

# Pharmaceutical Registration Manual

Under license production / finished import -April 2023



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## 1- Introduction:

The Islamic Republic of Iran requires each importer of pharmaceutical related products to register the brand, supplier and the manufacturer in the Ministry of Commerce (MOC) and Ministry of Health (MOH) of Iran prior to importing any products to the country.

The websites to the chamber of commerce and MoH are as follows:

Iran Chamber of commerce - <https://iccima.ir/>

Iran Ministry of Health - <https://www.fda.gov.ir/>

The first step in the registration process is to register the brand name of the parent company in the Ministry of Commerce of Iran. In order to do so, the agent of the parent company requires submitting a true copy of the “Exclusive Distributorship Agreement” between the two companies to the MOC. This document should be signed and approved by the Ministry of Commerce or Chamber of Commerce and the Embassy of Iran in the parent company’s country of origin.

After registering the parent company’s name and brand in MOC, the agent in Iran has to apply for registering the manufacturing plants of the products in Ministry of Health of Iran. MOH requires a list of documents that has to be given by the parent company and submitted by the agent in order to register the manufacturing plant prior to registration of the products.

Each product/raw material that is imported to Iran, requires an IRC Code (Iran Registration Code). This IRC code is a unique code for each and every product. In order to obtain the IRC Code, the agent has to register each product/raw material in MOH and the TTAC - Tracing, Tracking and Authentication Control System ([www.ttac.ir](http://www.ttac.ir)).

The registration process is time consuming; it normally takes around 6 to 8 months (depending on the product) to register a manufacturer and its products in the MOC and MOH. Bear in mind that the mentioned time exceeds if the documentation submitted is incomplete or has to be revised.

Note: Iran MOH has the right to audit the manufacturing plant before Issuing the IRC.

The current manual is published to help you grasp a better understanding towards the Iranian Ministry of Health registration procedures in detail. The forms and samples of such documents are put within the appendix as a reference for you.

Pharmaceutical under license production refers to a product whose pharmaceutical name, formulation, manufacturing method, all physicochemical properties are in accordance with the Product License Holder's (PLH) file, and all components and packaging, as well as the final product, have the product specifications of the PHL and have been approved.

**Illustrated and arranged by**

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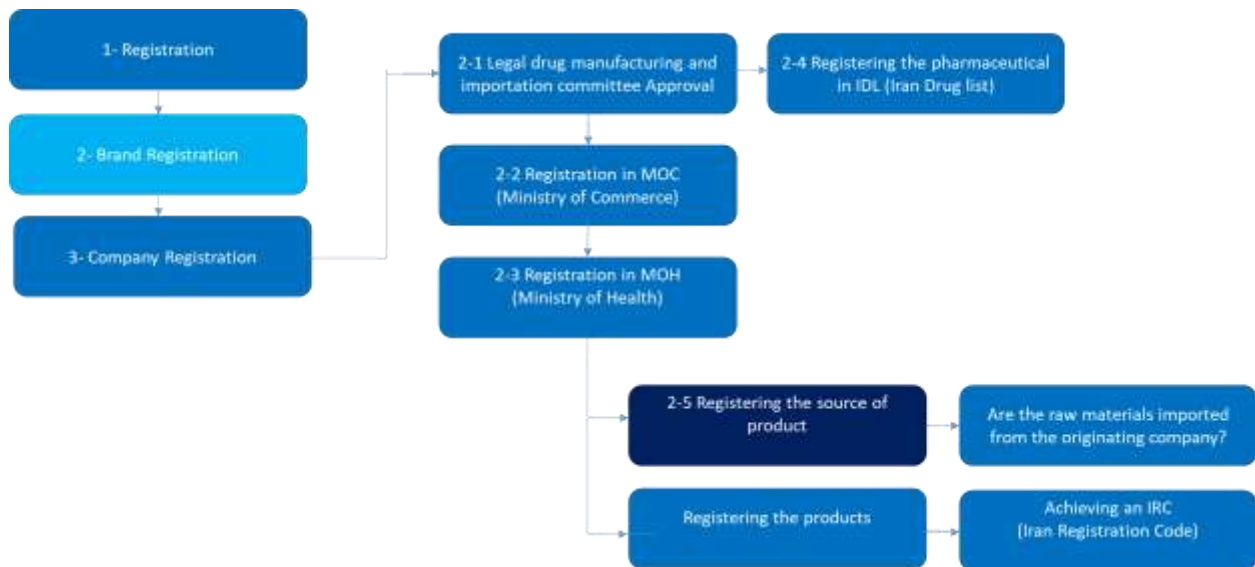
**Regulatory Affairs Manager**

