PBCH
PATRICIA BELTRAN CH.
TRADUCTORA OFICIAL
RES. No. 1615 - MAYO 27 / 82

CERTIFIED TRANSLATION

TODOS POR UN NUEVO PAÍS
PAZ EQUIDAD EDUCACIÓN

RESOLUTION No. **2016015505** OF MAY 2, 2016
By which the certification of Good Manufacturing Practices (GMP) is given to
ASPIRO PHARMA LIMITED, IDENTIFIED NUMBER OF LICENSE 36/MD/AP/2013/F/G

The Director of Drugs and Biological Products of the Colombian Food and Drug Administration Institute [INVIMA], in exercise of the powers conferred by Decree 549 of 2001 and Decree 2078 of 2012, Resolution No. 2014037846 of 14 November 2014; and taking into account the following.

BACKGROUND

That under INVIMA file No. 2015138553 dated October 20, 2015, the Legal Representative of AKAR COLOMBIA S.A.S., Mister Ram Reddy Kolkoor requested a visit for the Certification of Good Pharmaceutical Manufacturing Practices for the establishment **ASPIRO PHARMA LIMITED**, located at Biotech Park Phase-III, Karkapatla (V), Medak (Dist.), Telangana, Pin-502279-India, for which it attached, among other documents: Certificate of Existence and Legal Representation of the establishment, Inspection Guide of Laboratories or Pharmaceutical Production Facilities for obtaining the Certificate of Compliance with Good Manufacturing Practices duly completed, payment receipt number 1176506-81 of DAVIVIENDA Bank, for the payment of the rights of the visit, among other documents.

That on the days 28,29,30, 31 March and April 1 of 2016, professionals from the Drugs/Medical and Biological Substances Direction of INVIMA visited the facilities of **ASPIRO PHARMA LIMITED**, located at Survey No. 321, Biotech Park Phase-III, Karkapatla (V), Medak (Dist.), Telangana, Pin-502279-India, in order to certify compliance with Good Pharmaceutical Manufacturing Practices, issuing the following technical concept: "*Once evaluated compliance with the requirements set forth in the Series of Technical Reports of the WHO, series 823, Technical Report 32: Good Manufacturing Practices for Pharmaceutical Products, adopted by Resolution 03183 of August 23, 1995, Decree 549 of March 29, 2001, Inspection Guide for Laboratories or Pharmaceutical Production Facilities, adopted by Resolution 01087 of July 2001, Resolution 3028 of August 2008 and Decree 2086, 2010 of the Ministry of Social Protection, the inspection team of the Colombian Food and Drug Administration Institute [**INVIMA**], concludes that* **ASPIRO PHARMA LIMITED**, located at Survey No. 321, Biotech Park Phase-III, Karkapatla (V), Medak (Dist.), Telangana, Pin-502279-India ***COMPLIES*** *with the* ***GOOD PHARMACEUTICAL MANUFACTURING PRACTICES***

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(GMP) *for the manufacture of drugs with the active ingredients and dosage forms hereby related:*

STERILE		
ACTIVE INGREDIENT		***DOSAGE FORMS***
COMMON	*LIQUID*	*Small-volume parenteral solution (vials)*
	SOLID	*Small-volume powders for injection and small-volume lyophilized powders in vials*

1. *COMMON: They are active ingredients not antibiotics (beta-lactam and non-beta-lactam), not sexual endocrine active substances (androgens and oestrogens) and their precursors, non-hormonal non-sexual, non-antineoplastic non-immunosuppressive, radiopharmaceuticals and non-biological.*
2. *Sterile solutions are moist heat terminally sterilized, provided the characteristics of the container and formulation allows it, otherwise they are sterilized by sterile filtration (0.22 micron filter) with subsequent aseptic filling and sealing.*
3. *The initial solution of lyophilized powders is sterilized by sterile filtration (0.22 micron filter) with subsequent aseptic filling.*
4. *The manufacture of sterile products in powder form for reconstitution is performed in aseptic environment with sterile starting materials.*
5. *The above technical concept, only authorizes the manufacture of products with the active ingredients and described dosage forms that require and do not require cold chain.*
6. *Any modification made on conditions assessed and certified during this audit, regarding equipment, areas, production processes, principal technical staff or the companies contracted for the performance of critical production activities and quality control, must be notified to INVIMA so that it assesses and verifies whether an extension visit is required or a verification of the technical concept issued, in accordance with the provisions of the relevant Sanitary Standards under penalty of actions as may be required".*

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CONSIDERATIONS

That Article 1 of Decree 549 of 2001 provides that laboratories manufacturing medicines/drugs produced domestically or imported, must apply for the certificate of Good Manufacturing Practices.

