

GUIDELINES ON
REGISTRATION OF IMPORTED
PHARMACEUTICAL PRODUCTS

IN THE ISLAMIC REPUBLIC OF IRAN

MINISTRY OF HEALTH AND MEDICAL EDUCATION

DEPUTY FOR FOOD AND DRUG

DIVISION OF PHARMACEUTICAL AND NARCOTIC AFFAIRS

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Regulations on Marketing Authorization of Pharmaceutical Products

According to article 14 of the Act on Medical Affairs, Pharmaceuticals and Foodstuff (passed in 1955 and amended in 1988), in the Islamic Republic of Iran the Ministry of Health and Medical Education (MOH) is the main body that, as the Iranian National Drug Regulatory Authority, regulates and implements the imports, registration, and customs release of any sort of pharmaceutical products.

As stated in the article 20 of the aforesaid Act, the MOH enforces standards and authorizes the manufactures and imports of pharmaceuticals and biological products. Imports of pharmaceuticals that are listed by the Iranian Drug Evaluation Committee Secretariat can be performed according to the following ten articles: (The aforesaid list is available at www.fdo.ir)

Article One) Registration Application:

1-1) Any legal entity that holds an exclusive agency of the Product License Holder (PLH) or Marketing Authorization Holder (MAH), can apply for the registration and imports of the related pharmaceuticals at the Division of Pharmaceutical and Narcotic Affairs. The applicant has to present the followings for registration also:

1-1-1) The application form in appendix 1 filled out by the applicant

1-1-2) A photocopy of the exclusive letter of authorization endorsed by the Iranian Embassy in the country of origin.

1-1-3) An Agency registration certificate issued by the Iranian Ministry of Commerce

1-2) In case the application is approved by the expert council, the applicant has to:

1-2-1) Introduce a qualified pharmacist as a responsible pharmacist to the Division of Pharmaceutical and Narcotic Affairs to follow up the registration and related affairs in that office.

1-2-2) The preliminary documents discussed in the sections 1-7 of article 2 have to be submitted to the Division of Pharmaceutical and Narcotic Affairs within 6 months of the approval. The application will be nullified, should the documents are not submitted within 6 months.

Article Two) Documents Required for Registration

The application for registration must be submitted on the company letterhead.

The following documents also must be attached:

2-1) A photocopy of the preliminary approval of the Division of Pharmaceutical and Narcotic Affairs

2-2) A photocopy of the responsible pharmacist's license

2-3) The original copy of the exclusive letter of authorization issued by the Product License Holder (PLH) or Marketing Authorization Holder (MAH) endorsed by the Iranian Embassy in the country of origin. (a photocopy of the letter of

authorization have to be included in the dossier of each product, the original exclusive letter of authorization also must be presented which will be returned upon verification)

The exclusive letter of authorization must be on the letterhead of the awarding company, sealed and signed by the director in charge, and it must include the followings, as a minimum:

- A) Name and address of the Product License Holder (PLH) or Marketing Authorization Holder (MAH)
- B) Name and address of the authorized agent
- C) The name of the product(s), pharmaceutical & dosage form
- D) Date of issue of the letter of authorization
- E) Validity date of agency
- F) Authorities assigned to the agent

In case the agency is issued by a regional office, a photocopy of the letter of the parent company consisting the authorities assigned to the regional office has to be submitted. The photocopy needs to be endorsed by the Iranian Embassy in the country of origin.

- 2-4) The original copy of the Certificate of a Pharmaceutical Product (CPP), that should conform to the format recommended by the World Health Organization (WHO) and shown in appendix 2, issued by the pharmaceutical competent authority of the country of export or European Medicines Evaluation Agency (EMA). The CPP needs to be endorsed by the Iranian Embassy in the country of origin along with the Summary of Product Characteristics (SPC).
- 2-5) The original copy of the GMP certificate for manufacturing and packaging site(s) issued by the pharmaceutical competent authority of the country of origin and endorsed by the Iranian Embassy in the country of origin. (This certificate is required only if in the CPP the GMP Standards of the manufacturing and packaging site(s) are not stated.)
- 2-6) The global registration status endorsed by the chamber of commerce and the Iranian Embassy in the country of origin.

NOTE:

The Medicine in question has to be registered and has consumption records in at least one country other than the origin country. (Appendix 3)

- 2-7) Drug Importing Application Form (DIAF), Appendix 4, which has to be completed by the Product License Holder (PLH) or Marketing Authorization Holder (MAH).

