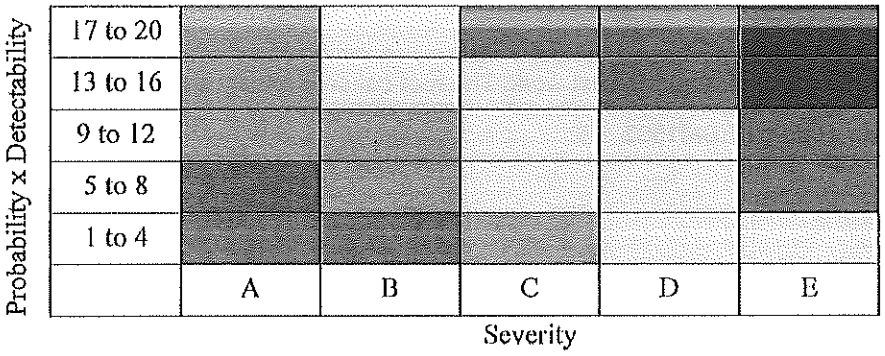
Only possible issue would be a customer complaint due to missing components, missing print on cartons, damaged cartons or delay in delivery while rectifying the issue

Assigned Probability: 2

Unlikely to occur - but it may occur at some point

Assigned Detectability: 1

Always detected by packaging leader via the XMV and Checkweigher during production
There are additional in-process checks: once during initial packaging and once more during check weighing/printing, as well as reconciliation of printed carton against the total physical units. (as described in Section A).
Once complete, all documentation is to be reviewed by Production Management and QA.



Key;

	Indicates assessed as a NEGLIGIBLE RISK
	Indicates assessed as a MINOR RISK
	Indicates assessed as a MODERATE RISK.
	Indicates assessed as a MAJOR RISK
	Indicates assessed as a SEVERE RISK

Initial Risk to Quality Assessment: Negligible Risk ☐ Minor Risk ☑ Moderate Risk ☐
Major Risk ☐ Severe Risk ☐ (please tick one)

Signed: _____ Date: 07-Nov-22

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E) Effect Upon Quality / Justification Attachment No.(s): N/A ☑

There is no impact on quality as the product will not be sent out to the customer without procedding through the checkweigher and printer as per our SOP. However, upon discussion and through the risk assessment it is evident that there is a minor risk and that there is a chance that delivery to the customer may be delayed while this issue is being resolved.

As this is minor risk and with probability 2 and detectability 1, the minor risk is sufficiently mitigated and therefore the risk level is considered acceptable.

Signed: Date: 07-NOV-23

F) Proposed Further Actions Attachment No.(s): N/A ☑

Proposed Corrective/Preventative Actions:

1) Engineering to work with Mettler Toledo to fix the issue and root cause analysis (refer to EBM1562)

2) Production Management and Quality to review document to ensure that the steps were followed correctly and that there are no issues to traceability or quality.

Expected Completion Date: Nov 24 / 22 verified by QA 13NOV23 Department(s) Responsible: Production/Engineering

Proposed By: Luckshen Thurairajah Date: 07-NOV-23

Approved by (Department Manager/Supervisor): Date: 07NOV 23

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G) Conditional Approval

Approval is given with the following conditions: Yes ☐, N/A ☑ (please tick)
If yes state conditions (or Attachment No. _____)

N/A AD 09NOV23
Approved by (Department Manager/Supervisor): Date:
Approved by (QA Manager or Delegate): Date:

H) Final Approval

Regulatory Affairs Approval N/A ☑
Signed: Date:
Conditional Approval Requirements met and verified Yes ☐, No ☐, N/A ☑ (please tick)
Signed: Date:
Risk assessed as minor. The probability and detectability levels indicate acceptable control for the severity level, therefore deviation is approved.
Approved by (Department Manager/Supervisor): Date: 09NOV23
Approved by QA Manager (or Delegate): Date: 09/Nov23

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I) Completion of Further Actions Attachment Yes ☐; No ☑; N/A ☐ (please tick)

Action(s) completed Successfully: Yes ☑; No ☐. (please tick)

Comment: M23 071BRN was retrieved and released as required. EBM1562 was raised and has been CT 11-DEC-23 pre ~~conditionally~~ approved as required - the EBM will be used to identify & rectify the issue/root cause.

Further actions Required: Yes ☐; No ☑. (please tick) CR / CAR No(s). N/A

Verified by: [signature] Date: 11-DEC-23

Department Manager/Supervisor Signed: [signature] Date: 11DEC23

J) Initial Closeout of Deviation - QA

QA Manager (or Delegate) Signed: [signature] Date: 11Dec23

Effectiveness Check Required: Yes ☐; No ☑. (please tick) See Attachment No.(s): N/A

Assigned Risk to Quality on Closeout: Minor

K) Closeout of Effectiveness Check QA

Effectiveness of Actions Deemed Acceptable: Yes ☐; No ☐; N/A ☑ (please tick)

Comments: Minor quality risk, effectiveness check not required.

Further Action Required: Yes ☐; No ☑ (please tick). If Yes through CAR / CR No. N/A

QA Manager (or Delegate): [signature] Date: 11Dec23

L) Final Closeout of Deviation - QA

QA Manager (or Delegate): [signature] Date: 11Dec23

Verified by Head of Quality (or Delegate): [signature] Date: 12Dec23