That Paragraph 2 of Article 2 of Decree 549 of 2001, states that if the result of the visit establishes that the drug laboratory complies with Good Manufacturing Practices, INVIMA shall issue the compliance certificate of GMP.

That Article 6 of Decree 549 of 2001, establishes that it corresponds to the **COLOMBIAN FOOD AND DRUG ADMINISTRATION INSTITUTE [INVIMA],** or whoever it assigns, to issue the certificate of compliance of Good Manufacturing Practices, by means of a Resolution.

That Article 6 of Decree 2086 of 2010 amending Article 7 of Decree 549 of 2001 regarding the validity of the Certificate of Compliance with Good Manufacturing Practices provides that the certificate of compliance with Good Manufacturing Practices shall have a validity of three (3) years from the date of execution of the granting act and shall be renewed for a period equal to its validity.

That professionals from the Drugs/Medical and Biological Substances Direction conceptualized in their visit conducted during the days 04, 05, 06, 07 and 08 of April, 2016, that the facilities of **ASPIRO PHARMA LIMITED**, located at Survey No. 321, Biotech Park Phase-III, Karkapatla (V), Medak (Dist.), Telangana, Pin-502279-India, COMPLIES with GOOD PHARMACEUTICAL MANUFACTURING PRACTICES for manufacturing drugs, therefore this office,

RESOLVES

ARTICLE ONE.- Grant the **CERTIFICATION** of compliance with Good Pharmaceutical Manufacturing Practices for a term of three (03) years as from the execution of this Resolution to the establishment **ASPIRO PHARMA LIMITED**, located at Survey No. 321, Biotech Park Phase-III, Karkapatla (V), Medak (Dist.), Telangana, Pin-502279-India, because it **MEETS** the **GOOD PHARMACEUTICAL MANUFACTURING**

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PRACTICES (GMP) for the manufacture of drugs with the active ingredients and dosage forms pharmaceutical forms hereby related:

STERILE		
ACTIVE INGREDIENT		***DOSAGE FORMS***
COMMON	*LIQUID*	*Small-volume parenteral solution (vials)*
	SOLID	*Small-volume powders for injection and small-volume lyophilized powders in vials*

1. COMMON: They are active ingredients not antibiotics (beta-lactam and non-beta-lactam), not sexual endocrine active substances (androgens and oestrogens) and their precursors, non-hormonal non-sexual, non-antineoplastic non-immunosuppressive, radiopharmaceuticals and non-biological.
2. Sterile solutions are moist heat terminally sterilized, provided the characteristics of the container and formulation allows it, otherwise they are sterilized by sterile filtration (0.22 micron filter) with subsequent aseptic filling and sealing.
3. The initial solution of lyophilized powders is sterilized by sterile filtration (0.22 micron filter) with subsequent aseptic filling.
4. The manufacture of sterile products in powder form for reconstitution is performed in aseptic environment with sterile starting materials.
5. The above technical concept, only authorizes the manufacture of products with the active ingredients and described dosage forms that require and do not require cold chain.
6. Any modification made on conditions assessed and certified during this audit, regarding equipment, areas, production processes, principal technical staff or the companies contracted for the performance of critical production activities and quality control, must be notified to INVIMA so that it assesses and verifies whether an extension visit is required or a verification of the technical concept issued, in accordance with the provisions of the relevant Sanitary Standards under penalty of actions as may be required".

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ARTICLE TWO.- Notify personally the content of this Resolution to the Legal Representative and/or Attorney of the company **ASPIRO PHARMA LIMITED,** informing that against this decision is applicable an appeal for reversal that may be lodged within the tenth (10^{th}) following day counted from the notification of this Resolution, before the Director of Drugs and Biological Products of INVIMA, in accordance with what is set out in Article 76 of the Administrative Legal Action Code Law 1437 of 2011.

ARTICLE THREE.- This Resolution is effective as of its final judgment.

NOTIFY AND EXECUTE

(Signature)

LUZ HELENA FRANCO CHAPARRO
Director of Drugs and Biological Products

Designed: A. Hernandez (Ph.Ch.) (Signed)
Technical Revision: n. Chinome (Ph.Ch.) (Signed) F. Cepeda (Biol.) (Signed)
Legal Revision: J.Quiroz (Lawyer) (Signed)
Approved: A. Cadena, Coordinator GTM (Signed)
Filed: Exp.421E

(Translated on July 5, 2016)