Upon considering and approval of the above-mentioned documents, the applicant will be communicated to present the Dossier of the Medicine within 6 months to the Division of Pharmaceutical and Narcotic Affairs. Should the applicant fail to do so, the registration will be considered null and void.

NOTE:

The presented Dossier will be considered according to the time table provided in Appendix 5.

The applicant shall dispatch the following documents to the Division of Pharmaceutical and Narcotic Affairs by an official letter:

2-8) A photocopy of the bank receipt for paying the registration fee according to the Iranian annual budget law. The receipt has to be endorsed by the financial office of the Deputy for Food and Drug.

2-9) The completed form for Registration of Medicines (Appendix 6)

2-10) The Dossier

The Dossier has to be typed and presented in English and it has to be included the followings:

2-10-1) An official letter presented by the Product License Holder (PLH) or Marketing Authorization Holder (MAH) on introducing the qualified person who contributed to the Dossier including their name, workplace address, contact telephone and fax numbers, E-mail address and their signature specimen

2-10-2) The Dossier should preferably be presented in CTD format (Common Technical Document), or else its contents should conform to the list set forth in Appendix 7.

2-10-3) Presenting the chromatograms and peaks (identification, analysis, impurities) of the active ingredients and finished product related to the batch number mentioned in the Dossier

2-10-4) In case the reference used in analysis of the active ingredients and finished product is not a valid pharmacopoeia, the In House method has to be presented along with the related documents of validation.

2-10-5) A sample of the Persian translation of the leaflet and packaging as stated in Appendix 8

The Dossier has to be thoroughly studied by the Responsible Pharmacist of the agency and presented to the Division of Pharmaceutical and Narcotic Affairs. The applicant will be notified of any sort of shortcomings upon reviewing the documents by the experts of the Division of Pharmaceutical and Narcotic Affairs. Then the responsible pharmacist has to remedy the shortcomings within six months. Obviously, this period will not be counted in the time schedule for registering the product. Should the applicant fail to complete the Dossier within this period, the registration procedure will be nullified and the applicant has to start the registration from scratch.

NOTE:

The applicant has to respond to the shortcomings thoroughly each time, otherwise reconsideration of the Dossier shall not be possible.

In case any sample of the product is required to be dispatched to the Division of Quality Control Laboratory of Deputy for Food and Drug, the matter shall be communicated to the applicant.

Two copies of the Dossier should be available in the archives of the authorized agency in Iran, and if required a copy shall be sent to the Division of Quality Control Laboratory of Deputy for Food and Drug.

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NOTE 1:

The registration of the medicine in question is possible only under the same name and the same manufacturing site as in the country of origin.

NOTE 2:

In case the name of the medicine to be registered in Iran is different from the name of the medicine in the country of origin and other consuming countries, the same has to be clearly indicated in the CPP. Also, the PLH/MAH has to approve the identity of formulation, manufacturing methods and manufacturing site of the two different names.

NOTE 3:

As for the marketing authorization of biological medicines and controlled medicines, the related regulations have to be obliged as well as the regulations set forth in this guidelines.

NOTE 4:

The authorized agent in Iran will be held responsible for the contents of the Persian leaflet as for its conformity with the manufacturer's leaflet.

NOTE 5:

In case the Division of Pharmaceutical and Narcotic Affairs requires, a conformed copy of GMP approval of the manufacturing site(s) issued by the U.S. Food and Drug Administration (FDA), or European Medicines Evaluation Agency (EMA), or Australia's Therapeutic Goods Administration (TGA), or World Health Organization (WHO) that is endorsed by the Iranian Embassy in the country of origin shall be presented.

NOTE 6:

If the Expert council requires, the results of bioequivalency studies or clinical trial or Post Marketing Surveillance (PMS)in Iran shall be presented and approved by the Quality Control and Clinical Trial Section of the Division of Pharmaceutical and Narcotic Affairs

NOTE 7:

In case the Expert council requires a GMP audit to the manufacturing company, the same will be communicated to the applicant.

Article Three) Announcement of the Registration Number in Iran:

Upon evaluation of the aforesaid documents, the issue will be discussed in the expert council. Upon approval of the expert council, the Marketing Authorization License (Appendix 9) will be issued for the applicant and the IRC* will be announced.

Article Four) Pricing:

The authorized agent in Iran shall present the related pricing documents to the Pricing Committee of the Division of Pharmaceutical and Narcotic affairs.

*IRC: Iran Registration Code

NOTE 1:

The importer shall enter into a contract with a pharmaceutical distribution company.

NOTE 2:

The authorized agent in Iran shall approach the Division of Pharmaceutical and Narcotic Affairs to obtain the relevant regulations on promoting the pharmaceutical products and shall feel committed to these regulations.

NOTE 3:

As the Expert council urgently requires the need for reporting Adverse Drug Reactions (ADR), agencies are bound to report any sort of the Adverse Drug Reactions of their imported pharmaceutical products and the Periodic Safety Update Report(s) (PSUR) to the ADR Center of the Deputy for Food and Drug.

Article Five) Validity of the Marketing Authorization License:

The Marketing Authorization License will be valid for four years from the date of issue. The agency has to submit the followings to the Division of Pharmaceutical and Narcotic Affairs to renew the license six months before the expiry date of the license:

- 5-1) The original copy of the exclusive letter of authorization as stated in part 2-3
- 5-2) A valid Agency Registration Certificate issued by the Iranian Ministry of Commerce
- 5-3) Certificate of a pharmaceutical Product (CPP) as stated in part 2-4
- 5-4) A photocopy of the Responsible Pharmacist's license
- 5-5) The bank receipt for license renewing fee
- 5-6) A photocopy of the existing Marketing Authorization License
- 5-7) An approval issued by the Product License Holder (PLH) or its Marketing Authorization Holder (MAH) on non-variation in the formulation, manufacturing methods and manufacturing site, and etc. of the medicine in question
- 5-8) A sample of the packaging (including the primary packaging, secondary packaging, label, strip, cartridge, vial, outer packaging lable)
- 5-9) A specimen of the product
- 5-10) The latest approval of the Division of Quality Control Laboratory of Deputy for Food and Drug on the imported consignment of the medicine in question

Upon considering and approval of the above-mentioned documents, they will be referred to the expert council for renewing the license.

In case the authorized agent in Iran fails to meet the requirements of license renewing, it will lose marketing authorization.

Article Six) The Nullification of the Marketing Authorization License:

The Marketing Authorization License will be nullified in the following cases according to the decrees issued by the expert council:

- 6-1) The medicine in question is eliminated from the Iranian Drug List.
- 6-2) If proved that presented documents for registration are not genuine or are forged.

- 6-3) If proved that the pharmaceutical product has serious side effects and its consumption has been forbidden by the World Health Organization (WHO) or other national or international competent authorities.
- 6-4) If a competent national authority presents documentary evidence on the side effects of the registered brand
- 6-5) If proved that the manufacturer does not abide by the GMP standards or recurrently violates from the principles.
- 6-6) If the medicine fails to respond appropriately to the tests conducted by the Division of Quality Control Laboratory of Deputy for Food and Drug

In case the manufacture of the pharmaceutical product is terminated or its marketing authorization is suspended in the country of origin, the authorized agent in Iran shall immediately communicate the same to the Division of Pharmaceutical and Narcotic Affairs.

Article Seven) Variations:

Any change on the authorized agent, the manufacturer, the ownership of the manufacturer, the country of origin, the manufacturing and packaging site, and in the contents of the Dossier shall be officially announced by the Product License Holder (PLH) or Marketing Authorization Holder (MAH) and the same shall be communicated to the Division of Pharmaceutical and Narcotic Affairs by the authorized agent in Iran.

The documents required for any of the above-mentioned changes are as following that shall be officially presented to the Division of Pharmaceutical and Narcotic Affairs:

7-1) Authorized agent change:

- A) A letter from the Product License Holder (PLH) or Marketing Authorization Holder (MAH) on nullifying the previous agent endorsed by the Iranian Embassy in the country of origin.
- B) A letter from the Product License Holder (PLH) or Marketing Authorization Holder (MAH) on assigning the new agent endorsed by the Iranian Embassy in the country of origin as stated in part 2-3.
- C) An Agency Registration Certificate issued by the Iranian Ministry of Commerce

Upon presenting the documents in part 7-1 the IRC of the registered medicine will be transferred to the new agent.

7-2) Changes in the name or address of the Product License Holder (PLH) or Marketing Authorization Holder (MAH): New CPP shall be presented for any product as stated in part 2-4.

