

#### **FOOD AND DRUGS AUTHORITY**

DOC. TYPE: FORM

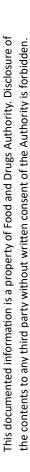
DOC NO.: FDA/MFD/FOR - 06

TITLE: APPLICATION FORM FOR GOOD MANUFACTURING PRACTICES (GMP) VARIATION

# APPLICATION FORM FOR GOOD MANUFACTURING PRACTICES (GMP) VARIATION

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**CONFIDENTIAL** 





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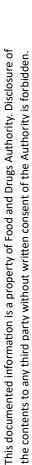
Effective Date: 30/09/2024

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# Variation to a Registered Finished Medicinal Product Facility Application form

Please complete each section of this application form electronically as a Word Document and as a scanned signed Pdf file. Ensure that the electronic and the printed versions of the completed form accompany your submission. Consult the Guideline on Licensing of Drug Manufacturing Facilities (FDA/MFD/GDL-02/03) for variation types and supporting documents to be submitted

1.0	Administrative Information
1.1	Application Name and address:
1.2	Location Address
1.3	Dosage forms manufactured on site
1.4	Licence/Certificate Number for site
1.5	Variation type: (tick all applicable options)
	☐ Minor variation – notification
	☐ Minor variation – prior approval
	☐ Major variation
1.6	Variation Description:
1.7	Reason for variation:
1.8	Associated Finished Pharmaceutical Product (FPP) Name (if applicable)
2.0	Variation Details





2.1

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**Variation Description** 

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	Single variation	riations		
2.2	Summary of proposed changes:			
	Current details	Prop	oosed details	
	December the share we			
2.3	Reason for change:			
2.4	Date of implementation (for Notif	ications only)		
2.5	Impact on product quality, safety	and efficacy:		
2.6	Relevant documentation (protoco	ols, reports etc.):		
The	e following documents have been subm	nitted together with this	application form:	
	Note: All documents must be provided be valid.	for this application to		
	Supporting documentation			
	All supporting documents as stipulated should be included in this submission	d for the change in the	☐ Yes	
L			1	l



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(For multiple variations (grouped variations), reproduce this section 2 and provide separate summaries for each proposed variation.)

3.0	Declaration
Pleas	se check all declarations that apply.
I dec	are that:
	For each change, all conditions for the change requested are fulfilled.
	There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.
	The information submitted is true and correct.
Name	ə: 
Signa	ature: Date: