Personal Care & Hygiene Registration Manual

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Introduction

The Islamic Republic of Iran requires each importer of beauty and health care 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 supplier in the Ministry of Commerce of Iran. In order to do so, the agent of the supplier 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 Supplier's country of origin.

After registering the Supplier's name and brand in MOC, the distributor 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 gathered by the Supplier and submitted by the Distributor in order to register the manufacturing plant prior to registration of the products.

Each product 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 distributor has to register each product in MOH and the TTAC - Tracing, Tracking and Authentication Control System (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 in complete or have 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.

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Document list for MOC

Letter of Authorization (LOA) is a letter with the exact format of Ministry of Commerce. As explained the mentioned document must be legalized by Chamber of Commerce of parent company country and the attested by the Iranian embassy in the country of origin. If the manufacturer is different from the seller, then there should be one more declaration letter which declares the business relationship between the two companies. One letter should be issued on the seller's letter head, and the other on the manufacturer's letterhead. The declaration letter and LOA samples are within the appendix.

Document List for the MOH

In the following are the list of documents necessary for registering the manufacturer plant in the MOH:

1- OFAC License**
2- GMP Certificate
3- PMF (Plant master file)
4- FSC (Free Sale Certificate)
5- Health Certificate
6- Certificates & Approval
7- Analysis sheets
8- Samples from each item

** If your company owns a manufacturing plant in the United States, you will need to apply for an OFAC License prior to submitting the documents to MOC and MOH of Iran.

OFAC License

Any American supplier that owns a manufacturing plant in the U.S should apply for an OFAC License prior to start any other procedure. Office of Foreign Asset Control (OFAC) is an agency of the United States Department of the Treasury. OFAC administers and enforces economic and trade sanctions based on U.S. foreign policy and national security goals against targeted foreign states, organizations, and individuals.

If your company is a US based company but your products are manufactured outside USA, there is no need to apply for an OFAC license to Export your products to Iran.

Good Manufacturing Practice (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

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

Plant Master File (PMF)

A Plant Master File has to be filled out for each and every production, plant of the Supplier. Plant Master File contains several questions regarding the manufacturing plant in general such as the location, the pipeline, QC, Plant utilities and etc. Please refer to the Appendix to view the Plant Mater File questions.

The entire documents for Plant Master File should be in English and they have to be printed on the Factory's letter head. All the pages of these two documents have to be signed and stamped by either the QA or QC of the manufacturer.

Note: questions number 10,11 and 14 are very important to be replied in details. They are about the location and situation of factory's laboratories, tools and instruments which are using for quality control of the products and the physical, chemical, microbiological tests. It is also about the method and type of the above tests, such as measuring density and PH which should be explained completely.

Free Sale Certificate

You can find the Template of Free sale certificate in the Appendix. The authorized Body such as MOH in Spain or IKW in Germany (for each country the authorized body is announced) can issue this certificate. The certificate has to be signed and approved by the Iranian Embassy.

In the following are the points to be mentioned in the Free Sales Certificate:

1. The full address and the phone number of the manufacturer must be stated**.**
2. The Certificate has to be on a letterhead of the authorized body.
3. All pages of the certificate must be signed, stamped and bundled together.
4. Note that a Free Sales Certificate per Manufacturing Plant must be submitted. As an example, if a number of products are being manufactured in a factory in Italy and the other products are being manufactured in France, it will require two separate Free Sale Certificates, one for the manufacturing plant in Italy and one for the manufacturing plant in France.
5. Make sure the Brand name is indicated in front of each product in the Product Table. As presented in 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:

ABC® Shampoo
ABC®, Shampoo for dry hair
ABC®, Shampoo for normal hair
Etc…
ABC® Conditioner
ABC®, Conditioner for dry Hair
ABC®, Conditioner for normal Hair
Etc…
ABC® Body Wash
ABC®, Body Wash Energy
ABC®, Body Wash Active
Etc…

Health Certificate

The Template of the Health certificate is within 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 just 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. Make sure that you have stated the date correctly since this document is valid only for a year from the date of issue.
2. Make sure that the full address and the phone number of the **manufacturer** is stated**.**
3. The Certificate has to be on a letterhead of either the manufacturer or the authorized body.
4. 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:

ABC® Shampoo
ABC®, Shampoo for dry hair
ABC®, Shampoo for normal hair
Etc…
ABC® Conditioner
ABC®, Conditioner for dry Hair
ABC®, Conditioner for normal Hair
Etc…
ABC® Body Wash
ABC®, Body Wash Energy
ABC®, Body Wash Active
Etc…

Certificates & Approvals

You have to declare and attach a copy of any certificate and approvals that you carry for your manufacturing plant, you company and your products. Some of these Certificates and approvals are:

-ISO 9000 series: International Standard Organization

-ISO 14000

-ISO 17025

-ISO 22000:2005

-BRC: British Retail Consortium

-FDA: Food & Drug Administration and others.

Please be noted factories which have FDA approval will be granted for some points. For example, some documents will not be needed or audit by MOH, SGS or TUV will be omitted.

Analysis Sheets

MOH requires an analysis Sheet for every individual product. The analysis sheets should contain information about physical, chemical and biological properties of the product. The Analysis sheets have to be printed on the Manufacturer's letter head and have to be signed and stamped by QC or QA of the Manufacturer.