7-3) Changes in the ownership of the Product license Holder (PLH) or Marketing Authorization Holder (MAH):

- A) A copy of the exclusive letter of authorization as stated in part 2-3
- B) An Agency Registration Certificate issued by the Iranian Ministry of Commerce

- C) An official letter from the previous PLH/MAH on transfer of the ownership of the company to the new company endorsed by the Iranian embassy in the country of origin
- D) Presenting a new CPP for any product as stated in part 2-4

7-4) Changes in the manufacturing and packaging site(s):

- A) Presenting a new CPP for any product as stated in part 2-4
- B) The original copy of the GMP certificate for the new manufacturing and packaging site(s)
- C) The approval of the Division of Quality Control Laboratory of Deputy for Food and Drug on the new imported consignment of the medicine in question
- D) An official letter presented by the Product License Holder (PLH) or Marketing Authorization Holder (MAH) showing that the contents of the Dossier already submitted are fully obliged in the new manufacturing and packaging site(s).

7-5) Changes in the contents of the Dossier

Any change in the contents of the Dossier (formulation, manufacturing methods, packaging, etc.) shall be officially and thoroughly communicated to the Division of Pharmaceutical and Narcotic Affairs.

Article Eight) Proforma Invoice:

After registering the pharmaceutical product, the proforma invoice for imports will be admitted according to the following regulations:

- 8-1) Three copies of the proforma invoice shall be presented. The contents of the proforma invoice shall be confirmed (sealed and signed) by the responsible pharmacist.
- 8-2) The International Non-Proprietary Name (INN), Proprietary Name, Pharmaceutical and Dosage Form stated in the proforma invoice shall be the same as in the Dossier.
- 8-3) Name and the address of the manufacturing site stated in the proforma invoice shall be the same as in the presented documents.
- 8-4) Type of packaging and pack size of the product stated in the proforma invoice shall be the same as in the Dossier.
- 8-5) The shelf life of the product shall be stated in the proforma invoice and it should have appropriate shelf life (at least 2/3 of the shelf life) at the time of delivery.

Article Nine) Invoice:

All the importing companies that abide by the following regulations can present a commercial invoice to release their goods from the customs:

Obviously prior to the commercial invoice the proforma invoice and the order registration sheet of goods shall be admitted to the Division of Pharmaceutical and Narcotic Affairs. If goods are imported without foreign exchange transfer, the Division of Pharmaceutical and Narcotic Affairs shall be notified of the imports, otherwise, the importer will be held responsible.

- 9-1) Three copies of the invoice shall be presented. The contents of the invoice shall be confirmed (sealed and signed) by the responsible pharmacist.
- 9-2) Presenting the original copy of the applicant of the relevant proforma invoice
- 9-3) The commercial invoice has to refer to the number and the dated of the relevant proforma invoice
- 9-4) The International Non-Proprietary Name (INN), Proprietary Name, Pharmaceutical and Dosage Form, pack size, name and the address of the manufacturing site stated in the invoice shall be the same as in the proforma invoice.
- 9-5) The batch number and the shelf life of the product shall be stated in the commercial invoice and it should have appropriate shelf life (at least 2/3 of the shelf life) at the time of delivery. Otherwise, a packing list that contains this information shall be presented. The presented packing list should bear the number and the dated of the relevant invoice.
- 9-6) Presenting the certificate of analysis that includes information on all delivered batches by the company in charge of releasing the goods.

The responsible pharmacist of the importing company has to keep the original copy of the certificate of analysis.

Article Ten) Duties of the responsible pharmacist

10-1) Reviewing and approving the contents of all documents for marketing authorization based on the relevant regulations

10-2) Any change or amendment in the contents of documents for marketing authorization shall be followed by the responsible pharmacist and the same shall be reported to the Division of Pharmaceutical and Narcotic Affairs.

10-3) Presenting and approval of all certificates if required

10-4) Presenting the response to deficiency letter(s) to the Division of Pharmaceutical and Narcotic Affairs.

10-5) Supervision over the procurement of the medicine to make sure that all contents of the Dossier, rules, bylaws, and the regulations of the Ministry of Health are being implemented.

NOTE:

Stating the IRC and the bar code on the secondary packaging of the medicine is mandatory and the same shall be supervised by the responsible pharmacist.

