MEDICINE: GENIRIC APPLICATION

STEP 1: (APPLICATION TYPE)

Application Sub Concern: (drug, vitamin drug, narcotics)

Line Extension Type: Applicable (***specify type***) Not applicable

Submission type:

- (•) Local
- ( ) Import

Marketing Authorization Holder (MAH)

Country**: ……**

Name of MAH: ……..

Office Address: ……..

STEP 2: (INGREDIENTS)

Add New Ingredients

(If more than one API, you have to fill above info for each one)

Name of Active Ingredient(s): ……..

Quantity: ……

API Reference :

- (•) Monograph; Monograph Name: ……
- ( ) In House

Specification No. : ……

Specification Date: ……

Add New Excipient

(You have to fill below info for each one)

Name of Excipient(s): ……

Quantity: ……

Excipient Reference:

- ○ Monograph; Monograph Name: ……
- ○ In House

Function: ……

STEP 3: (CLINICAL USE & ATC CODE)

Dispense Category: ……

Package Leaflet Revision No.: ……

Package Leaflet Revision Date: ……

Package Leaflet Type:

- ☐ Professional
- ☐ Patient

Indications / Uses of Product: ……

Administration Route: ……

Does this product have an ATC Code?

- ◉ Assigned; ……
- ○ Not assigned (*if not assigned yet).*

STEP 4: (PRODUCT INFORMATION)

4.1. GENERAL INFORMATION

Trade Name in Country of Origin (for Import Drug): ……

Proposed Trade Name in Jordan: ……

Product Strength: ……..

Dosage Form: ……..

Package Size: ……..

Product Reference Pharmacopeia:

- ◉ Monograph; Monograph Name: ……..
- ○ In House

Shelf Specification No.: ……

Shelf Specification Date: ……..

Release Specification No.: ……..

Release Specification Date: ……

Suggested Public Price: …… *(For each pack size)*

Do you have a Diluent as a part of product package?

- ☐ yes
- ☐ No

Type of Diluent: ……..

Packaging Material: ……..

Shelf Life: ……

Diluent Specification No.: ……..

Diluent Specification Date: ……..

Storage Conditions: ……

4.2. PACKAGING INFORMATION

Administration Device (if Applicable): ……

Primary Packaging material: ……..

Secondary Packaging material : ……

Shelf Life: ……

Shelf Life after Opening Container: ……

Shelf Life after Reconstitution or Dilution: ……

Storage Conditions: ……

Storage Conditions after First Opening: ……

4.3. STABILITY STUDY

Stability Conditions: ***(should be filled for accelerated and for real time conditions)***

Temperature	.℃
Humidity:	%
Duration:	Month(s)
Light:	Cd
Pressure	Bar

Study Summary Sheets for Every Stability Study:

Batch Number: ……

Batch Size: ……

Name of Manufacturer: ……..

Date of Manufacturing: ……..

Expiry Date: ……..

Batch Type: ……

4.4. OTHER INFORMATION

General information:

Invoicer: ……

Shipment Country: ……..

Criteria of pharmaceutical products (CPP):

- Has CPP (certificate of pharmaceutical product) from country of Origin?

If Yes; Reason:

CPP Country: ……., CPP No.: ……., CPP Date: ……..

If No; Reason:

- Do you have a marketing authorization (or free sales) certificate from a reference country?

If Yes; Certificate Country: ……., Certificate No: ……., Certificate Date: ……

If No; Reason: ……

- Do you have any material of animal source contained in any component of the product?

If Yes; Material: ……..

Animal: ……

Animal Part: ……..

Country: ……..

Free From BSE/TSE Certificate Number: ……

STEP 5: (MANUFACTURERS)

5.1. ACTIVE INGREDIENT(S) MANUFACTURER *(FOR EACH API SHOULD BE FILLED*

Name of supplier: ……..

Name of manufacturer: ……..

Office address: ……..

Plant address: ……..

Phone: ……..

Fax: ……

Postal zip code: ……..

Country: ……..

City: ……..

Activity: …….. (This will be API production but sometimes it may be involved in other steps like micronisation….etc)

- Is it CEP certified?

Yes; CEP No.: ……

No; Other Certificate: ……..

Name of active ingredients: ……

5.2. EXCIPIENTS MANUFACTURER *(**THIS IS OPTIONAL**)*

Name of supplier: ……..

Name of manufacturer: ……..

Office address: ……..

Plant address: ……..

Phone: ……..

Fax: ……

Postal zip code: ……..

Country: ……..

City: ……..

Activity: ……..

Name of Excipients: ……

5.3. FINISHED PRODUCT MANUFACTURER

Is this product under-license?

- Yes; Name of licensor: ……..
- No

Finished Product Manufacturing Sites?

- Complete
- Contract

Manufacturing site type: *(for each step: bulk, primary packaging, secondary packaging, batch releaser)*

Country: ……

Name of manufacturer: ……

Production line: ……..

Plant Address: ……

5.4. DILUENT MANUFACTURER

Country: ……..

Name of manufacturer: ……..

Production line: ……

STEP 6: (BIOEQUIVALENCE)

- Does this Product have a Bioequivalence Study?

If Yes:

Study Title: ……

Study Protocol No: …… Study Protocol Date: ……..

Study Condition: Fed, Fast

Study Initiation Date for Period I: …… Study Initiation Date for Period II: ……

Clinical Site: ..... Clinical Country: .....

Bio-analytical Site: ..... Bio-analytical Country: .....

Bio-analytical Completion Date: .....

Clinical site / Inspection Report GCP Date From: .....To: .....

Bio-analytical Site / Inspection Report GLP Date From: .....To: .....

If No; Bioequivalence:

- Is it Bio-waiver Request or other type?

If Bio-waiver Request:

BW Request Reason: .....

- Dissolution?

If Yes;

Dissolution Method: .....

Proof of dose proportionality: .....

If No; Study Type: .....

If Other Study;

Study Title: .....

Study Protocol No: ..... Study Protocol Date: .....

Study Condition: Fed, Fast

Study Initiation Date for Period I: ..... Study Initiation Date for Period II: .....

Clinical Site: ..... Clinical Country: .....

Bio-analytical Site: ..... Bio-analytical Country: .....

Bio-analytical Completion Date: .....

Clinical site / Inspection Report GCP Date From: ..... To: .....

Bio-analytical Site / Inspection Report GLP Date From: .....To: .....

Reference Products Information

Reference Product Name: ……..

Reference product strength: ……

Reference product dosage for : ……

Manufacturer: ……..

COA: ……

Marketing Authorization Holder (MAH) : ……..

Bio-batch No: ……

Test Products Information

Bio-batch Manufacturer: ……

API Source : ……

Master Formula No : ……

Master Formula Date: ……..

Bio-batch No : ……..

Bio-batch Size : ……..

Bio-batch Type:

- ○ Pilot
- ○ Production

COA: ……..

STEP 7: (SCIENTIFIC ADVICE)

- Was there any formal scientific advice given by the JFDA for this medicinal product?

○ If Yes; Scientific Advice Number: …… Scientific advice Date: ……..

Priority Request

Please Tick the Appropriate box(s) if your application fulfill one or multiple conditions from below as a priority request:

☐ Therapeutic advantage; Drugs that appears to have Therapeutic advantage / Treat life threatening disease / an advance over available therapy

☐ First-Second Generic; First – Second Generic

☐ Listed on JFDA Website; Drugs listed on JFDA website as market needed

☐ Has a priority approval in reference country; Drugs that approved according to priority in one of the reference countries

Status of the Application in other Regulatory Agencies

Authorization Description: ……

Notes: …….