	<b>FM-016-11</b>	<b>Date Effective: 08-Aug-22</b>	<b>Page 1 of 5</b>
<b>DEVIATION REPORT</b>			

**Deviation Number:** \_\_\_\_\_

**Product(s) / Items(s) Affected:** \_\_\_\_\_

**Batches Affected:** \_\_\_\_\_

**Reference(s):** \_\_\_\_\_

**Date(s) of Occurrence:** \_\_\_\_\_

**Date of Discovery:** \_\_\_\_\_

**A) Description of Deviation**

Attachment No.(s): \_\_\_\_\_ N/A ☐

Signed: _____	Date: _____

**B) Investigation / Root Cause(s)**

Attachment No.(s): \_\_\_\_\_ N/A ☐

Signed: _____	Date: _____

**C) Immediate Action Taken**

Attachment No.(s): \_\_\_\_\_ N/A ☐

Signed: _____	Date: _____

Authorisation signature and date:	Reference: SOP-030
<b>Confidential.</b> Staff must comply with the current version of the document. Reproductions of this document are uncontrolled and may not be the current version. Not for unauthorised distribution.	
TE-002-03	


<b>pharmaxis</b>	<b>FM-016-11</b>	<b>Date Effective: 08-Aug-22</b>	<b>Page 2 of 5</b>
<b>DEVIATION REPORT</b>			

Deviation Number: \_\_\_\_\_

**D) Risk Assessment**

Attachment No.(s): \_\_\_\_\_ N/A ☐

RAN Reference (if applicable):															
Justification of Risk Level Assigned															
Assigned Severity: _____															
Assigned Probability: _____															
Assigned Detectability: _____															
Probability x Detectability	17 to 20														
	13 to 16														
	9 to 12														
	5 to 8														
	1 to 4														
		A	B	C	D	E									
Severity															
		<table border="1"> <tr> <td></td> <td>Indicates assessed as a NEGLIGIBLE RISK</td> </tr> <tr> <td></td> <td>Indicates assessed as a MINOR RISK</td> </tr> <tr> <td></td> <td>Indicates assessed as a MODERATE RISK.</td> </tr> <tr> <td></td> <td>Indicates assessed as a MAJOR RISK</td> </tr> <tr> <td></td> <td>Indicates assessed as a SEVERE RISK</td> </tr> </table>					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
	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														
<p><b>Key;</b></p>															
Initial Risk to Quality Assessment:    Negligible Risk <input type="checkbox"/> Minor Risk <input type="checkbox"/> Moderate Risk <input type="checkbox"/> Major Risk <input type="checkbox"/> Severe Risk <input type="checkbox"/> (please tick one)															
Signed:			Date:												

	<b>FM-016-11</b>	<b>Date Effective: 08-Aug-22</b>	<b>Page 3 of 5</b>
<b>DEVIATION REPORT</b>			


Deviation Number: \_\_\_\_\_

**E) Effect Upon Quality / Justification** Attachment No.(s): \_\_\_\_\_ N/A ☐

Signed: _____	Date: _____

**F) Proposed Further Actions** Attachment No.(s): \_\_\_\_\_ N/A ☐

<b>Proposed Corrective/Preventative Actions:</b>	
Expected Completion Date: _____	Department(s) Responsible: _____
Proposed By: _____	Date: _____
Approved by (Department Manager/Supervisor): _____	Date: _____

	<b>FM-016-11</b>	<b>Date Effective: 08-Aug-22</b>	<b>Page 4 of 5</b>
<b>DEVIATION REPORT</b>			

**Deviation Number:** \_\_\_\_\_

**G) Conditional Approval**

Approval is given with the following conditions: Yes ☐, N/A ☐ (please tick)


If yes state conditions (or Attachment No. \_\_\_\_\_)

Approved by (Department Manager/Supervisor):	Date:
Approved by (QA Manager or Delegate):	Date:

**H) Final Approval**

Regulatory Affairs Approval N/A <input type="checkbox"/>	
Signed:	Date:
Conditional Approval Requirements met and verified Yes <input type="checkbox"/> , No <input type="checkbox"/> , N/A <input type="checkbox"/> (please tick)	
Signed:	Date:
Approved by (Department Manager/Supervisor):	Date:
Approved by QA Manager (or Delegate):	Date:

Authorisation signature and date:	Reference: SOP-030
<b>Confidential.</b> Staff must comply with the current version of the document. Reproductions of this document are uncontrolled and may not be the current version. Not for unauthorised distribution.	
TE-002-03	

	<b>FM-016-11</b>	<b>Date Effective: 08-Aug-22</b>	<b>Page 5 of 5</b>
<b>DEVIATION REPORT</b>			

**Deviation Number:** \_\_\_\_\_

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

Action(s) completed Successfully: Yes <input type="checkbox"/> ; No <input type="checkbox"/> . (please tick)	
Comment:	
Further actions Required: Yes <input type="checkbox"/> ; No <input type="checkbox"/> . (please tick)	CR / CAR No(s). _____
Verified by:	Date:
Department Manager/Supervisor Signed:	Date:

**J) Initial Closeout of Deviation - QA**

QA Manager (or Delegate) Signed:	Date:
Effectiveness Check Required: Yes <input type="checkbox"/> ; No <input type="checkbox"/> . (please tick) See Attachment No.(s): _____	
Assigned Risk to Quality on Closeout:	

**K) Closeout of Effectiveness Check QA**

Effectiveness of Actions Deemed Acceptable: Yes <input type="checkbox"/> ; No <input type="checkbox"/> ; N/A <input type="checkbox"/> (please tick)	
Comments:	
Further Action Required: Yes <input type="checkbox"/> ; No <input type="checkbox"/> (please tick). If Yes through CAR / CR No. _____	
QA Manager (or Delegate):	Date:

**L) Final Closeout of Deviation - QA**

QA Manager (or Delegate):	Date:
Verified by Head of Quality (or Delegate):	Date:

Authorisation signature and date:	Reference: SOP-030
<b>Confidential.</b> Staff must comply with the current version of the document. Reproductions of this document are uncontrolled and may not be the current version. Not for unauthorised distribution.	
TE-002-03	