10-6) Other than Good Manufacturing Practice (GMP), the responsible pharmacist has to be fully familiar with the principles of Good Storage Practice (GSP), and Good Distribution Practice (GDP) which include the followings, as a minimum:

- Being informed of the storage, shipment and packaging of the medicine based on the relevant regulations
- Supervision over the humidity and temperature of the warehouse
- Supervision over the security system of the warehouse
- Supervision over proper warehousing methods and training the warehouse personnel
- Supervision over delivering the imported consignments to the distribution companies based on the announced regulations

- Supervision over the recalled, refunded and faulty medicines and reporting the same to the Division of Pharmaceutical and Narcotic Affairs
- Storing samples of the imported medicines of each batch based on the relevant regulations
- Informing the medical health care professionals based on the relevant regulations and approving the promotions for obtaining permits
- Issuing the distribution permit for some pharmaceutical products based on the relevant regulations
- Other than the archives of the company, the responsible pharmacist is bound to keep the following documents:
 - A) Documents required to prove the relevant supervisions
 - B) Documents related to complaints, follow-ups, and assigning the affairs to the relevant departments, and outcomes of the measures taken
 - C) Current circular letters of the Ministry of Health and Medical Education
 - D) Statistics for imports and damages of each year

NOTE:

The responsible pharmacist is bound to present the sample(s) as well as the required documents to the Division of Quality Control Laboratory of Deputy for Food and Drug. The numbers of the medicines and the documents required is shown in the appendixes 10 and 11.

Appendix 1

Application Form for Registration of Imported Pharmaceutical Product

International Non-Proprietary Name (INN):	
Proprietary Name :	
Pharmaceutical & Dosage Form :	
Packaging for Iran (Type of Packaging, the Number/Volume in Each Pack):	
Pharmaceutical Group:	
Name of Manufacturer(s)/Country(ies):	
Name of Product License Holder (PLH)/Marketing Authorization Holder (MAH):	
Authorized Agent in Iran:	
Name the Valid International Certificate(s) of the product, if any, (Such as U.S. FDA Certificate, EMEA Certificate, etc.):	
The global registration status:	
Country	Proprietary Name

Appendix 2



World Health Organization

Model certificate of a pharmaceutical product

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Certificate of a pharmaceutical product¹

This certificate conforms to the format recommended by the World Health Organization

No. of certificate

Exporting (certifying country):

Importing (requesting country):

1. Name and dosage form of the product:

1.1. Active ingredient(s)² and amount(s) per unit dose³:

For complete composition including excipients, see attached⁴:

1.2. Is this product licensed to be placed on the market for use in the exporting country?⁵ (yes/no)

1.3 Is this product actually on the market in the exporting country?

If the answer to 1.2. is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B⁶:

2.A.1. Number of product license⁷ and date of issue:

2.A.2. Product license holder (name and address):

2.A.3. Status of product license holder⁸: (Key in appropriate category as defined in note 8)

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is⁹:

2.A.4. Is a summary basis for approval appended?¹⁰ (yes/no)

2.A.5. Is the attached, officially approved product information complete and consonant with the license?¹¹ (yes/no/not provided)

2.A.6. Applicant for certificate, if different from license holder (name and address)¹²:

2.B.1. Applicant for certificate (name and address):

2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:⁹

2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)

2.B.4. Remarks¹³:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable)¹⁴

If not or not applicable, proceed to question 4.

3.1. Periodicity of routine inspections (years):

3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?¹⁵ (yes/no/not applicable)¹⁴

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product¹⁶: (yes/no)

If no, explain:

Address of certifying authority:

Telephone:

Fax:

Name of authorized person:

Signature

Stamp and date

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-license holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
 - a. manufactures the dosage form;
 - b. packages and/or labels a dosage form manufactured by an independent company; or
 - c. is involved in none of the above.
9. This information can only be provided with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
 - a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of origin;
 - b. the product has been reformulated with a view to improving its stability under tropical conditions;
 - c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
 - d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
 - e. any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

- 15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).**
- 16. This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.**

Appendix 3

List of Countries in Which (Name of Drug with Strength and Pharmaceutical Form) is Registered :

We hereby confirm that, to the best of our knowledge, the following list is a true representation of the registration status of the preparation (Name of Drug).

Country	Trade Name	Registered Since	Registration No	Marketed Since

Name and Title of Responsible Official in the Company :

Signature of Responsible Official in the Company :

Date and Stamp :

Appendix 4

Drug Importing Application Form

1- Drug information

Product (Trade) name (as used in the country of origin) :	
Active substance(s) :	
Strength :	
Pharmaceutical form :	
Route of administration :	
Container, closure and administrative device (s) :	
Pack size and strengths used in the country of origin :	
Pack size for Iran :	
Shelf life period (In the country of origin):	
Shelf life period (In Iran):	
Shelf life (after reconstitution or dilution) :	
Shelf life (after first opening container) :	
Storage conditions :	

2- Manufacturer

Product license/ Marketing authorization holder (Name, address & country) :	
Number and date of the first marketing authorization / Renewal (In the country of origin):	
Number and date of the first marketing authorization (In the world) :	
Number of product license and date of issue:	
Manufacturer of finished product (Name, address & country):	

Responsibility	Name , Address & Country
Manufacturer(s) of the active substance(s):	
Manufacturer(s) of dosage form :	
Labeling :	
Primary packaging :	
Secondary packaging :	
Analytical testing :	
Batch release :	
Final release :	
Alternative manufacturing site/packaging site:	

3- Authorized agent in Iran

Name & address :	
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4- Qualitative and quantitative composition

4-1- Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)

- **List the active substance(s) separately from the excipient(s)**

Name of the active substance(s)*	Quantity	Unit	Reference

Name of the excipient(s)*	Function	Quantity	Unit	Reference

Note : * the active substance should be declared by it's recommended INN, Accompanied by it's salt or hydrate relevant.

Details of any overages-these should not be included in the formulation columns but stated below :

- Active substance (s) :
- Excipient (s) :
- Incompatibilities of the excipients :

4-2-a- List of materials of animal and/or human origin contained or use in the manufacturing process of the medicinal product.

NONE	
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Name	Function			Human	Animal (to precised) be	Animal origin Susceptible to TSE			
	AS	EX	R				Ye s		N O
							Ye s		N O
							Ye s		N O
							Ye s		N O
							Ye s		N O
							Ye s		N O

* 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

4-3- Coloring , flavoring and perfume compounds

4-4- A specimen of the lable and leaflet

5- Clinical particulars

5-1- Therapeutic indications

5-2- Pharmacodynamic properties

5-3- Pharmacokinetic properties

5-4- Contra – indications

5-5- Warnings and precautions

5-6- Interaction with other medicinal products and other forms of interaction

5-7- Use in pregnancy and lactation

5-8- Effects on ability to drive and use machines

5-9- Undesirable effects

5-10- Overdose

6- Names and titles of official signatories of registration dossier/Signature

- **This is to certify that the information contained here in 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 :**

Appendix 5

Time Table for Evaluation of Dossier In the Division of Pharmaceutical and Narcotic Affairs

All Dossiers will be classified in one of the following four tracks (based on the time they are presented to the Division of Pharmaceutical and Narcotic Affairs):

- A) Track one (Fast Track).....3-month period
- B) Track two6-month period
- C) Track three12-month period
- D) Track four24-month period

Note: The time needed for responding to deficiency letter will not be included the above-mentioned periods.

Track 1: (3-month period) Application for imports of pharmaceuticals that are neither domestically manufactured nor imported.

Track 2: (6-month period) Application for imports of pharmaceuticals that have one domestic manufacturer or one importer.

Track 3: (12-month period) Application for imports of pharmaceuticals that are not domestically manufactured but are imported by two or three importers.

Track 4: (24-month period) Other cases

Note 1: The Dossiers for herbal medicines and biological products are excepted from the above tracks.

Note 2: In case the authorized agent in Iran fails to complete a submitted Dossier within the stated period, the Dossier will be excluded for six months.

Appendix 7

Contents of Dossier

PART A: Administrative and Prescribing Information

A.1. Summary of Product Characteristics

A.2. Pharmacology and Toxicology Reports

A.3. Clinical Trials

A.4. Bioequivalency Study

A.5. Labeling

A.5.1. Original Labeling

A.5.2. Persian / English Labeling

A.6. Package Leaflet

A.6.1. English Package Leaflet

A.6.2. Persian Package Leaflet

A.7. Sample of Product

PART B : Drug Substance

B.1. Name and Site(s) of Manufacture

B.2. Specifications and Routine tests

B.3. Nomenclature and Description

B.3.1. Condensed Formula

B.3.2. Chemical Abstracts Name

B.3.3. CAS Number

B.3.4. Non-proprietary Name (INN) and United States Adopted name (USAN)

B.3.5. Description

B.4. Method of Manufacture

B.4.1. Flow Chart of the Synthesis

B.5. Development Chemistry

B.5.1. Evidence of Structure

B.5.2. Physico-Chemical Characterization

B.5.3. Analytical Validation

B.6. Impurities

B.6.1. Organic Impurities (Related Substances)

B.6.2. Volatile Impurities (Residual Solvents)

B.7. Batch Analysis

B.7.1. Certificate Analysis and Batch Analysis

B.7.2. Reference Standard or Materials

B.8. Container Closure System

B.9. Stability Studies (According to ICH Requirements)