## 2- Under license production terms

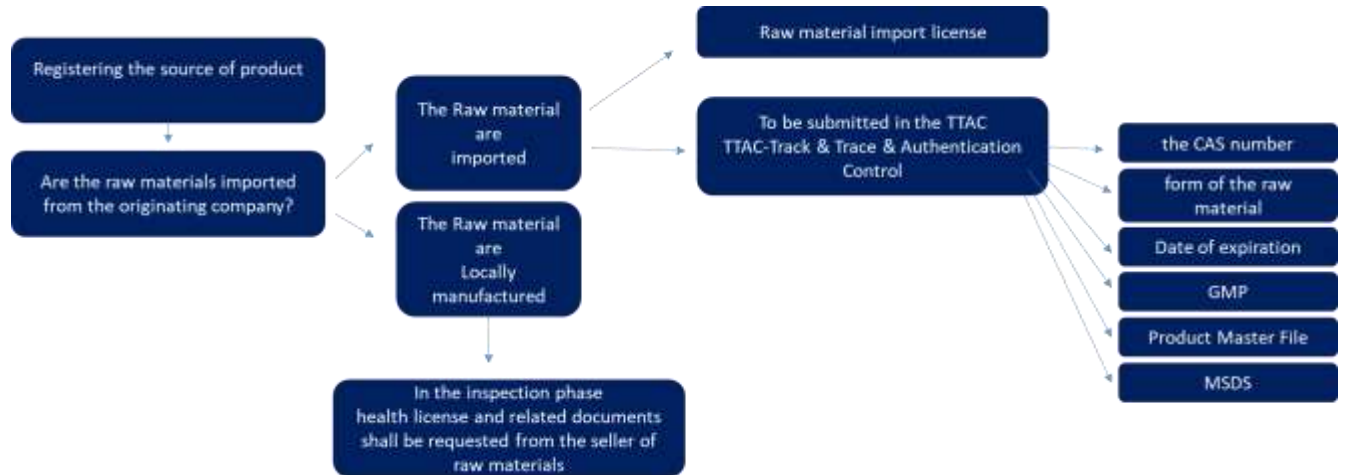
2-1 The pharmaceutical product selected for Under license production must be in-line with the Iranian Drug list

2-2 Should not be stated within the illegal manufacturing or importing pharmaceutical list

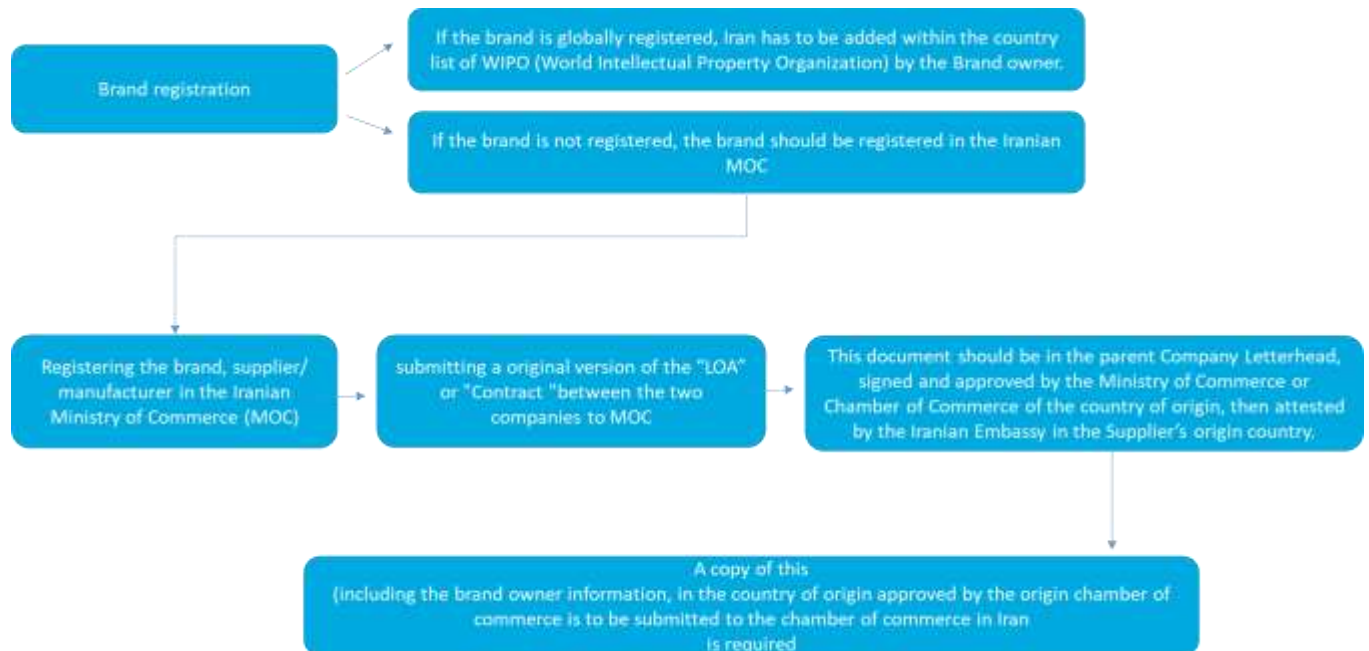
2-3 Must have US FDA (Food and Drug Administration) or European Medicines Agency (EMA) approvals



