Requirements
to the Registration of Medicinal products
in the Republic of Armenia

Yerevan
2017

Requirements to the Registration of Medicinal products in the Republic of Armenia

Current requirements to the registration are based on the legislative acts mentioned below: The Laws of the Republic of Armenia "On Medicinal products", "On State Taxes", and the Decree of the Government of the Republic of Armenia No 347 of 25 April, 2001 "On adopting the Rule of Registration of Medicinal products and Assessment Fees for Registration of Medicinal products in the Republic of Armenia", amended by Government Decrees No 148-N of 3 February, 2005, No 1000-N of 3 September, 2009, No 266-N of 10 March, 2011 and No 122-N of 14 February, 2013, as well as Decree of the Government of the Republic of Armenia No 1603-N of 25 November, 2010 "On adopting the Rules of Good Manufacturing Practice for Medicinal products", Decree of the Government of the Republic of Armenia No 1809-N of 26 September, 2013 "On adopting the Rules of Good Manufacturing Practice Compliance Inspection and Certification of the Medicinal products and APIs in the Republic of Armenia", the Order No 123-N of the Ministry of Health of the RA dated 7 February, 2006 on approval of "The Procedure of Assessment of Medicinal products for Registration in the Republic of Armenia, the table of minimum quantities of samples submitted with application, the fianl assessment report template, the Format and Description of the Registration Certificate and the List of variations of medicinal products registered in the Republic of Armenia that do not require new registration.'' amended by the Orders of the Ministry of Helath No 665-N of 14 June, 2006, No 07-N of 18 July, 2011, No 05-N of 7 March, 2012, No 13-N of 23 April, 2014 and the Order No 189-A of the Ministry of Health of the Republic of Armenia dated 6 February, 2014 "On adopting the maximum amount of GMP compliance inspection fee for the medicinal products and APIs manufactured in the Republic of Armenia" (Annex 13).

1. General provisions

1.1. It is allowed to import, produce, store, distribute, sell and use only those medicinal products on the territory of the Republic of Armenia which are registered in the Republic of Armenia.

1.2. Registration of medicinal products, refusual and withdrawal of registration is carried out by the Ministry of Health of the Republic of Armenia, and of veterinary vaccines, serums and diagnostics - by the Ministry of Agriculture of the Republic of Armenia.

1.3. Registration of medicinal products is conducted based on the results of the scientifically justified criteria and assessment of quality, efficacy and safety of medicinal products. Assessment of medicinal products for registration is carried out by the "Scientific Centre of Drug and Medical Technology Expertise after Academician Emil Gabrielyan" (hereinafter referred to as "Scientific Centre"[1]).

1.4. Every registration of medicinal products is carried out according to each manufacturer (firm) and also to each country of origin if the production of the same medicinal product is carried out in different countries by the same manufacturer.

1.5. The quality of medicinal products registered in the Republic of Armenia should comply with the requirements of Pharmacopoeias currently used in the Republic of Armenia: the XI State Pharmacopoeia of the former USSR, the European Pharmacopoeia (Ph Eur), the International Pharmacopoeia (Ph Int), the American Pharmacopoeia (USP), the British Pharmacopoeia (BP), the German Pharmacopoeia (DAP), the German Homeopathic Pharmacopoeia (HAB), the French Pharmacopoeia (PhF) and in some cases - temporary Pharmacopoeial monographs approved by the Ministry of Health of the Republic of Armenia.

1.6. The following is subject to registration in the Republic of Armenia:

[1] Address: 49/4 Komitas av., Yerevan 0051, Armenia, Tel.: (+374 10) 23 16 82, 23 08 96, Fax: (+374 10) 23 29 42, 23 21 18, E-mail: admin@pharm.am, website: http://www.pharm.am/

1.6.1. new (original) and generic medicinal products (including immunobiological, veterinary, homeopathic),

1.6.2. additional dosage strengths, pharmaceutical forms and new indications of registered medicinal products,

1.6.3. new combination of medicinal products.

1.7. Registration is not required for medicinal products which are made in Pharmacies in accordance with Prescriptions and in the cases defined by the Government of the Republic of Armenia.

1.8. For medicinal products of major therapeutic and public health interest intended for the treatment of serious or life threatening diseases or condition, the assessment for registration may be carried out within the framework of state budget by the Government Order. The list of this low demand but vital medicines is adopted by Ministry of Health (the list is available on the website of the Scientific Centre).

1.9. The period of validity of registration of medicinal products in the Republic of Armenia is 5 years. At the expiry date of the term of the registration of the medicinal product, it is subject to new registration.

1.10. In case of changes in the composition, manufacturing technology, international nonproprietary names of registered medicinal products, as well as in case of new therapeutic indications, revealing of new properties, medicinal products are subject to new registration. The Ministry of Health defines the List of variations of medicinal products registered in the Republic of Armenia that do not require new registration (Annex 1).

1.11. The information on medicinal product registered in the Republic of Armenia is included in the Register of Medicinal products according to the Order of the Ministry of Health regarding registration of medicinal products in the Republic of Armenia which is regularly published due to the legislation of the Republic of Armenia. An electronic version of the medicinal products register is also available on the website of the Scientific Centre http://www.pharm.am/index.php/en/register-of-medicines

2. Submission of an application for registration

2.1. The applicant should submit an application for the purpose of registration to the Scientific Centre attaching an original document confirming the payment of State tax, registration dossier, samples, reference standards or materials. The documents should be submitted in Armenian, Russian or English languages and, if possible an electronic version as well (Circular Letter of the Scientific Centre N0101029012 dated 24.03.2012).

2.1.1 The State tax should be paid by the applicant in order and amount defined in legislation of the Republic of Armenia (Annex 2). It may be transffered from any bank of the Republic of Armenia to the following account of the State Treasury: 900005016168. The document confirming the payment of State tax should include the following information: name, pharmaceutical form, dosage strength, as well as the name of manufacturer and/or marketing authorization holder of a medicinal product. In case the applicant does not have a representative or representation office in the Republic of Armenia, the State tax can be transffered to the bank accounts of the Scientific Centre with detailed indication - “State tax”, the name, pharmaceutical form, dosage strength, as well as the name of manufacturer and/or marketing authorization holder of a medicinal product. The Scientific Centre undertakes to transfer the received amount to the Treasury in time difined by legislation of the Republic of Armenia (Circular Letters of the Scientific Centre N0201014409 dated 18.03.2009 and N0101034916 dated 09.03.2016).

