DECLARATION ON QUALITY MANAGEMENT SYSTEM FOR ATYPICAL ACTIVE PHARMACEUTICAL INGREDIENT (API) MANUFACTURER BY COMPETENT PERSON

PART A: PRODUCT DETAILS

Product Name	
Product Reference Number[1]	
Name of Atypical API	
Name of Atypical API Manufacturer	
Address[2] of Atypical API Manufacturer	
Name of Finished Product Manufacturer	
Address[2] of Finished Product Manufacturer	
Product Registration Holder	

PART B: DECLARATION BY COMPETENT PERSON

The undersigned hereby declare that:

i. I am authorized to release the finished product based on the predetermined specification and responsible to put the finished product in the market.

ii. The manufacturer and/ or supplier of the atypical API is an approved supplier according to the finished product manufacturer's quality management system.

iii. I hereby reviewed the quality of the concerned Atypical API which is stated in Part A.

iv. I undertake to ensure that the Atypical API specified in Part A has been manufactured in accordance with recognised quality management system.

v. I have reviewed the manufacturing process of the atypical API which is received by the finished product manufacturer to be used as API in the manufacturing process of the concerned finished product.

vi. Each lot or batch of the atypical API shall be tested against and comply with the specifications established by the finished product manufacturer for that atypical API.

vii. I have reviewed the distribution activities conducted by the supplier for the atypical API which is used as API in the manufacturing process of the concerned finished product.

PART C: NAME AND SIGNATURE OF COMPETENT PERSON RESPONSIBLE FOR THIS DECLARATION

This declaration is submitted by the following Competent Person[3] of the finished product manufacturer (stated in Part A):

Signature of Competent Person:	Signature of Superintendent:
……. (Together with official stamp) Name: Designation: Date:	……. (Together with official stamp) Name: Designation: Date:

1. *This refers to the reference number assigned to the finished product submitted for registration with National Pharmaceutical Regulatory Agency (NPRA).*
2. *State the site address(es) in detail, including the building numbers (Lot No. or block no.) & country.*
3. *Competent person: The personnel who is responsible to release the finished product and placing the finished product in the market.*