## Registering the source of the product:



## Brand registration procedure:



### **3- General requirements for initially applying for import/under license manufacturing**

3-1 Distribution agreement for under license production

3-2 A timetable for each of the under license manufacturing phases in addition to stating the place of the production facility and packaging

3-3 Certificate of Pharmaceutical Product (CPP) or Free Sale Certificate

3-4 International approvals if necessary

3-5 An original version of the GMP

Please note the following:

All documentation stated in the above, must be issued by a legal authority of the country of origin (parent company) on the parent company letter head, approved by the ministry of commerce or the chamber of commerce in the country of origin then attested by the Iranian embassy in the country of origin.

A document containing the registration information of the brand owning company in the country of origin, which has been approved by the Chamber of Commerce, must be submitted to the Chamber of Commerce.

Once the stated documents are reviewed, the case shall be mentioned in the legal committee for drug manufacturing and importation.

Then after the approval for importing or under license manufacturing is achieved, all documents requested in clause 3 have to be legalized and shared with the Iranian MoH in order to proceed.

#### **4- Under license manufacturing phases**

Based on the importing/supplying company's request and achieving the approval for production from the legal committee for drug manufacturing and importation, under license manufacturing shall cover a part or all of the stages below:

4-1 Importing the finished dosage form (FDF) specifically for a certain time period

4-2 Importing the pharmaceutical as bulk\* and primary packaging

The definition of bulk means, the formulated product in the desired drug form before packaging

4-3 Manufacturing the first production series from the granule phase ready to be pressed (tablet) or to be filled (capsules)

4-4 Manufacturing the first production series from the API (Active pharmaceutical Ingredient) phase and pharmaceutical formulation

Please note that depending on the timetable and business model agreed between the two companies, each model requires different set of documentation.

## **5- Requested documents for each under license manufacturing collaboration method**

To be presented to the MOH:

### 5-1 – The importation of finished dosage form (FDF)

- Under license contract and its official translation – Original document and approved copy
- The legal committee for drug manufacturing and importation approval for under license manufacturing
- Technical responsible license copy
- CTD (Common Technical Document) from the PLH Product license holder
- GMP

Once the above mentioned documents are approved, the IRC (Iran Registration Code) for importing is presented.

### 5-2 – Primary packaging approval

- The CoA (Certificate of Analysis) of the pharmaceutical bulk along with the related quality control papers
- The Pharmaceutical Bulk Periodically stability test report (holding time) for the industrial batches from the PHL
- Packaging permeability tests results in Iran from the applicant
- The Analysis report of the packaging participants from the applicant
- GMP of the production site in Iran
- Artworks



5-3 – Manufacturing the first production series from the granule phase

- GMP
- CTD
- All documentation related to the using granule

5-4 – Manufacturing the first production series from the API phase

- GMP
- CTD
- All artworks having the how to use/instructions section and the ingredients part written in in English and Persian

### **Registration process in Iran for under license products:**

#### **A) Source registration:**

At first, source of origin must be separately registered in IFDA for every product.

Needed documents:

- The COA of premix issued by the manufacturing site and COA of raw materials.
- Manufacturing site GMP.

NOTE: All RM's sources must be registered in Iran, usually most raw material sources have been registered before by other companies. In case some sources have not been registered by now, we must register them by ourselves. For this, we need COA of raw materials.

## **B) Analysis of finished product samples:**

For each product, it's necessary to have adequate sample of the latest batch for analysis and stability test

- The analysis includes: assay of active ingredients according to your COA and label claim, appearance, flavor, percentage of humidity, microbial and heavy metal tests, integrity, for tablet and capsule; disintegration and dissolution, average weight, ....
- The accelerated stability test: samples are exposed to  $40\pm 2$  °C, Relative Humidity  $75\pm 5\%$  in chamber of accredited laboratory, and be analyzed for 0,3 and 6<sup>th</sup> months.

This step could be consequently done with the steps of A & C.

## **C) Submission of required documents to IFDA**

**Filled PMF:** PMF is a formal questionnaire which must be filled for every product separately (its responsibility is with us) and must include: formulation (active and inactive ingredients), dosage form, directions, side effects, caution and warning, storage condition, detailed manufacturing procedure for finished product, method of analysis for assay of all active ingredients, art work (Label, Leaflet, Box) (as bilingual), the name of original company, license holder and the manufacturing plant where filling will be done. Some of them will be written according to origin company's COA, COC and PMF/PIAF such as formulation, dosage form, ..., and others be written according the international references such as side effects, caution and warning.

The acceptable references by Iran FDA are US Pharmacopoeia, Natural Medicines, Health Canada, British Pharmacopoeia.

### List of documents needed for under license production in general:

- 1- GMP
- 2- List of countries in which the product has been registered and marketed (bearing the brand name, registration date and number)
- 3- Letter of Authorization (LOA)
- 4- Letter of approval of the production line of the product manufacturing X company in Iran by the parent company.
- 5- Letter of approval that the API used in the production process of under license manufacturing company is the same as the parent company API.
- 6- COA of premix powder or liquid
- 7- COA of API & excipient
- 8- COA of finished product
- 9- PIAF (Product Importation Application Form) signed and stamped by parent company
- 10- Method of analysis
- 11- MSDS
- 12- Detailed manufacturing procedure for finished product.
- 13- Master formula/Batch sheet (list of ingredients, API/EXCIPIENT & their Qty.)
- 14- Stability tests
- 15- Packaging material specification. (Foil/Blister/Bottle)
- 16- Art work files (Label, Leaflet, Box)
- 17- Samples of API and FDF are required.
- 18- If the brand name is registered in WIPO (World Intellectual Property Organization), add the name of Iran to it's list.
- 19- Trademark registration certificate in the country of origin and permission to use the brand name in Iran.

## **Good Manufacturing Practice (GMP)**

The GMP certificate has to be issued by one of recognized authorities and has to clearly mention the phrase of “Good Manufacturing Practice” in their letter.

## **Free Sale Certificate (FSC)**

You can find the Template of Free sale certificate in the Appendix. The authorized body can issue this certificate for you and you have to just get it signed and approved by the Iran Embassy.

Here are some points which should be noted in Free Sales Certificate:

1. Please make sure that you state the full address and phone number of the manufacturer.
2. The Certificate has to be on a letter head of the authorized body.
3. Please make sure that all pages of the certificate are signed, stamped and bundled together.
4. Please note that you have to submit a Free Sales Certificate per Manufacturing Plant. For example, if you have part of your product manufactured in a factory in Italy and you have some products manufactured in France, you will require 2 separate Free Sale Certificates, one for the manufacturing plant in Italy and one for the manufacturing plant in France.
5. Please make sure that you indicate the Brand name in front of each product in the Product Table.
6. The date of issue should not proceed to more than two years.

## Letter of Authorization(LOA)

One of the most important steps is to submit a true copy of a legalized “LOA”. We need to receive an authorization letter based on that we will be authorized for registration, manufacturing under license, marketing, distribution and sales your products as your business partner. You can find the sample of LOA in the Appendix.

## Health Certificate

You can find the Template of the Health certificate in the Appendix. This certificate has to be filled out either by your manufacturer and signed and approved by the authorized Body (such as MOH or Chamber of Commerce of your country) and Iran Embassy in the country of Origin. On the other hand, the authorized Body such as MOH or Chamber of Commerce of your country) can issue this certificate for you and you have to get it signed and approved by the Iran Embassy.

Here are some points to keep in mind while filling out the Health Certificate:

1. Please make sure that you have stated the date correctly since this document is valid only for a year from the date of issue.
2. Please make sure that you state the full address and phone number of the **manufacturer**.
3. The Certificate has to be on a letterhead of either the manufacturer or the authorized body.
4. Please make sure that all pages of the certificate are signed, stamped and bundled together.
5. Please note that you have to submit a Health Certificate per Manufacturing Plant. For example, if you have part of your product manufactured in a factory in Italy and you have some products manufactured in France, you will require 2 separate Health Certificate, one for the manufacturing plant in Italy and one for the manufacturing plant in France.
6. Please make sure that you indicate the Brand name in front of each product in the Product Table. Look at the sample below.

\*\*Sample: Brand of ABC has three different product categories: 1- Shampoo, 2- Conditioner and 3- Body wash. Here is how the product table looks like:

<b>ABC® Shampoo</b>
ABC®, Shampoo for dry hair
ABC®, Shampoo for normal hair
Etc...
<b>ABC® Conditioner</b>
ABC®, Conditioner for dry Hair
ABC®, Conditioner for normal Hair
Etc...
<b>ABC® Body Wash</b>
ABC®, Body Wash Energy
ABC®, Body Wash Active
Etc...

## APPENDIX 1- GMP

A GMP certificate is required in order to register the manufacturer plant in MOH of Iran. The table below includes the information about the recognized authority to issue a GMP for manufacturer in their country of Origin.

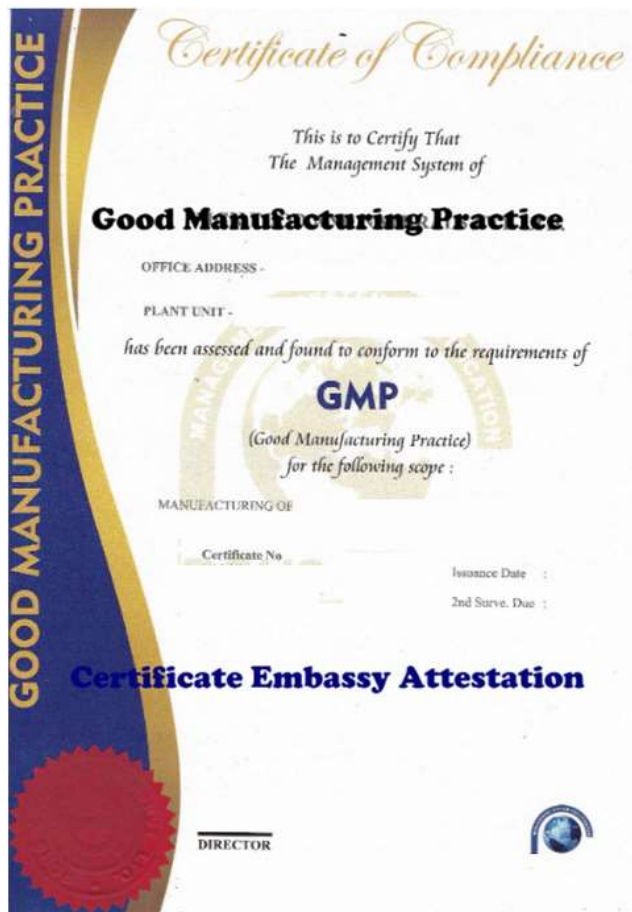
**Table1 – Authorized Bodies to Issue GMP in Origin Countries**

<b>Country</b>	<b>Types of Certificate &amp; Its Recognized Bodies</b>
<b>Australia</b>	GMP by TGA ( Therapeutic Good Administration )
	GMP by Australian CTFA
<b>Belgium</b>	GMP by Belgium Ministry Of Public Health
	GMP by DTIC
<b>Canada</b>	GMP by CCTFA( Canadian Cosmetic,Toiletry and Fragrance Association)
<b>France</b>	GMP by FEBEA (Fracisie Des Industries DE LA Parfumerie)
	GMP by AFSSAPS(Agence Francaise De Securite Saniaire Des Produits De Sante)
<b>Germany</b>	GMP by IKW (Industrieverband Koperflege Und Waschmittel ev)-the German Cosmetic , Toiletry Perfumary and Detergent Association
<b>Italy</b>	GMP by UNIPRO (Associazione Italiana Delle Imprese Cosmetiche)
<b>Japan</b>	GMP by Manufacturing License by the Prefectural Government
<b>Netherland</b>	GMP by Health In Spectorate
	GMP by N.C.V (Nederlandse Cosmetica Vereniging)
<b>Spain</b>	GMP by Stanpa (Asociacion De Perfumeria y Cosmetica)
<b>Sweden</b>	GMP by Lakemedel/fverket (Ministry of Health)
	GMP by K.T.F (Kemisk-Tekniska Leverantor for Boundet)
<b>Switzerland</b>	GMP by International Office For The Control of Medicines
	GMP by Kantonaes Laboratoirum Aargau
	GMP by Swiss Agency For Therapeutic Products
	S K W (Schweizerischer Kosmetik Und Washmittel Verband)
<b>U.S.A</b>	GMP By USCTFA

	General GMP Statement City / State Health Department
<b>United Kingdom</b>	GMP by BERR(Department For Business Enterprise & Regulatory Reform)

Ref: Ministry of Health of Islamic Republic of Iran

The GMP has to be issued by one of above recognized authorities and has to be signed and approved by Iran’s Embassy and related authority in the origin country. The authority has to clearly mention the phrase of “Good Manufacturing Practice” in their letter.





**APPENDIX 2-Free Sales Certificate**

Date:

Name of Licensee:

Name of Manufacturer:

Address:

Address:

Tel:

Tel:

Fax:

Fax:

Website:

Website:

Free Sales Certificate

This is to certify that the products of company (*Please name your company*), under .....Brand (*Name your Brand*) are freely sold in large scale in ..... (*Countries names*), and are freely and in large scale exported to other countries.

Products: (*List your products in details; please insert a table for this part*)

**APPENDIX 3- Letter of Authorization (LOA)**

We ....., located

.....

..... and represented by ..... as an authorized signatory to the title of

Managing Director Tel: ....., Email ..... **confirm that** ..... having

office at ....., Postal Code: ....., Phone: ..... Fax: .....,

Email: ..... website: ....., Registration number: ..... is our Exclusive

Distributor for Manufacturing under license from premix /API, Marketing, Distribution and Sales of the following products with the following brands in Iran territory.

Row	Product name/ consumable item	Description	Net wt
1.			
2.			
3.			
4.			
5.			

**Brand name:** .....

**Termination:** It will be after the expiry of the LOA and / or should the other party put an end to its business or its main interests, each party notifies the other party by giving written notice at least 6 months' calendar days before the effective date.

**Dispute Resolution:** Any difference, dispute, controversy and/or claim should be settled in accordance with the Arbitration Rules of the International Chamber of Commerce in .....

We also undertake to inform Iran health ministry/ FDO of any changes of this agreement or our new distributor in Iran territory for distributing our items in case of any nullification of this contract.

This agreement is valid for 5 years after the date of issue.

Sincerely yours,

Name: .....

Title: ....

Address: ....

Ph: ...

**APPENDIX 4- Certificate of Analysis (CoA)**

*Header:*

*Logo of the laboratory or company issuing the certificate (if applicable) Identification no. of the CoA*

Name and address of the laboratory  
issuing the CoA: \_\_\_\_\_

Identification no. of the CoA: \_\_\_\_\_ Name, address and  
contact person representing the originator  
of the request for analysis: \_\_\_\_\_

Registration no. of the sample: \_\_ Date received: \_\_\_\_\_ Quantity received:  
\_\_\_\_\_ Name of the product (International Nonproprietary  
Name (INN), brand name, etc.): \_\_\_\_\_

Dosage form, strength, package size (if applicable): \_\_\_\_\_ Type and material of the  
primary packaging: \_\_\_\_\_

Batch number: \_\_\_\_\_ Date of manufacture (if  
available): \_\_\_\_\_ Expiry date/retest  
date: \_\_\_\_\_ Name and address of the  
original manufacturer: \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_ Name and address of the  
repacker and/or trader (if applicable): \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_ Specifications for testing:  
\_\_\_\_\_

Test	Method reference <sup>1</sup>	Acceptance criteria	Result <sup>2,3</sup>	Compliance statement

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Additional information, if requested by the customer:

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Comments:

**Conclusion on compliance of the sample with the specifications:**

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Name of the head of laboratory or person authorized to approve the certificate:

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Phone: \_\_\_\_\_ Email: \_\_\_\_\_ Signature:  
Date: \_\_\_\_\_

**APPENDIX 5-PIAF**

*Product Importing Application Form (PIAF)*

### **1. Product Information**

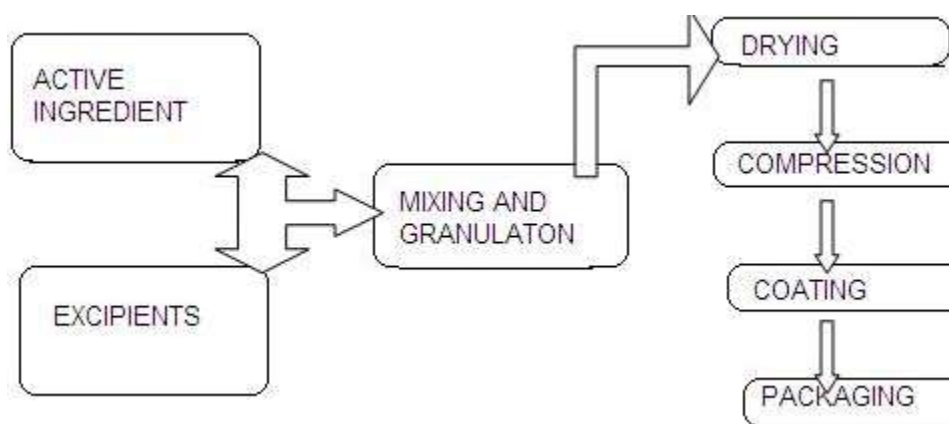
Product (Trade) name (as used in the country of origin)	
Active Substance(s)	
Strength	
Dosage form	
Route of Administration	
Container, closure and administrative device	E.g. :Carton box (96x43x132 mm) containing 4 blisters (85x125 mm) by 10 tablets.
Pack size	
Pack size and strengths used in the country of origin	
Shelf life period	
Shelf life (after reconstitution of dilution)	-
Storage condition	

**2. Manufacturer**

License/ Marketing authorization holder (name, address & country)	
Number and date of first marketing authorization/renewal	
Manufacturer of finished product (name, address & country)	

Flow chart indicating the different sites involved in the manufacturing process, packaging & release of the medicinal product:

E.g.:



Manufacturer of active substance(s) (name, address & country)	
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**3. Licensee in Iran**

Name & address	
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**4. Qualitative and quantitative composition**

4.1. Qualitative and Quantitative composition in terms of active substance(s) and excipient(s).

List the active substance(s) separately from the excipient(s).

Name of active substance(s)*	Quantity	Unit

Name of active excipient(s)	Function	Quantity	Unit

Note: the active substance should be declared by its recommended INN/Scientific name

4.2. a. List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product

NONE	<del>YES</del>
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Name	Function			Human	Animal (to be prescribed)	Animal origin Susceptible to TSE
	*AS	*EX	*R			

\*AS=active substance, \*EX= excipient (including starting materials used in the manufacture of the active substance/excipient), \*R= reagent/culture medium

4.2. b. List of constituents from other origins

CONSTITUENTS	Function	ORIGIN

4.3. Coloring, flavoring and perfume compounds

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4.4. A specimen of the label and leaflet

**5. Clinical Particulars**

5.1. Therapeutic indicators

5.2. Pharmacological action(s)

5.3. Contra-indications

5.4. Warnings and precautions

5.5. Interaction with other Medicinal Products and other forms of interaction



5.6. Uses in Pregnancy and Lactation

5.7. Effects on Ability to Drive and Use Machines

5.8. Undesirable Effects

5.9. Overdose

**6. Names and titles of official signatories of PMF / signature**

**This is to certify that the information contained herein is true and correct.**

Name and title of responsible official in the company:

Signature of responsible official in the company:

Date and Stamp:

Full Address:

**8. Method of analysis**

Pharmacopeia reference must be stated. If any of the methods is In house, validation of that method is also required.