2.1.2 The registration dossier, samples and reference standards or materials attached to an application should be submitted to the Scientific Centre along with acts on handling/acceptance (Annex 3, Annex 4 and Annex 5) (Circular Letter of the Scientific Centre N0101236415 dated 29.12.2015). It is recommended to submit hard copy of the registration dossier in two-whole folder with one-side printed A4-sized papers, and an electronic version on CD as a high quality PDF. It is also recommended to label both hard and electronic versions of the registration dossier with the name, pharmaceutical form and strength, manufacturer's and/or marketing authorization holder of the medicinal product, as possible (Circular Letter of the Scientific Centre N0101037816 dated 12.03.2016).

2.1.3 Considering the fact that according to the new law "On Medicines", discussing in the National Assembly, the registration dossier of a medicinal product should be submitted in the common technical document format (CTD), hereinafter it is recommended to follow attached list (Annex 11) and guideline (Annex 12) while compiling new registration dossier. The use of the logically structured format not only improves the effectiveness and transparency of an assessment, but also contributes to registration of safe, good quality and effective medicinal products, providing detailed data on finished product, as well as active substance and excipients presented in separate sections. Similar structure is also planned for documents submitting for registration of medicinal products in the framework of the Eurasian Economic Union (Circular Letter of the Scientific Centre N0101176716 dated 27.04.2016).

2.2. The applicant is responsible for the authenticity of the documents and reliable information submitted for the registration.

2.3. According to the order concerning classification of medicinal products as regards their supply (prescription-only or non-prescription) (Annex 6) the applicant should submit samples (in consumer packs) marked in Armenian and/or Russian and/or English for the medicinal products classified as "prescription-only", and in Armenian and/or Russian for the medicinal products classified as "non-prescription" for quality control testing either in the quantities defined by the Annex 7 or due to specifications submitted by the applicant. Besides the quantities refered to in Annex 7, one consumer pack as a laboratory-arbitrage should be submitted additionaly for each medicinal product. In case of solid pharmaceutical forms, if a consumer pack contains more units than it is necessary for testing, then laboratory-arbitrage sample is not required. If a consuer pack contains less units (1-7 tablets, capsules, syringes and etc.), then the testing is carried out by the ¼ quantities of required samples. The reference standards or materials should be submitted in the quantities defined by the specifications. The remaing shelf-life of the submitting samples should be at least 6 months, which is recommended to be taken into consideration for the reference standards or materials as well.

3. Registration procedure

3.1. Preliminary validation of the submitted registration dossier is carried out within a maximum of 10 days from the date of receipt of application by the Scientific Centre. The results (including information on incomplete or missing documents) are provided to the applicant in written form within 3 days with the information on amount of the assessment fee as well (Annex 8). It is recommended to submit required documents, samples and reference standards or materials at once, along with appropriate cover letter by indicating the name, pharmaceutical form, dosage strength, as well as the name of manufacturer and/or marketing authorization holder of medicinal product, the number and date of outgoing letter of the

Scientific Centre and also the names of attached documents (Circular Letter of the Scientific Centre N0101037816 dated 12.03.2016).

3.2. The assessment is started after the payment of the fee as an advanced payment in any manner not prohibited in the Republic of Armenia and in case of presences of the total sum and the legal basis (e.g. a contract and (or) a contract appendix and (or) a verified power of attorney).

3.3. In case the applicant fails to pay the assessment fee within 2 months upon receiving the written notification on payment, the submitted documents, samples and reference standards or materials are returned to the applicant.

3.4. Submitted documentation should be evaluated in the timeframe defined by the legislation of the Republic of Armenia by assessing the quality, safety, efficacy, risk/benefit ratio, the conditions for production of medicinal products, documents ensuring the quality of starting materials and finished product, shelf life and stability study reports, labelling, patient information leaflet, the reliability of information. Durimg the assessment it is checked the quality, safety and efficacy data compliance with the requirements defined by the legislation of the Republic of Armenia, the requirements adopted by the The International Council for Harmonisation of Technical Requirements for Pharmaceuticals (ICH) and the requirements of WHO guidelines. The testing of submitted samples should be started after ensuring the compliance of the specifications with the current Pharmacopoeias in the Republic of Armenia, which is mandatory in case of first submission or in case of changes in the specifications.

3.5. The maximum duration of assessment is 180 days except for:

3.5.1 Medicinal products registered in one of the member countries of European Union, the USA or Japan, The assessment of the medicinal products registered in the above-mentioned countries should be carried out within a maximum of 30 days in a simplified order without any testing. The following documents should be attached to the application either in English or in Armenian:

a) certified true copy of the registration certificate of the medicinal product in one of the member countries of European Union or in the USA, or in Japan, or Certificate of Pharmaceutical Product (CPP) in format approved by the World Health Organization issued in the last 2 years,

b) Summary of Product Characteristics (SmPC) approved by the authorized body of the country that has registered the medicinal product,

c) data on the qualitative and quantitative composition of the medicinal product (including excipients),

d) pharmacopoeial monographs or control methods, specifications of the medicinal product,

e) label of the medicinal product, packages, their colored mock-ups, patient information leaflet or the instruction for medical use for specialists and patients, as well as their electronic versions for all output forms indicated in the application in English or in Armenian,

f) Periodic Safety Update Report (PSUR).

In case the data mentioned in subpoint “c” do not comply with the similar data of the medicinal product registered in one of the full member countries of European Union or in the USA, or in Japan, then the assessment should be carried out under common procedure defined by Decree of the Government of the Republic of Armenia №347 of April 25, 2001.

3.5.2 The registration may be renewed after five years under the simplified procedure (new procedure according to the Decree of the Government of the Republic of Armenia №122-N). In this case the applicant should submit the application and following documents should be annexed:
a) letter regarding registration of the previously registered medicinal product under new procedure (Decree of the Government of the Republic of Armenia №122-N) and the lack of variations in previous registration dossier,
b) Periodic Safety Update Report (PSUR),
c) Document confirming the payment of the State tax in the order and amount approved by the Law of the Republic of Armenia "On State taxes"
After the payment of assessment fee the evaluation of the documents should be conducted within 15 days based on the application, and in case variations revealed, the registration is carried out under common procedure defined by Decree of the Government of the Republic of Armenia №347 of April 25, 2001.

3.6. In case of out of specification results the applicant should be notified in written form within 5 working days. The testing report includes the name, dosage strength, pharmaceutical form of medicinal product, as well as the name and country of manufacturer, batch number, shelf life, date of submission of a sample to the Quality Control Laboratory, date of issue of conclusion, specification indicators, results of testing, assessors and their signatures. The result of testing considered as negative even if one indicator does not comply with the specification.

3.7. During evaluation of medicinal product's quality, safety and efficacy the applicant should submit supplementary documents, samples and reference standards or materials in case of written query justified by the Scientific Centre. It is recommended to submit required documents, samples and reference standards or materials at once, along with appropriate cover letter by indicating the name, pharmaceutical form, dosage strength, as well as the name of manufacturer and/or marketing authorization holder of medicinal product, the number and date of outgoing letter of the Scientific Centre, and also list the names of attached documents (Circular Letter of the Scientific Centre N0101037816 dated 12.03.2016). The period for providing requirements is not included in the assessment timeframe. In case of negative result of testing the applicant can submit new samples of two batches different from the previous one in quantities defined in Annex 7 to conduct 2 quality control testings. In case the applicant fails to submit required documents, samples and reference standards or materials within 6 months, the assessment is terminated and the final assessment report about the refusal of registration is compiled.

3.8. The applicant may request to withdraw the application at any time before the end of the assessment. In this case the submitted documents, samples and reference standards or materials, as well as the assessment fee are not returned.

3.9. The assessment results should be summarized in the Scientific Centre and the final assessment report should be compiled as refered to in Annex 9 and submitted to the Pharmacological Council of the Ministry of Health (hereinafter Pharmacological Council) within 5 days attaching immediate and outer packaging, label, summary of product characteristics, patient information leaflet adopted as a result of assessment. In case the medicinal product is evaluated under simplified or new procedure (Decree of the Government of the Republic of Armenia №122-N) the assessment report should be submitted directly to the Ministry of Health.

3.10. Regardless of the assessment results the documents, samples and reference standards or materials, as well as the assessment fee submitted to the Scientific Centre for the purpose of registration are not returned.

3.11. After receiving the assessment results, within 15 days the Pharmacological Council provides a conclusion about registration or refusal of registration of the medicinal product in the Republic of Armenia, as well as conclusion about including medicinal products in the lists (Controlled medicinal product, Non-prescription medicinal product, and Essential medicinal products) adopted in the Republic of Armenia. The notice about the conclusion of the Pharmacological Council is provided to the applicant within 5 days (Circular Letter of the Scientific Centre N0101035016 dated 09.03.2016). The meetings of the Pharmacological Council are held at every 15 days, and the lists of medicinal products recommended to registration are placed on the official web site of the Scientific Centre within 5 days after the meetings.

3.12. Decision about registration of medicinal product is made by the Ministry of Health of the Republic of Armenia within 10 days on the base of the assessment results, conclusion of the Pharmacological Council and document confirming the payment of State tax. Decision about registration of medicinal product assessed under new procedure (Decree of the Government of the Republic of Armenia №122-N) is made by the Ministry of Health of the Republic of Armenia within 3 days on the base of possitive results of document assessment.

3.13. The registration certificate should be issued to applicant within 10 calendar days based on the decision of the Ministry of Health of the Republic of Armenia about registration of the medicinal product, and within 5 days - in case of new procedure (Decree of the Government of the Republic of Armenia №122-N). The format and description of registration certificate approved by the Ministry of Health of the Republic of Armenia are submitted in Annex 10. Approved patient information leaflet, summary of product characteristics, color mock-ups of packages of the registered medicinal product is available on the Scientific Centre offficial web site within 5 days from the date of issuance of the order about registration of medicinal product in the Republic of Armenia (Circular Letters of the Scientific Centre N0401126314 dated 30.10.2014 and N0101013115 dated 06.02.2015).

3.14. Both approved documents and sample (including subsequent changes) are the bases for aidentification of medicinal products, quality control and (or) official information at all stages of circulation of medicinal product in the Republic of Armenia. The sample of medicinal product includes pharmaceutical form, immediate and (or) outer packaging, labeling, patient information leaflet, color mock-ups of packages as well.

3.15. The applicant should inform the Scientific Centre about any new change of medicinal product registered in the Republic of Armenia according to the Order of the Ministry of Health by submitting the document justifying the purpose and reason of change, as well as documents confirming the payment of State tax and assessment fee. Submitted documents should be assessed within a maximum of 30 days. After possitive assessment result variations not requiring new registration are taken into consideration and added to the registration dossier, about which the applicant should be notified in written form within 3 days. In case the data indicated in the registration certificate are changed, the registration certificate of medicinal product registered in the Republic of Armenia should be reformulated by keeping the same registration certificate's number and adding the subsiquent number of change after fraction symbol. Approved patient information leaflet, summary of product characteristics, color mock-ups of packages of registered medicinal product are available on the Scientific Centre offficial web site within 5 days from the date of issuance of the order about reformulation of registration certificate of the medicinal product registered in the Republic

of Armenia in case of post-registration changes when reformulation of registration certificate is needed, and within 2 days from the date of outgoing letter issued by the Scientific Centre in case of post-registration changes when reformulation of registration certificate is not needed (Circular Letters of the Scientific Centre N0401126314 dated 30.10.2014 and N0101013115 dated 06.02.2015).

3.16. In case of import of medicinal product into the Republic of Armenia through other distribution channels, than the ones agreed with the marketing authorization holder, prior the importation, the distributor should submit application providing following information:

1) Name, address, telephone number and e-mail address of importer,

2) Trade name of the imported medicinal product, International Nonproprietary Name(s) of active substance(s),

3) Pharmaceutical form, Dosage strength, Presentation and Packaging, Manufacturer (name, address, country), Name of marketing authorization holder and confirmation document of the assessment fee payment,

4) Original Quality Certificate issued by the manufacturer or copy with the stamp of supplier.

3.16.1. Samples, labeling for immediate container and outer packaging (color mock-ups) and patient information leaflet should be submitted with application.

3.16.2. The Scientific Centre should evaluate submitted documents and samples within a maximum 15 working days comparing the samples or color mock-ups of the immediate and outer packaging, patient information leaflet, certificates, application information of imported medicinal product with the equivalent product already marketed in the Republic of Armenia, as well as with the information obtained from the official web sources. In connection with the assessment of an application the Scientific Centre may contact the drug regulatory authority in the exporting country and ask for more information about the product.

3.16.3. In case of positive decision the application is accepted as an amendment to the existing marketing authorization and included in the separate register.

3.16.4. Import authorization may be granted in case of fulfilling all legal requirements and submission proving documents, and if there is written confirmation on commitment to report any new data concerning safety and efficacy as defined in part 9 of Article 15 of Law on Medicines in the Republic of Armenia.

3.16.5. In case of content and language differences between leaflets of imported and registered medicines, an importer should take responsibility for providing a medicine with approved leaflet and putting stickers with the name, telephone number and address of importer on leaflet and packaging.

3.17. The results of assessment for registration of medicinal products can be appealed according to the legislation of the Republic of Armenia.

4. Refusal, revokation and suspension of medicinal products Registration

4.1. Medicinal product registration, re-registration and renewal of registration certificate should be refused if the assessment revealed that:

1) Data confirming safety and/or efficacy are missing or are insufficiently substantiated by the applicant, and/or the risk-benefit balance is not considered to be favourable;

2) The quality does not comply with the provisions of the law, or the actual qualitative and quantitative composition is not as declared in the registration documents;

3) The manufacturing does not comply with the rules of “Good manufacturing practice” defined by the Ministry of Health;

4) The medicinal product name, summary of the product characteristics (SmPC), packaging, labeling, marking, or patient information leaflet (PIL) do not comply with the legal requirements defined by the Republic of Armenia;

5) Foreign or international organizations, or drug regulatory authorities of other countries have provided substantiated and reliable negative data on the medicinal product;
6) The medicinal product contains chlorofluorocarbons (freons), except when the pharmaceutical form not containing freon has not been developed yet;
7) Incomplete or obviously false or distorted data or documents have been submitted;
8) The product is not registered in the applicant's country, except for medicinal products registered in member states of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) defined by the decree of the Republic of Armenia Government;
9) There are unjustified deviations from the ICH documents/guidelines;
10) The residual quantities of veterinary medicinal product in foodstuff of animal origin exceed the maximum limits defined by the Republic of Armenia legislation and other legal acts;
11) The name of medicinal product of the other applicant coincides with a medicinal product name that is already registered, but the active ingredients or their quantities are different;
12) The PIL and SmPC of medicinal product registered under the simplified procedure do not comply with the PIL and SmPC of the medicinal product registered in the ICH member state; or
13) The medicinal product contains excipient(s) prohibited for use in medicinal product, the list of which is defined by the Ministry of Health.
4.2. In case of rejecting medicinal product registration, re-registration, or renewal of registration certificate, or when the expert examination is terminated in cases stipulated by this Law, the documents, samples, standards and assessment fees submitted for registration should not be returned.
4.3. The medicinal product registration, re-registration, or renewal of registration certificate should be revoked if:

1) It is revealed non-compliance of safety, efficacy, and quality with the established requirements, specifications, and new scientific data which is life-threatening and cannot be corrected;

2) Foreign or international organizations, or drug regulatory authorities of other countries have provided substantiated and reliable negative data on the medicinal product;
3) The results of quality control testing of three different series were negative in post-registration period of medicinal product.

4) Cases of serious adverse reactions, which result in death, is life-threatening, requires hospitalization, results in disability or incapacity, or is a congenital anomaly/birth defect, were reported during the post-registration safety monitoring.

4.4. In case of medicinal product registration is revoked, it should be prohibited to manufacture, import, distribute, supply, sale or use of such medicinal product.
4.5. The registration of medicinal product should be suspended if:
1) The marketing authorization holder has submitted a substantiated application;
2) It is revealed non-compliance of safety, efficacy, and quality with the established requirements, specifications, and new scientific data which can be corrected;
3) The marketing authorization holder has not informed about new data on product quality, safety, or efficacy, or has not made changes in the registration documents in accordance with the new data; or

4) The marketing authorization holder has made changes in the registered medicinal product documents or product packaging, label, or marking, or PIL and SmPC which were not agreed upon with the Ministry of Health.

Annex 1

List

of variations of medicinal products registered in the Republic of Armenia that do not require new registration

1. Changes in the content of GMP certificate or manufacturing license adopted by the relevant bodies of the country of origin that do not include the name, address or country of the manufacturer.
2. Change in the name of a medicinal product (trade name and/or international nonproprietary name) in case the composition and indication of the finished product remain unchanged.
3. Change in the name of manufacturer and/or the name of the marketing authorization holder, in case the country of origin remains unchanged.
4. Replacement of an excipient with a comparable excipient, except for the adjuvant for vaccines or a biological excipient.
5. Change or replacement of coloring agent currently used in the finished product.
6. Addition, deletion or replacement of neutral flavoring agent currently used in the finished product.
7. Change in coating weight of tablets and change in weight of capsule shells.
8. Changes in qualitative composition of immediate packaging except for sterile products.
9. Deletion of one of the therapeutic indications of the finished product (in case safety characteristics remain unchanged).
10. Deletion of one of the routes of administration.
11. Change in the manufacturer of the active substance.
12. Change in batch size of an active substance, in case quality control data of active substance indicate that consistency of manufacturing process remained unaffected and physical properties of active substance remain unchanged
13. Changes in the specification of an active substance due to improvement of test procedure, addition of new methods and tightening of specification limits.
14. Changes in manufacturing process that do not involve a change of specification of finished product, in case the assessment of medicinal product for new manufacturing process proves that safety, efficiency and quality characteristics are unchanged.
15. Change in batch size of the finished product, in case the consistency of manufacture remains unaffected.
16. Changes in the specification of the finished product due to improvement of test procedure, addition of new methods and tightening of specification limits.
17. Changes in synthesis of excipients of the finished product, in case specifications, composition and quantitative impurity profile remain unchanged.

18. Changes in specifications of excipients due to improvement test procedure, addition of new methods and tightening of specification limits.
19. Change in the shelf life of the finished product in case of its prolongation, not exceeding five years.
20. Change in the shelf life of the finished product after first opening.
21. Change in the shelf life of the finished product after dilution or reconstitution
22. Changes in the storage conditions of the finished product
23. Changes in the methods of quality control of active substances of the finished product
24. Changes in the methods of quality control of the finished product
25. Change to comply with an update of the relevant monograph of the Pharmacopoeias
26. Changes in testing methods of non-pharmacopoeial excipients
27. Change to a test procedure of the immediate packaging of the finished product
28. Changes in testing methods of the supplier or devices
29. Changes in pack shape, size, design and number of units (e.g. tablets, ampoules, etc.) in a pack
30. Change or addition of imprints, bossing or other markings on tablets or printing on capsules.
31. Change of dimensions of tablets, capsules, suppositories or pessaries without change in quantitative composition and avareage weigth.

Annex 2

Rate
of the State Tax for registration of medicinal product in the Republic of Armenia

№	Type of application for registration	Rate of the State Tax (Armenian dram)
1.	First and additional pharmaceutical form and dosage strength of medicinal products containing new active substances	70000
2.	New combination of known medicinal products	40000
3.	First and additional pharmaceutical form and dosage strength of generic medicinal products	40000
4.	New indications	10000
5.	Herbal preparations and other preparations of natural substance	10000
6.	Homeopathic medicinal products	2000
7.	Dietary supplements	20000
8.	Reformulation of the registration certificate	5000

Annex 3

Act on handling-acceptance of documents [2]

Dossier(s) of the following medicinal product is (are) submitting in purpose of registration:

Trade name, dosage form and strength of medicinal product	
Name and address of manufacturer	
Name and address of marketing authorization holder	
Submitted documents:	**availability / quantity**
Application	☐
Original of the document confirming the payment of State tax signed by the Centre's accounting department	☐
Official letter confirming the choice of registration procedure (for new procedure or for simplified)	☐
Registration Documents (Dossier)	
Electronic device (CD)	
Data on qualitative and quantitative composition of medicinal product, pharmacopoeial monographs, specification and methods of analysis – in 2 hard-copies	☐

Who handed over	**Who accepted**
name of company	**name of company** "Scientific Centre of Drug and Medical Technology Expertise after Academician Emil Gabrielyan" JSC
name of department	**name of department** General and external affairs department
name, last name	**name, last name**
date, signature, seal/stamp	**date, signature, stamp**

[2] *The act shall be submitted either by marketing authorization holder or by its authorized representative in 2 copies filled, printed, signed and sealed/stamped in advance.*

Annex 4

Act on handling-acceptance of samples[3]

Sample(s) of the following medicinal product is (are) submitting in purpose of registration:

Trade name, dosage form and strength of medicinal product		
Name and address of manufacturer		
Name and address of marketing authorization holder		
Sample batch [4]		
quantity		
shelf life		
marking language		
storage conditions[5]		
instruction for use (leaflet insert)	☐	☐
quality certificate	☐	☐
***only* for laboratory expertise**	☐	☐

Who handed over	**Who accepted**
name of company	**name of company** "Scientific Centre of Drug and Medical Technology Expertise after Academician Emil Gabrielyan" JSC
name of department	**name of department [6]** General and external affairs department Narcotics and other controlled substances management department
name, last name	**name, last name**
date, signature, seal/stamp	**date, signature, stamp**

[3] *The act shall be submitted either by marketing authorization holder or by its authorized representative in 2 copies filled, printed, signed and sealed/stamped in advance.*

[4] *It is necessary to fill in the 2nd and 3rd columns of table in case you submit different batches of samples of the same medicinal product.*

[5] ***It is necessary to mark "not complied" in the line "storage conditions" of the table in case required special storage** conditions for submitted samples are not kept./*

[6] *Choose appropriate department. NOTE. Samples of narcotics or other controlled substances should be handed over to the Head of Narcotics and other controlled substances department of the Center.*

Annex 5

Act on handling-acceptance of standard[7]

Standard(s) of the following medicinal product is (are) submitting in purpose of registration:

Trade name, dosage form and strength of medicinal product			
Name and address of manufacturer			
Name and address of marketing authorization holder			
Standard name[8]			
batch[9]			
quantity			
shelf life			
storage conditions[10]			
quality certificate	☐	☐	☐

Who handed over	**Who accepted**
name of company	**name of company** "Scientific Centre of Drug and Medical Technology Expertise after Academician Emil Gabrielyan" JSC
name of department	**name of department [11]** General and external affairs department Narcotics and other controlled substances management department
name, last name	**name, last name**
date, signature, seal/stamp	**date, signature, stamp**

[7] *The act shall be submitted either by marketing authorization holder or by its authorized representative in 2 copies filled, printed, signed and sealed/stamped in advance.*

[8] *It is necessary to fill in the 2nd, 3rd and 4th columns of table in case you submit different standards of the same medicinal product.*

[9] *It is necessary to fill in the 2nd, 3rd and 4th columns of table in case you submit different batches of the same standard for the same medicinal product.*

[10] ***It is necessary to mark "not complied" in the line "storage conditions" of the table in case required special storage** conditions for submitted standards are not kept.*

[11] *Choose appropriate department. NOTE. Samples of narcotics or other controlled substances should be handed over to the Head of Narcotics and other controlled substances department of the Center.*

Annex 6

Rules
for classifying a medicinal product as subject to a medical prescription or for supply without prescription

I. General provisions

1. In the assessment of a medicinal product's suitability for use without prescription nature of the active substance, indications, maximum single dose, maximum daily dose, pharmaceutical form, packaging, labeling, package size in relation to the recommended duration of the treatment are considered.

II. Criteria for classifying a medicinal product as non-prescription or prescription- only medicine

2.Medicinal products should be subject to medical prescription, when they

1) are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision,
2)are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health,
3) contain substances or preparations thereof the activity and/or side-effects of which require further investigation,
4) are normally prescribed by a doctor to be administered parenterally,
5) contain, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance,
6) are likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes,
7) contain a substance which, by reason of its novelty or properties, could be considered as belonging to the group envisaged in the point 6,
8) are reserved for treatments which can only be followed in a hospital environment,
9) are used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere,
10) are intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

III. Assessment of application

3. In order to evaluate the criteria of direct or indirect danger caused by medicine utilized without medical supervision, even when used correctly, the following factors should be addressed:
1) *Direct danger/safety profile*,
2) *Indirect danger/safety profile*,
3) *Self-assessment*,

4) *Risk and consequences of incorrect use,*
5) *Patient information*

4. During assessment of a direct danger (a danger when the product is used correctly, according to the patient information) should be taken into account

1) toxicity: a medicinal product not subject to medical prescription should have low general toxicity and no relevant reproductive toxicity, genotoxic or carcinogenic properties,
2) interactions: a medicinal product not subject to medical prescription should have no interactions with commonly used medicines which can produce serious adverse reactions,
3) adverse reactions. a medicinal product not subject to medical prescription should have low risk of serious type dose-dependent adverse reactions in the general population and very low risk of serious not dose dependent reactions;
4) the possibility of preventive action (for example, if there is a clear identifiable risk group that can be excluded).

(c) the safety of a medicinal product: it is relative to that of the alternative treatment

5. An example of indirect danger, even when the product is used correctly, according to the patient information, would be where symptomatic treatment might mask/hide an underlying condition requiring medical attention and supervision. Use of the medicine might delay diagnosis and definitive treatment and jeopardise the chance of more successful therapy. An indirect danger is also present if wider use of a medicinal product would increase the risk of resistance to the product, in particular in the general population, to such an extent that the usefulness of any medicinal product is likely to be compromised or if the symptom is commonly the outward manifestation of a diverse range of underlying pathologies and where the patient cannot easily discern the underlying disease.

6. It is important that the condition or symptoms, for which a medicinal product is not a subject to a medical prescription is indicated, can be correctly assessed by the patient and that the product can be used without medical supervision. This means that the patient should be capable of excluding conditions which could appear to be similar to the indications but unsuitable for treatment with the medicine in question.

7.Medicine may not be used in self-medication if there is a high incidence of conditions listed as contraindications, precautions or warnings, or a high rate of usage of interacting drugs in the population, in case of patients likely to use the medicine, may increase the incidence and risk of misuse. It is important that the danger to health is small, if the patient uses the product where it is not indicated, uses it for a longer period than recommended**,** exceeds the recommended dose or fails to heed warnings or contraindications.

8. Patient information should be clear and sufficient enough for the patients to use the medicine appropriately in the absence of medical supervision. The label should describe the situations where the product should not be used, guidance on action to take if the medicine does not have the desired effect or cause an adverse effect. The product information (package leaflet and label) should in such cases recommend appropriate action (e.g. consulting a doctor or a pharmacist within the time stated in the label/package leaflet).

9. Medicinal products should be subject to medical prescription when they are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to

human health. Known incorrect use for products not subject to a medical prescription could lead to restrictions on the product or reclassification for supply subject to a medical prescription.

10. Further investigation of substances activity and/or side-effects may be necessary when a medicinal product has only recently been granted a marketing authorisation or because of limited experience/use of the product (e.g. low) or when it is proposed that the medicinal product will be available without prescription in a new strength, at a new dose, using a new route of administration, new age group or for a new indication particularly when the indication has not previously been authorised for a medicinal product not subject to a medical prescription sales. Experience in other markets, which have sufficient post-marketing surveillance, should be taken into consideration. In case of lower dose it is necessary to confirm that the reduced dose retains the efficacy.

IV. Conditions for classification

11. Decision about the supply status is making during marketing authorization of each medicinal product in the Republic of Armenia by the Order of the Ministry of Health based on the assessment report and Pharmacological Committee conclusion.

12. According to the Order of the Ministry of Health of the Republic of Armenia the supply status is stated in the Registration Certificate and Register of Medicinal products.

13. Application for a change in the classification for the supply may be submitted only by marketing authorization holder providing following data:

1) a pre-clinical and/or clinical summaries of animal studies or studies on humans that show low general toxicity and no relevant reproductive toxicity, carcinogenic or genotoxic properties,
2) at least 5 year’s experience of prescription use,
3) numbers of patients treated, demographic details, indications for use and dose,
4) reports of postmarketing safety surveillance studies, including published literature,
5) consequences of drug interactions,
6) consequences concerning misuse, use for longer periods than recommended, as well as the use of higher doses,
7) justification of time period for treatment in case of changes in indications and doses.

14. Package, label and patient information leaflet should be in compliance with packaging, labeling and package leaflet requirements in the Republic of Armenia for a medicinal product classified for supply without a medical prescription.

Annex 7

Table

Minimal quantities of samples of medicinal products submitting with application for registration

Pharmaceutical form	Minimal quantities of samples necessary for one laboratory testing
1. Tablets	60 unit
2. Capsules	60 unit
3. Dragee	60 unit
4. Cubes and other	40 unit
5. Gums	40 unit
6. Suppositories	40 unit
7. Powders, granules for solution	40 gram
8. Powder for inhalation	20 gram
9. Topical powder	20 gram
10. Suspensions	100 milliliter
11. Emulsions	100 milliliter
12. Syrups	100 milliliter
13. Elixir, mixture	100 milliliter
14. Tinctures, extracts	60 milliliter
15. Drops (eye, ear, nose and other) containing one active substance more that one active substance	40 milliliter 60 milliliter
16. Oils (castor, rosehip, sea buckthorn and other)	50 milliliter (gram)
17. Solutions, regardless of the type of solvent	100 milliliter
18. Aerosol volume up to 50 milliliter volume above 50 milliliter	3 pack 2 pack
19. Spray	50 milliliter
20. Solutions for injection	30 milliliter
21. Solutions for infusion	200 milliliter
22. Concentrates for infusion	50 milliliter
23. Lyophilized powders	5 gram
24. Ointments, creams	60 gram
25. Liniments	60 gram
26. Pastes	60 gram
27. Gel	60 gram
28. Sterile or small volume ointments, oils, creams, gels (for eye, ear, nose, lips and other)	10 gram
29. Pencil	4 unit
30. Pads, sponges, tissues, membranes,	10 unit

implicators soaked with medicines	
31. Balsams	2 pack
32. Plasters	4 pack
33. Shampoo	60 milliliter
34. Lotion	60 milliliter
35. Lacquer	10 milliliter
36. Glue	2 pack
37. Herbal tey	30 gram

Annex 8

FEES
Payable for Medicinal product Registration Assessment in the Republic of Armenia

№	**Type of application for registration**	**Assessment Fee (including VAT)** (thousand Armenian dram)
1	**The first dosage form and dosage strength of generic medicinal products**	**900**
	• each additional pharmaceutical form	450
	• each additional dosage strength	240
	• each new indication	450
2	**New combination of known medicinal products**	**1200**
3	**The first pharmaceutical form and dosage strength of the medicinal products containing new active substances**	**2250**
	• each additional pharmaceutical form and dosage strength	1200
4	**The first pharmaceutical form and dosage strength of Homeopathic medicinal products**	**240**
	• each additional pharmaceutical form, dosage strength and new indication	60
5	**Herbal preparations and other preparations of natural origin and Dietary supplements**	**240**
6	**Reformulation of the registration certificate**	**24**

If the same manufacturer's medicinal product, already registered in the Republic of Armenia, is also manufacturing in other countries, the payment amount for every additional country-manufacturer's medicinal product registration will be half of the approved amount indicated in the table above.

Annex 9

Assessment Report
Final

Applicant ————————

Registration case ————————-

Registration procedure (simplified, common) ————————

Name of the product ————————-

Dosage ————————-

Pharmaceutical form ————————-

International Nonproprietary Name, quantitative composition of the active substance (s) —

Packaging, output form ————————

Type of product (veterinary, homeophatic, immunological, herbal, radioctive, prescription-only, non-prescription) ————————

Manufacturing sites involved in the manufacturing process including dosage form manufacturer, bulk manufacturer, packager, finished product manufacturer, quality control and batch release sites (name, address, country)————————-

Marketing authorisation holder (name, address, country) ————————

Anatomical Therapeutic Chemical (ATC) code ————————-

Indications ————————

Shelf life ————————-

Storage conditions ————————

Registration (refusual of registration) in other countries ————————-

Testing results ————————-

Bioequivalence evaluation results ————————

Efficacy and safety evaluation results ————

The benefit / risk ratio conclusions ————————

Day, month, year ————————-

Signature ————————-

Annex 10

Description of the registration certificate

1. The certificate (attached) is printed on the watermarks protected paper of 210 mm x 297 mm (A4) size.

2. The format is outlined by navy blue frame on all sides of 15 mm depth.

3. The color coat of arms of the Republic of Armenia is printed inside the frame of the format in the upper central part. The phrase "MINISTRY OF HEALTH REPUBLIC OF ARMENIA" is printed in Armenian capital letters on the left side of the coat of arms, and the same in English capital letters on the right side. The phrase "REGISTRATION CERTIFICATE" in Armenian and English capital letters is printed below the coat of arms between which the number of registration certificate is mentioned, following to which the information is provided in the sequence mentioned bellow in Armenian and English languages:

1) Name of the product,

2) Dosage,

3) Pharmaceutical form,

4) International Nonproprietary Name, quantitative composition of the active substance (s),

5) Packaging, output form,

6) Type of product,

7) All manufacturing sites involved in the manufacturing process (name, address, country) for example dosage form manufacturer, bulk manufacturer, packager, finished product manufacturer, quality control and batch release sites,

8) Marketing authorisation holder (name, address, country),

9) Date of issue (day, month, year),

10) Date of Expiry (day, month, year):

4. Immediate and outer packaging, label, summary of product characterstics and patient information leaflet are attached to registration certificate by giving a reference in the registration certificate.

5. While filling certificate, if the data for different points of certificate are of large volume, it should be submitted as a numbered appendix (ces) attached to the certificate by giving reference to relevant point.

6. The certificate and appendix(ces) is(are) signed either by Administration Head or Deputy Minister of the Ministry of Health.

7. The round seal with the coat of arms of the Republic of Armenia should be available on the same page, at the bottom of the certificate.

8. The registration certificate has a serial number. The serial number started with the Armenian capital letters (A, B and so) and followed by numbers. The serial number consists of 7 numbers and the numbering begins from right to left, starting from 0000001. One serial number consists of 9999999 certificates, after which the serial number is changed to letter "B" and the numbering is started again from 0000001, and so on as needed. The serial number is printed outside the frame on the 20 mm height of the right bottom corner, the letters and numbers are facing upwards.

ՀԱՅԱՍՏԱՆԻ ՀԱՆՐԱՊԵՏՈՒԹՅԱՆ
ԱՌՈՂՋԱՊԱՀՈՒԹՅԱՆ
ՆԱԽԱՐԱՐՈՒԹՅՈՒՆ

MINISTRY OF HEALTH
REPUBLIC OF ARMENIA

ԳՐԱՆՑՄԱՆ ՀԱՎԱՍՏԱԳԻՐ
CERTIFICATE OF REGISTRATION
N

Արտադրանքի անվանումը /Name of the product:

Դեղաչափը / Dosage:

Դեղաձևը / Pharmaceutical form:

Միջազգային ոչ սեփականատիրական անվանումը, ակտիվ բաղադրատարրերի քանակ (ներ) ը International Nonproprietary Name, quantitative composition of the active substance (s):

Փաթեթավորումը, թողարկման ձևը / Packaging, output form:

Արտադրանքի տեսակը / Type of product:

Արտադրական գործընթացում ներառված արտադրողները (անվանում, հասցե, երկիր) / All manufacturing sites involved in the manufacturing process (name, address, country):

Գրանցման հավաստագրի իրավատերը (անվանում, հասցե, երկիր)/ Marketing authorization holder (name, address, country):

Գրանցվել է (օր, ամիս, տարեթիվ) / Date of issue:

Վավեր է մինչև (օր, ամիս, տարեթիվ) / Date of expiry:

Կցված են գրանցված դեղի ընդհանուր բնութագիրը, ներդիր թերթիկը և փաթեթը /Approved summery of product characteristics, package leaflet and labeling are attached.

Հայաստանի Հանրապետության
Առողջապահության նախարարության
աշխատակազմի դեկավար
Ministry of Health
Head of staff

ստորագրություն / signature

Կ.Տ/seal

COMMON TECHNICAL DOCUMENT

Module 1: Administrative information

1.0 Cover Letter
1.1 Comprehensive Table of Contents
1.2 Application Form (free form)
1.3 Product Information
1.3.1 SmPC, Labelling and Package Leaflet (also electronic versions in Microsoft Word format)
1.3.2 Mock-up (also electronic version in PDF)
1.3.3 Specimen
1.3.4 Consultation with Target Patient Groups /if available/
1.3.5 Product Information already approved in other countries
1.3.6 Braille /if available/
1.4 Information about the Experts
1.4.1 Quality
1.4.2 Non-Clinical
1.4.3 Clinical
1.5 Specific Requirements for Different Types of Applications
1.5.1 Information for Bibliographical Applications
1.5.2 Information for Generic, 'Hybrid' or Bio-similar Applications
1.5.3 (Extended) Data / Market Exclusivity /if available/
1.5.4 Exceptional Circumstances
1.5.5 Conditional Marketing Authorisation
1.6 Environmental Risk Assessment
1.6.1 Non-GMO
1.6.2 GMO
1.7 Information relating to Orphan Market Exclusivity
1.7.1 Similarity
1.7.2 Market Exclusivity /if available/
1.8 Information relating to Pharmacovigilance
1.8.1 Pharmacovigilance System
1.8.2 Risk-management System
1.9 Information relating to Clinical Trials
1.10 Information relating to Paediatrics
Additional Data
1.11 Manufacturing Authorisation(s) for all manufacturing sites involved in the manufacturing process of the medicinal product and the active substance issued by the competent authority of country of origin (original or verified copy).
1.12 GMP certificate(s) or other GMP statement(s) for all manufacturing sites involved in the manufacturing process of the medicinal product and the active substance issued by the competent authority of country of origin (original or verified copy).
1.13 Letters of access to Active Master File(s) or copy of Ph. Eur. Certificate(s) of suitability. Ph. Eur. Certificates of suitability for TSE.
1.14 Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications.
1.15 Written consent(s) of the competent authorities regarding GMO release in the environment.

