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TALLAHASSEE FLORIDA

JAN 07 2016
J. HARRIS

COVER LETTER

TO: Registration Section
Division of Corporations

ICROM SpA

SUBJECT: _____

Name of corporation - must include suffix

Dear Sir or Madam:

The enclosed "Application by Foreign Corporation for Authorization to Transact Business in Florida," "Certificate of Existence," or "Certificate of Good Standing" and check are submitted to register the above referenced foreign corporation to transact business in Florida.

Please return all correspondence concerning this matter to the following:
Corrado Taborelli

_____
Name of Person

ICROM SpA

_____
Firm/Company

Via delle Arti 33

_____
Address

Concorezzo, Italy 20863

_____
City/State and Zip code

corrado.taborelli@icrom.com IN USA: CONSALVO@PRIME-PHARMA.COM

_____
E-mail address: (to be used for future annual report notification)

For further information concerning this matter, please call:

Corrado Taborelli _____ at (39-039) 604-1742 From 09:00 to 18:00
Name of Person Area Code Daytime Telephone Number

STREET/COURIER ADDRESS:
Registration Section
Division of Corporations
Clifton Building
2661 Executive Center Circle
Tallahassee, FL 32301

MAILING ADDRESS:
Registration Section
Division of Corporations
P.O. Box 6327
Tallahassee, FL 32314

Enclosed is a check for the following amount:

☒ $70.00 Filing Fee ☐ $78.75 Filing Fee & Certificate of Status ☐ $78.75 Filing Fee & Certified Copy ☐ $87.50 Filing Fee, Certificate of Status & Certified Copy

FLORIDA DEPARTMENT OF STATE
Division of Corporations

November 19, 2015

CORRADO TABORELLI
VIA DELLE ARTI 33
CONCOREZZO, ITALY 20863,

SUBJECT: ICROM S.P.A.
Ref. Number: W15000076013

RECEIVED
2016 JAN -7 PM 12:41
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

We have received your document for ICROM S.P.A. and your check(s) totaling $70.00. However, the enclosed document has not been filed and is being returned for the following correction(s):

Name of business must be included on line 1.,

The name must contain a word that will clearly indicate that it is a corporation. Such words include: CORPORATION, CORP., COMPANY, CO., INC., and INCORPORATED.

The document must be signed by the chairman, any vice chairman of the board of directors, its president, or another of its officers.

Please return your document, along with a copy of this letter, within 60 days or your filing will be considered abandoned.

If you have any questions concerning the filing of your document, please call (850) 245-6051.

Jenna D Harris
Regulatory Specialist II

Letter Number: 515A00024475

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TALLAHASSEE, FLORIDA

APPLICATION BY FOREIGN CORPORATION FOR AUTHORIZATION TO TRANSACT BUSINESS IN FLORIDA

IN COMPLIANCE WITH SECTION 607.1503, FLORIDA STATUTES, THE FOLLOWING IS SUBMITTED TO REGISTER A FOREIGN CORPORATION TO TRANSACT BUSINESS IN THE STATE OF FLORIDA.

1. ICROM SpA - INCORPORATED
(Enter name of corporation; must include "INCORPORATED," "COMPANY," "CORPORATION," "Inc.," "Co.," "Corp," "Inc," "Co," or "Corp.")

ICROM SpA - INCORPORATED
(If name unavailable in Florida, enter alternate corporate name adopted for the purpose of transacting business in Florida)

2. ITALY (State or country under the law of which it is incorporated)

3. IT00828970152 (FEI number, if applicable)

4. 1996 (Date of incorporation)

5. _____ (Date of duration, if other than perpetual)

6. N/A (Date first transacted business in Florida, if prior to registration)
(SEE SECTIONS 607.1501 & 607.1502, F.S., to determine penalty liability)

7. Via delle Arti 33, Concorezzo, Italy 20863 (Principal office address)

_____ (Current mailing address, if different)

8. Name and street address of Florida registered agent: (P.O. Box NOT acceptable)

Name: PRIME PHARMA CORP.

Office Address: 4858 West Gandy Blvd. - Tel (813)778-4480

Tampa (City), Florida 33611 (Zip code)

2013 JAN -7 PM 3:5[illegible]

9. **Registered agent's acceptance:**

Having been named as registered agent and to accept service of process for the above stated corporation at the place designated in this application, I hereby accept the appointment as registered agent and agree to act in this capacity. I further agree to comply with the provisions of all statutes relative to the proper and complete performance of my duties, and I am familiar with and accept the obligations of my position as registered agent.

Paolo Bonalumi - PRIME PHARMA CORP.
(Registered agent's signature)

10. Attached is a certificate of existence duly authenticated, not more than 90 days prior to delivery of this application to the Department of State, by the Secretary of State or other official having custody of corporate records in the jurisdiction under the law of which it is incorporated.

11. Names and business addresses of officers and/or directors:

A. DIRECTORS

Chairman: Pierfrancesco Morosini

Address: Via delle Arti 33, Concorezzo, Italy 20863

Vice Chairman: N/A

Address:

Director: Plant: Eugenio Fumagalli

Address: Via delle Arti 33, Concorezzo, Italy 20863

Director: N/A

Address:

B. OFFICERS

President: Arnaud Moor

Address: 6 Rue Barbès, BP 177, Levallois-Perret, France 92305

Vice President: N/A

Address:

Secretary: N/A

Address:

Treasurer: N/A

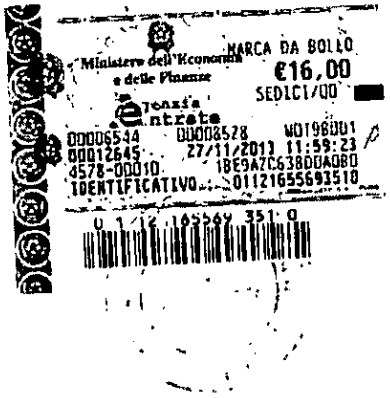
Address:

NOTE: If necessary, you may attach an addendum to the application listing additional officers and/or directors.

12. _____
Signature of Director or Officer

The officer or director signing this document (and who is listed in number 11 above) affirms that the facts stated herein are true and that he or she is aware that false information submitted in a document to the Department of State constitutes a third degree felony as provided for in s.817.155, F.S.

13. Pierfrancesco Morosini - Chaiman ICROM SpA
(Typed or printed name and capacity of person signing application)



Agenzia Italiana del Farmaco

AIFA

Certificate No: IT-API/97/H/2015

CERTIFICATEOF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer ICROM S.P.A.
Site address Via Delle Arti, 33 - 20863 CONCOREZZO (MB)

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24th April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2013/09/27, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.
The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1736

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Part 2

Name and address of the site:

ICROM S.P.A. - Via Delle Arti, 33, 20863 CONCOREZZO (MB)

Name of the active Substances manufactured or imported:

AMISULPRIDE
BEPOTASTINE BESILATE
BORTEZOMIB
BRINZOLAMIDE
BRINZOLAMIDE STERILE
BROMOPRIDE
BUTIZIDE
DIACEREIN
DIBROMOTYROSINE
EPINASTINE HYDROCHLORIDE
FLUORESCEIN SODIUM
GLIBENCLAMIDE
GLIQUIDONE
LEVOSULPIRIDE
METOCLOPRAMIDE HYDROCHLORIDE
MINOXIDIL
RISPERIDONE
SULPIRIDE
TIANEPTINE SODIUM
TIAPRIDE HYDROCHLORIDE

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

AMISULPRIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates

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	3.1.2. Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

BEPOTASTINE BESILATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot

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	numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **BORTEZOMIB**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates Special Requirements Other: Cytotoxic **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **BRINZOLAMIDE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing **3.6.2.** Microbiological testing (excluding sterility testing)

3 - Manufacturing Operations - Active Substances **BRINZOLAMIDE STERILE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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3 - Manufacturing Operations - Active Substances BROMOPRIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations- Active Substances BUTIZIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **DIACEREIN**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **DIBROMOTYROSINE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: *purification,crystallisation*
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **EPINASTINE HYDROCHLORIDE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	***General Finishing Steps***
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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3 - Manufacturing Operations - Active Substances FLUORESCEIN SODIUM	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. *Physical processing steps* drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances GLIBENCLAMIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation **3.5.2.** *Primary Packaging (enclosing / sealing the active substance within a* packaging material which is in direct contact with the substance)

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	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **GLIQUIDONE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **LEVOSULPIRIDE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps *drying,sieving* **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

METOCLOPRAMIDE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation **3.5.2.** *Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)* **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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3 - Manufacturing Operations - Active Substances MINOXIDIL	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. *Physical processing steps* drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances RISPERIDONE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps *drying,sieving* **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a

	packaging material which is in direct contact with the substance) **3.5.3.** *Secondary Packaging (placing the sealed primary package within an* outer packaging material or container. This also includes any labelling ofthe material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **SULPIRIDE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving,milling/micronisation **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **TIANEPTINE SODIUM**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: *purification,crystallisation*
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving,milling **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

TIAPRIDE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: purification,crystallisation
3.5	**General Finishing Steps**
	3.5.1. *Physical processing steps* drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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AIFA

Restrictions or clarifying remarks:

Terminal sterilisation of Brinzolamide by gamma irradiation is outsourced.Milling and micronisation operations are outsourced.

Rome, 2015/08/14

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Dott.ssa Isabella Marta
AIFA – Manufacturing Authorization Office

AIFA Italian Medicines Agency
Manufacturing Authorization Office
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