B.10. References

PART C : Drug Product

C.1. Manufacturer(s) Name and Address

C.2. Description and Composition of Drug Product

C.2.1. Composition

C.2.2. Pharmaceutical Development

C.3. Method of Preparation

C.3.1. Manufacturing Formula Standard

C.3.2. Manufacturing Process

C.3.3. Flow chart of Manufacturing Process

C.3.4. Equipments

C.3.5. Validation of the Manufacturing Process

C.4. In-process Controls

C.5. Re-process

C.6. Control of Starting Materials

C.6.1. Active Substance (s)

C.6.1.1. Active Substance(s) Described in a Pharmacopoeia

C.6.1.2. Active Substance(s) Not Described in a Pharmacopoeia

C.6.1.3. Scientific Data

C.6.1.3.1. Manufacturer

C.6.1.3.2. Certificate Analysis and Batch Analysis

C.6.1.3.3. Reference

C.6.2. Other Ingredients

C.6.2.1. Excipients Described in a Pharmacopoeia

C.6.2.2. Excipients Not Described in a Pharmacopoeia

C.6.2.3. Scientific Data

C.6.2.3.1. Manufacturer

C.6.2.3.2. Certificate and Batch Analysis

C.6.3. BSE / TSE Risk Clarification

C.6.4. Packaging Material

- C.6.4.1. Specification and Routine Tests**
 - C.6.4.1.1. Primary Packaging**
 - C.6.4.1.2. Secondary Packaging**
- C.6.4.2. Scientific Data**
 - C.6.4.2.1. Manufacturer**
 - C.6.4.2.2. Batch Analysis**
 - C.6.4.2.3. Compatibility**

C.7. Control Tests on the Finished Medicinal Product

C.7.1. Release Specifications

C.7.2. Control Methods

C.7.2.1. Test Procedures for identification and Quantitative Determination of Active Substance(s)

C.7.2.2. Identification and Determination of Other Ingredients

C.7.2.3. Determination of Pharmaceutical-Technical Properties

C.7.3. Scientific Data

C.7.3.1. Validation of Analytical Methods

C.7.3.2. Certificate Analysis and Batch Analysis

C.8. Stability

C.8.1. Stability Tests on the Active Substance(s)

C.8.2. Stability Tests on the Finished Product

C.8.2.1. Stability Specification

C.8.2.2. Batches Tested and Packaging

C.8.2.2.1. Batches Tested According to ICH Guidelines

C.8.2.2.2. Supportive Stability Data

C.8.2.3. Stability Tests after Reconstitution or after First Opening

C.8.2.4. Study Methods

C.8.2.4.1. Batches Tested According to ICH Guidelines

C.8.2.4.2. Supportive Stability Data (Real-Time Studies)

C.8.2.5. Stability Data Tables

C.8.2.6. Supportive Stability Data

C.8.2.7. Conclusions

C.8.2.8. Stability Tests after Reconstitution or After First Opening

C.8.2.9. Ongoing Stability Studies

Note 1:

Any typographical errors or corrections made in the Dossier including standard ranges and the dispatched results of the test shall not be acceptable.

Note 2:

Pharmacology and Toxicology Reports shall be available in the authorized agency, and they shall be presented to the Division of Pharmaceutical and Narcotic Affairs if necessary.

Note 3:

For items that are not the same as the origin brand, the Periodic Safety Update Report(s) (PSUR) shall be submitted to the ADR Center of the Deputy for Food and Drug.

Appendix 8

Regulations on Packaging of Pharmaceutical products

- 1) It is necessary to adhere to the relevant regulations on labeling and packaging of pharmaceutical products.
- 2) Printings on and in the package should be both in English and Persian.

Note:

The second language, other than Persian should be English.

2-1) If it is not possible to translate all material into Persian, the followings is the least that has to appear on the secondary packaging.

2-1-1) Pharmaceutical product name (both international non-proprietary and proprietary names) and pharmaceutical and dosage form

2-1-2) Direction for use (using the leaflet or printings on secondary packaging)

2-1-3) Preferably stating the "SHOULD NOT BE USED DURING PREGNANCY" (for group-x pharmaceuticals)

2-1-4) Stating "KEEP OUT OF REACH OF CHILDREN"

2-1-5) Stating "SEE THE LEAFLET INSIDE"

2-1-6) Authorized agent name (in Iran)

2-1-7) Storage condition

2-1-8) Stating "REGISTRATION NUMBER IN IRAN" and bar code compatible with EAN13 on the secondary packaging.

In case a pharmaceutical product is imported without the secondary packaging, it is necessary to state "REGISTRATION NUMBER IN IRAN" (IRC) on the immediate packaging.

2-2) The following information can be stated in English on the packaging of pharmaceutical products such as vials, ampoules, cartridges, blisters, and strips, and pharmaceutical products that are supplied with secondary packaging:

2-2-1) Pharmaceutical product name (both international non-proprietary and proprietary names) and pharmaceutical and dosage form

2-2-2) The name of the Product license Holder (PLH) or Marketing Authorization Holder (MAH) and the country

2-2-3) Batch number of the manufacturer

2-2-4) Expiry date (MM/YY)

2-3) Contents on the outer packaging label (carton or shrink-wrap) shall be both in Persian and English.

The following information is the least to be printed on the carton or shrink-wrap:

2-3-1) Pharmaceutical product name (both international non-proprietary and proprietary names) and pharmaceutical and dosage form

2-3-2) Batch number of the manufacturer

2-3-3) Storage condition

2-3-4) The name of the Product license Holder (PLH) or Marketing Authorization Holder (MAH) and the country

2-3-5) Expiry date (MM/YY)

The importing company is allowed to translate the label and attach the translated material on the carton or the shrink-wrap.

3) The importing company is bound to supply the first consignment of pharmaceutical products along with appropriate Persian translation of leaflet.

3-1) The patient information leaflet shall be presented in both Persian and English.

3-2) In case the pharmaceutical product includes two leaflets for the patient and the physician, the translation of the patient information leaflet is sufficient, but the physician leaflet in English shall be presented along with the product as well.

3-3) It is necessary to include name, address, telephone number, fax number, and E-mail address of the authorized agent in Iran in the leaflet.

3-4) A Persian translation of the patient information leaflet and the packaging shall be submitted.

3-5) The responsible pharmacist will be held responsible for any discrepancies between the contents of the patient information leaflet, packaging and the original medicine.

4) The authorized agent in Iran is bound to present the registered pharmaceutical product with appropriate packaging and leaflet in Persian along with Registration code in Iran and bar code within a year from the approval of the Expert council.

Note 1:

The authorized agent in Iran can supply the medicine during the above-mentioned period in English and with Persian leaflet.

Note 2:

Other than the proprietary name the international non-proprietary name of the product shall be stated on the leaflet and packaging.

Appendix 9

The Marketing Authorization License

IRC (Iran Registration Code):
International Non-Proprietary Name (INN):
Proprietary Name :
Pharmaceutical & Dosage Form :
Package Number: Package Size: Container: Closure:
Pharmaceutical Group:
Storage Conditions:
Shelf Life (at least 2/3 of the shelf life at the time of delivery has to be left):
Name of Manufacturer(s)/Country(ies):
Name of Product License Holder (PLH)/Marketing Authorization Holder (MAH) in the Country of Origin:
Authorized Agent in Iran:
Importer:
Date of Approval by the Expert Council :
Registration Fee already paid by the Authorized Agent in Iran. This License is valid for 4 years. Director General for the Division of Pharmaceutical and Narcotic Affairs.

Appendix 10

Requested quantities of the pharmaceutical products for submitting to the Division of Quality Control laboratory of Deputy for Food and Drug

No.	Pharmaceutical product	Quantity
1	Injection products with large volumes (serum, etc.)	20
2	Injection products with small volumes (1-2 cc)	100
3	Injection products with moderate volumes (5-10 cc)	100
4	Drops, ointments, and similar products (Sterile)	30
5	Oral solutions (syrups, suspensions)	20
6	Topical products (ointments, creams, sprays)	20
7	Shampoos	15
8	Tablets and capsules	200
9	Soaps	10
10	Suppositories	100
11	Vials for injection	30

The quantity of samples for anticancer medicines and chemotherapy is as following:

No.	Pharmaceutical product	Quantity
1	Vials and ampoules	Min. 30
2	Tablets and capsules	Min. 70
3	Topical products and liquids	Min. 10

For biological products, the Department for Biological Products of the Division of Pharmaceutical and Narcotic Affairs and the admitting section of the Division of Quality Control laboratory of Deputy for Food and Drug for vaccines and antisera shall recommend the required quantity.

Appendix 11

The documents required for dispatching the imported samples to the Quality Control Laboratories include:

- Complete documents for quality control including Certificate of Analysis, instructions (in case in-house method is used), along with validation method, peak, and the relevant calculations
- A valid packaged standard along with the relevant Certificate of Analysis