Personal care & Hygiene Registration Manual

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Contents

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Introduction

The Islamic Republic of Iran requires every importer of raw materials and Bulk products related to beauty and health to register the brand, supplier and manufacturer in the Ministry of Commerce (MOC) and Ministry of Health (MOH) of Iran before production under license.

Registration procedure

The first step for registration process is to register the brand name of the Brand owner in the Ministry of Commerce of Iran. In order to do so, the agent of the Brand owner requires submitting an original version of the “LOA” or "Contract "between the two companies to MOC. This document should be in the Company Letterhead and signed and approved by the Ministry of Commerce or Chamber of Commerce and attested by the Iranian Embassy in the Supplier’s origin country. Also, 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.

After registering the Brand in the chamber of commerce, the manufacturer in Iran has to apply for registering the manufacturing plant of the products in Ministry of Health of Iran. MOH requires a list of documents that has to be gathered by the brand owner and submitted by the agent in order to register the manufacturer plant prior to registration of the products.

The manufacturing license is usually issued for one year and can be renewed.

After issuing the manufacturing license, samples of the produced products along with shipping documents and other costs should be presented to syndicate in order to determine the price.

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

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

Procurement of raw materials for the production of licensed products

1- If the raw materials used in the production of the product are provided by the manufacturer of raw materials introduced by the owner of the brand, it is necessary to obtain a Raw material import license from the Ministry of Health: In the system TTAC, the necessary information must be entered which are: the CAS number, form of the raw material, the HS code, date of expiration, GMP and product master file and MSDS.

2- If the raw materials for the production of the product are prepared from the manufacturer in Iran, at the time of inspection, the health license and documents will be received from the seller of the raw materials and presented to the inspectors.

Every product must obtain a manufacturing license for production in Iran. This manufacturing license is a unique code for each and every product. In order to obtain the manufacturing license, the agent has to register each product in MOH.

The process of registration is time consuming; normally it will take about 3 to 6 months (depends on the product) to register a manufacturer and its products in the MOC and MOH. Of course, this time can be longer if there is a problem with the documents.

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

TDT Foreign Trade Department along with the Regulatory Department has designed this Manual to help you understand the items in the list of documents required for the registration processes. We have also included the forms and samples of such documents for you as appendixes. We hope that you find this manual useful and it would be a good help to fast forward your process.

** Please note that each product whether raw material or finished requires an IRC code.

TTAC - Tracing, Tracking and Authentication Control System (www.ttac.ir).

Requested document List for registration in the MOH

Here is the list of documents necessary for registering the manufacturer plant in **MOH**:

1- Letter of Authorization (**LOA**) which you will find the sample in the appendix is a letter with the exact format of **MOH**) In the text of the **LOA**, the permission to use the brand by the representative in Iran should be mentioned). As explained in introduction it should be legalized by Chamber of Commerce of each country and being certified by Iran Embassy there.

2- Document containing the registration information of the company owning the brand in the country of origin, which has been approved by the Chamber of Commerce.

3- COA of API & excipient & INCI

4- COA of finished product

5- Master formula (list of ingredients, API/EXCIPIENT & their)

6- MSDS (Martial safety data sheet)

7- Samples from each item and Art work files(Label)

8- Detailed manufacturing procedure for finished product

9- Packaging material specification

10- Name and specifications of resources and standards used in the manufacturing formula

11- Contract between the representative of the brand owner and the manufacturer in Iran