1.16 Marketing Authorisation or Certificate of Pharmaceutical Product (CPP) or Registration certificate issued by the competent authority either of country of origin or the country of Marketing authorization holder (original or verified copy).
1.17 Worldwide registration status: Copies of Marketing Authorisations or tabular listing (marketing authorization number, date of authorization, country, trade name and etc.).
1.18 Information on patent protection (including Armenia).
1.19 Information on trade mark protection (including Armenia).

Module 2 Summaries

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2.3 Quality Overall Summary – Introduction
2.3.1 Quality Overall Summary – Drug Substance
2.3.2 Quality Overall Summary – Drug Product
2.3.3 Quality Overall Summary – Appendices
2.3.4 Quality Overall Summary – additional Information
2.4 Nonclinical Overview
2.5 Clinical Overview
2.6 Nonclinical Written and Tabulated Summaries
2.6.1 Introduction
2.6.2 Pharmacology Written Summary
2.6.3 Pharmacology Tabulated Summary
2.6.4 Pharmacokinetics Written Summary
2.6.5 Pharmacokinetics Tabulated Summary
2.6.6 Toxicology Written Summary
2.6.7 Toxicology Tabulated Summary
2.7 Clinical Summaries
2.7.1 Summary of Biopharmaceutic and Associated Analytical Methods
2.7.2 Summary of Clinical Pharmacology Studies
2.7.3 Summary of Clinical Efficacy
2.7.4 Summary of Safety
2.7.5 References
2.7.6 Synopses of Individual Studies

Module 3 Quality

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3.2 Body of Data
3.2.S Drug Substance
3.2.S.1 General Information
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.1.3 General Properties
3.2.S.2 Manufacture
3.2.S.2.1 Manufacturer(s)
3.2.S.2.2 Description of Manufacturing Process and Process Controls
3.2.S.2.3 Control of Materials
3.2.S.2.4 Controls of Critical Steps and Intermediates

3.2.S.2.5 Process Validation and/or Evaluation
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3.2.S.3 Characterisation
3.2.S.3.1 Elucidation of Structure and Other Characteristics
3.2.S.3.2 Impurities
3.2.S.4 Control of Drug Substance
3.2.S.4.1 Specification
3.2.S.4.2 Analytical Procedures
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3.2.S.6 Container Closure System
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3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment
3.2.S.7.3 Stability Data

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3.2.P.2.2 Drug Product
3.2.P.2.2.1. Formulation Development
3.2.P.2.2.2 Overages
3.2.P.2.2.3 Physicochemical and Biological Properties
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3.2.P.3.1 Manufacturer(s)
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3.2.P.3.3 Description of Manufacturing Process and Process Controls
3.2.P.3.4 Controls of Critical Steps and Intermediates
3.2.P.3.5 Process Validation and/or Evaluation
3.2.P.4 Control of Excipients
3.2.P.4.1 Specifications
3.2.P.4.2 Analytical Procedures
3.2.P.4.3 Validation of Analytical Procedures
3.2.P.4.4 Justification of Specifications
3.2.P.4.5 Excipients of Human or Animal Origin

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3.2.P.5.6 Justification of Specifications
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3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment
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Module 4 Nonclinical Study Reports

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4.2.1.2 Secondary Pharmacodynamics
4.2.1.3 Safety Pharmacology
4.2.1.4 Pharmacodynamic Drug Interactions
4.2.2 Pharmacokinetics
4.2.2.1 Analytical Methods and Validation Reports
4.2.2.2 Absorption
4.2.2.3 Distribution
4.2.2.4 Metabolism
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4.2.2.6 Pharmacokinetic Drug Interactions (nonclinical)
4.2.2.7 Other Pharmacokinetic Studies
4.2.3 Toxicology
4.2.3.1 Single-Dose Toxicity (in order by species, by route)
4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)
4.2.3.3 Genotoxicity
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4.2.3.3.2 In vivo (including supportive toxicokinetics evaluations)
4.2.3.4 Carcinogenicity (including supportive toxicokinetics evaluations)
4.2.3.4.1 Long-term studies (in order by species, including range-finding studies that cannot be appropriately included under repeat-dose toxicity or pharmacokinetics)
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4.2.3.4.3 Other studies
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4.2.3.5.2 Embryo-foetal development
4.2.3.5.3 Prenatal and postnatal development, including maternal function
4.2.3.5.4 Studies in which the offspring (juvenile animals) are dosed and/or further evaluated
4.2.3.6 Local Tolerance
4.2.3.7 Other Toxicity Studies (if available)
4.2.3.7.1 Antigenicity
4.2.3.7.2 Immunotoxicity
4.2.3.7.3 Mechanistic studies (if not included elsewhere)
4.2.3.7.4 Dependence
4.2.3.7.5 Metabolites
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5.3.2 Reports Of Studies Pertinent To Pharmacokinetics Using Human Biomaterials
5.3.2.1 Plasma Protein Binding Study Reports
5.3.2.2 Reports Of Hepatic Metabolism and Drug Interaction Studies
5.3.2.3 Reports Of Studies Using Other Human Biomaterials
5.3.3 Reports Of Human Pharmacokinetic (PK) Studies
5.3.3.1 Healthy Subject PK and Initial Tolerability Study Reports
5.3.3.2 Patient PK and Initial Tolerability Study Reports
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5.3.3.4 Extrinsic Factor Pk Study Reports
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5.3.4.2 Patient PD and PK/PD Study Reports
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5.3.5.4 Other Study Reports
5.3.6 Reports of Post-marketing Experience
5.3.7 Case Report Forms and Individual Patient Listings
5.4 Literature References

Common Technical Documents of Medicinal Products Registration

http://www.pharm.am/attachments/article/183/Appendix_2_%20Notice%20to%20Applicants_eng.pdf

Annex 13

Maximum amount of GMP compliance inspection fee for the medicinal products and APIs manufactured in the Republic of Armenia

Service type	Fee (Armenian dram)
GMP compliance inspection	840 000