Samples from each item

MOH requires a number of samples for each product for testing and quality control. The samples have to be sent to the distributor in Iran so he/she can submit them to the MOH along with the analysis sheets.

Note: the number of samples may be different for different products.

Appendix 1 - GMP

Appendix 2 - Plant Master File

1- Name and Address of the Site

2- Factory's Foundation Date (Complete Details)

3- Telephone/Fax Number/Webpage/Mail Box

4- Production Group:

   a. Raw Material: □ Cosmetics □ Hygienic □ Packaged

   b. Finish Product: □ Cosmetics □ Hygienic □ Packaged

5- Type of Products Manufactured

6- Brand Name of the Product

7- Is the Factory the Main Producer? Or Does It Operate Under any License?

8- Is the Factory Producing Private Label Products?

9- Personnel:

   a. Personnel qualifications, experience and responsibilities of key quality personnel

   b. Training program

10- Building and Facilities:

   a. Administration

   b. Description of manufacturing areas

   c. Material storage and warehousing

   d. Laboratories

   e. Water system

   f. Cleaning and sanitation

11- Equipment

   a. Production

   b. Quality control Laboratories

   c. R&D

   d. Maintenance

   e. Qualification, validation and calibration

   f. Cleaning and sanitation

12- Documentation & Certificates

a. Preparation revision and distribution of documents
b. Copies of all the approvals & certificates
c. The list of the countries that these products have been exported to them
d. Submitting the name and the country of the raw material suppliers of the factory

13- Production

a. Description of the production operation
b. Handling of starting materials, packaging materials, finished products, quarantine, release and storage
c. Handling of rejected materials
d. In-Process sampling procedures and controls
e. Final product sampling procedures and controls
f. Reprocessing
g. Description of general policy for process validation
h. Packaging
i. Labeling

14- Quality Control

a. Description of the quality control system
b. The list of instruments available in the quality control laboratory and control during processing laboratory (if applicable)
c. Samples at the blank forms used in different stages of the quality control

15- Distribution, Complaints and Product Recall

a. Distribution procedure
b. Handling of complaints and product recall

16- Contract Production and Analysis

a. Assessment of GMP compliance of the contract manufacturer

17- A Brief Explanation of the Monitoring of the Site by the Authorities of the Country.

Appendix 3 – Free Sales Certificate

Date:

Name of Importer:

Address:

Tel:

Fax:

Website:

Name of Manufacturer:

Address:

Tel:

Fax:

Website:

Free Sales Certificate

We hereby certify that the products of our company including **……** *(Please name you products)***,** under **……** Brand *(Name your Brand)* is freely sold in large scale in …… *(Countries names)*, and are freely and in large scale exported to any countries.

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

..

..

..

We hereby certify that the manufacturer of the following products: *(List your products in details; please insert a table for this part)*

..

..

..

Is …. *(Name of your Company).*

Appendix 4 – Health Certificate

Date:

Name of Importer:	**Name of Manufacturer:**
Address:	Address:
Tel:	Tel:
Fax:	Fax:
Website:	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

Appendix 5 – Letter of Authorization

Supplier letter head

Reference No.:

Issuance Date:

To: Islamic Republic of Iran Ministry of Health and Commerce

Letter of Authorization

We, (Supplier name) having office at ..... Tel....., Fax ....., Email: ..... hereby confirm that **Mehr Gostar Tamin Daroo Co. (MGTD)** represented by Mr. Ali Babaie as the CEO, having office at No 40, Bokharest Street, Tehran, Iran, Postal Code: 1513755313, Phone: +98 (21) 88104494 Fax: +98 (21) 88104454, Email: info@mgtd.co , website: www.mgtd.co , Registration number: 342195 is our **Exclusive Distributor** for Registration, Importation, Marketing, Distribution and Sales of the following products with the following brands in **Iran** territory.

Products name	**Brand name**	**Manufacturer 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 Paris/ France.

We also undertake to inform Iran Ministry of Health 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 agency agreement is valid for 5 years.

Sincerely yours,

Name

Title

Stamp

Appendix 6 – Declaration Letter

Manufacturer Letterhead

Reference No.

Issuance Date:

To: Islamic Republic of Iran Ministry of Health and Commerce

Declaration Letter

We, (Manufacturer Name) having office at ……., Tel ……, Fax ……., Email: ……., registered No ….. , hereby confirm that (supplier name) is authorized to sell our Products to **Health Invest Tamin co. (HITCO)** represented by Mr. Ali Babaie as the CEO, having office at No 56, Alvand Street, Tehran, Iran, Postal Code: …….., Phone: +98 (21) ……. Fax: +98 (21) ……., Email: ……. , website: www.hitcoholding.com , Registration number: 342195 which is the **Exclusive Distributor** of our supplier for the following Products with the following brands in Iran territory.

Product name	**Brand name**	**Manufacturer name**

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 Paris/ France

Termination: It will be after the expiry of LOA.

This agency agreement is valid for 5 years.

Sincerely yours,

Signature

Name

Title

Appendix 7- Analysis sheet

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[1]	Acceptance criteria	Result[2,3]	Compliance statement

Additional information, if requested by the customer:

Comments:

Conclusion on compliance of the sample with the specifications:

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

Phone: _____ Email: _____ Signature:
Date: