General Requirements

For the Rules and Procedures Governing Manufacturing for Export Purposes

Code: NP. PPMA.006

Version No: 1

Version date: 2021

Effective date: 2021

Annex (1): Application Form for Manufacturing Pharmaceutical Products for Export Purposes

To be printed on the company's official letterhead and stamped with the company seal

Application Form for "Manufacturing for Export"					
1) Company / Applicant Information					
Name of the Applicant Company:			Name of the Product Owning Company: (or its representative / authorized agent)		
Name of the Manufacturer:			Production Line and Licensing Status:		
Contact No.:			E-mail Address:		
2) Product Information					
Product Name:			Pharmaceutical Form: Final Form for Export:		
Country of Origin: (Registration license attached, including the composition statement)			Country of Marketing / Distribution: (Proof of marketing authorization attached)		
- Active raw materials required to be imported:			- Final Product:		
#	Active Ingredients	Quantity	Unit	Product Quantity	Unit
1					
2					
3					
Other products are manufactured at the same manufacturer containing the same active raw materials included in the aforementioned product.					
☐ Yes			☐ No		
Please specify these active ingredients: 1---------- 2---------- 3----------					

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Annex (2): Declaration Form for Manufacturing for Export of Pharmaceutical Products

To be printed on the company's official letterhead and stamped with the company seal

To: Export Support and Follow-up Administration – Egyptian Drug Authority
Greetings,

With reference to the request for approval of manufacturing for export for the product submitted on: _____, we hereby declare that:

We, _____, fully undertake the following:

1. **That the import of raw materials, manufacturing process, and export of the final product are entirely under the responsibility of the company, with no liability whatsoever on the Egyptian Drug Authority.**
2. **That the manufactured product or any remaining quantities of raw materials will not be circulated within the Arab Republic of Egypt.**
3. **That raw materials imported under the manufacturing-for-export system will not be used in the production of locally registered products with the Egyptian Drug Authority, and likewise, raw materials of locally registered products will not be used in manufacturing under the export-only system.**
4. **That the products manufactured for export comply in composition, specifications, and requirements with the regulations of the country of origin and/or the country of marketing.**
5. **That the company bears full responsibility for the safety, efficacy, quality, and suitability of the active raw materials used in the product, and their intended purpose, with no liability whatsoever on the Egyptian Drug Authority.**
6. **That shipments of imported raw materials do not contain any narcotic substances, explosives, radioactive materials, or any prohibited substances.**
7. **That all data provided in the submitted documents are true and accurate.**

With highest respect and appreciation,
Responsible Person Name:
Job Title: **Company Seal**
Signature:
Date:

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Annex (3): Export Approval Request Form in Case of Manufacturing for Export of Pharmaceutical Products

To be printed on the company's official letterhead and stamped with the company seal

To: Export Support and Follow-up Administration – Egyptian Drug Authority

Greetings,

- Kindly provide approval regarding the export of the shipment covered by the letter and its details as follows:

Date of Request	
Company Name	
Invoice No.	
Invoice Date	
Invoice Value / Currency	
Manufacturing for Export Approval Number	
Destination Country	
Customs Port	

With best regards,

Responsible Manager – Job Title:
Name:
Signature:

** The request must be stamped with the company seal and printed on the company's official letterhead bearing the company logo.

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Annex (5): Export Declaration Form

To be printed on the company's official letterhead and stamped with the company sea

To: Export Support and Follow-up Administration – Egyptian Drug Authority

Greetings,

- Regarding the export of the shipment covered by Invoice No. _____ to the country of _____, the company hereby undertakes that the export process is entirely under the company's responsibility, without any liability whatsoever on the Egyptian Drug Authority.

- The company also undertakes that the products listed in the invoice, as well as their raw materials, are the responsibility of the manufacturing company, and that no non-compliance decisions have been issued against them.

Responsible Manager – "Job Title":
Name:
Signature:

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Annex (5): Export Approval Request Form in Case of Manufacturing for Export of Pharmaceutical Products

To be printed on the company's official letterhead and stamped with the company seal

To: Export Support and Follow-up Administration – Egyptian Drug Authority

Greetings,

- Kindly provide approval regarding the export of the shipment covered by the letter and its details as follows:

Date of Request	
Company Name	
Invoice No.	
Invoice Date	
Invoice Value / Currency	
Destination Country	
Customs Port	

With best regards,

Responsible Manager – Job Title:
Name:
Signature:

Upload