**APPENDIX 6-MSDS (Material safety Data Sheet)**

**SAFTY DATA SHEET**

**SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**Contact information**

**General**

Product identifier	
Synonyms	
Trade names	
Chemical family	
Relevant identified uses of the substance or mixture and uses advised against	

**SECTION 2 - HAZARDS IDENTIFICATION**

Classification of the substance or mixture	
Other/Supplemental	
GHS hazard pictogram	
GHS signal word	
GHS hazard statements	
GHS precautionary statements	
Other hazards	
Note	

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**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**

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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

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**SECTION 4 - FIRST AID MEASURES**

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**SECTION 5 - FIREFIGHTING MEASURES**

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**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

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**SECTION 7 - HANDLING AND STORAGE**

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<b>SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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<b>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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Information on basic physical and chemical properties	
Appearance	
Color	
Odor	
Odor threshold	
pH	
Melting point/ freezing point	
Initial boiling point and boiling range	
Flash point	
Evaporation rate	
Flammability (solid,gas)	
Upper/lower flammability or explosive limits	
Vapor pressure	
Vapor density	
Relative density	
Water solubility	
Partition coefficient (n-octanol/water )	
Auto-ignition temperature	

Decomposition temperature	
Viscosity	
Molecular formula	
Molecular weight	

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### **SECTION 10 - STABILITY AND REACTIVITY**

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Reactivity	
Chemical stability	
Possibility of hazardous reactions	
Conditions to avoid	
Incompatible materials	
Hazardous decomposition products	

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### **SECTION 11 - TOXICOLOGICAL INFORMATION**

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The information included in this section describes the potential hazards of the individual ingredients.

Irritation/Corrosion	
Sensitization	
STOT-single exposure	
STOT-repeated exposure/Repeatdose toxicity	
Reproductive toxicity	
Carcinogenicity	
Aspiration hazard	

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### **SECTION 12 - ECOLOGICAL INFORMATION**

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Persistence and Degradability	
Bioaccumulative potential	
Mobility in soil	

Results of PBT and vPvB assessment	
Other adverse effects	

**SECTION 13 - DISPOSAL CONSIDERATIONS**

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**SECTION 14 - TRANSPORT INFORMATION**

**SECTION 15 - REGULATORY INFORMATION**


**SECTION 16 - OTHER INFORMATION**

Full text of H phrases and GHS classifications	
Sources of data	
Abbreviations	
Issue Date	
Revisions	
Disclaimer	

## APPENDIX 7- Stability Test

### STABILITY STUDY

Studying time:

Experimental conditions to which the product was subjected:

The product was stored at controlled temperature and humidity at 30 +/- 2°C temperature and 65% +/- 5% Relative Humidity, preserving the product in its original container, protect from light.

Formula product:

Packing material:

Description of the lots studied:

lots

studied	Batch type	Date elaboration	Date expiration	Start date	analysis
---------	------------	------------------	-----------------	------------	----------

Finish date

Test and analytical methods:

Product specification:

Storage Condition: 30±2°C temperature and 65%±5% Relative Humidity

Reference:

Packaging:

Mfg.Date:

Exp.Date:

Parameters Initial

3 Months

6 Months

9 Months

12 Months

18 Months

24 Months

Standard Limit

Comments:

Analyst  Approved

Rejected QC manager Authorized Person

CONCLUSIONS OF THE STUDY OF STABILITY



## APPENDIX 8 – Health Certificate

**Date:**

**Name of Importer:**

Address:

Tel:

Fax:

Website:

**Name of Manufacturer:**

Address:

Tel:

Fax:

Website:

### Health Certificate

Products: *(List your products in details; please insert a table for this part)*

..

..

..

We hereby certify that the above mentioned products of our company have been laboratory tested for quality and have been approved for human use.

Their ingredients are by no means harmful to the human health or environment. we hereby state that above mentioned products are free for sale without any limitation in the country of origin.

We hereby state that the quality of all products sold to our distributor in Iran will be guaranteed.

Quality and safety of all our products which will be sold to our representative company: ..... *(Distributor company name in BOLD)* in Iran for the next one year will be guaranteed from the date of issuing this certificate.

The manufacturing company confirms compliance with the EU Cosmetics Directive concerning 1, 4-dioxane in products containing ethoxylated surfactants.

We confirm that products are not infected by TSE and BSE. Their Ingredients do not have any human or swine source.

Signature