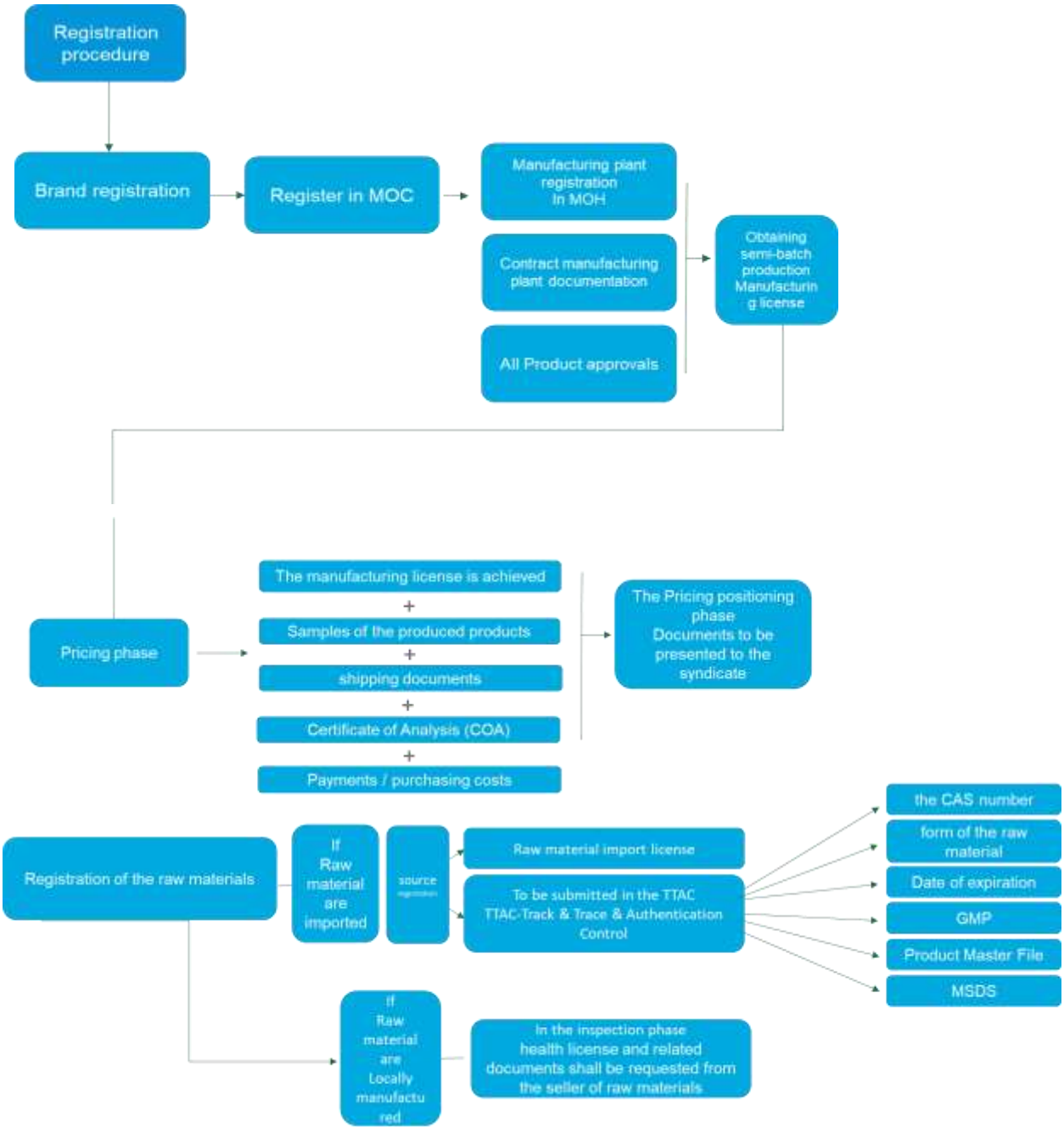
*** Also, during the review, registration and design process in the commissions, documents will be announced by the Food and Drug Administration and the deputy, which will be announced later.

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.

MOH requires few samples of each product for test 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.

Registration procedure



Some essential definitions

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.

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 we will announce the authorized body) can issue this certificate for you and you have just to 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 letterhead 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. 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

You can find the Template of 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 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. 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:

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 & Approval

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 few samples of each product for test 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 – 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 3 – 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 ……

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

Signature

Appendix 4 – 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 **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: ……. Fax: +……., Email: i……. , website: www.hitcoholding.com , Registration number: ……. 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 5 – 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: …. 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 6 - 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[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:

Appendix 7 - MSDS (Material safety Data Sheet)

SAFTY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTUREAND 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	

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU	GHS Classification	%

		EINECS/ELINCS List		

SECTION 4 - FIRST AID MEASURES

SECTION 5 - FIREFIGHTING MEASURES

SECTION 6 - ACCIDENTAL RELEASE MEASURES

SECTION 7 - HANDLING AND STORAGE

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

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	

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	
Chemical stability	

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

SECTION 11 - TOXICOLOGICAL INFORMATION

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	

SECTION 12 - ECOLOGICAL INFORMATION

Persistence and Degradability	
Bioaccumulative potential	
Mobility in soil	
Results of PBT and vPvB assessment	
Other adverse effects	

SECTION 13 - DISPOSAL CONSIDERATIONS

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	