Appendix II

Drug Importing Application form

I. 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	
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

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:

Manufacturer of active substance(s) (name, address & country)	

3.Impoter in Iran

Name & address	

4. Qualitative and quantitative composition

4.1. Qualitative end Qualitative 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	Reference

Name of active excipient (s)	Function	Quantity	Unit	Reference

Note: the active substance should be declared by its recommended INN, accompanied by its salt or hydrate relevant

-Details of any overages-these should not be include in formulation columns but started below:

Active excipient (s);

Active substance(s);

- Incompatibilities of excipients:

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

NONE	

Name	Function			Human	Animal (to be prescribed)	Animal origin Susceptible to TSE			
	AS	EX	R				Yes		No
							Yes		No
							Yes		No
							Yes		No

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 form other origins

4.3. coloring, flavoring and perfume compounds

4.4 A specimen of the e label and leaflet

5. Clinical Particulars

5.1 Therapeutic indicators

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 DMF / 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: