DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
ORA/OPQO/HQ 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	7/17/2018 - 7/22/2018
	FEI NUMBER 3003722350

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Sandro Utiyama, Site Manager - Director Supply Chain Scent & Care Division

FIRM NAME	STREET ADDRESS
Symrise, S. de R.L. de C.V.	Av. Republica Mexicana 200 Col. Garza Cantu
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Nicolas de los Garza, Nuevo Leon, Mexico 66480	Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

The observations noted in this Form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
Lack of Quality Unit oversight and control of documents.

Specifically,
A) There is a lack of control over the issuance of batch and production control records used to document the manufacturing of the drug products (b) (4) (b) (4)
B) The instrument identification numbers used in the analysis of APIs are not documented in the batch records or analytical data results in MYSAP.
C) QC analysts have the ability to delete raw chromatographic data files in the Total Chrome software.

OBSERVATION 2
There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, you do not have written procedures for:
1) Labeling procedures of finished products
2) Shipping of crude (b) (4) to (b) (4) and the QC release and return of the finished API (b) (4)
3) The QC release based on Certificate of Analysis for the raw materials (b) (4) Powder and (b) (4) (b) (4) in (b) (4)
4) User rights and privileges of instrument software, such as Total Chrome.

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	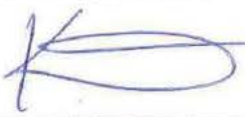	Kara D. Dobbin, Investigator	09/21/2018

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OBSERVATION 3
Failure to conduct process validation on the drug manufacturing process.

Specifically, you did not validate the number of times the (b) (4) process step may be repeated for the active pharmaceutical ingredient (API) (b) (4) In addition, you do not document the number of times the (b) (4) is repeated in the batch production records form, FO-MX-0356 Rev 1, (b) (4) batch record code (b) (4) _Rev0, effective date 7-May-2018.

OBSERVATION 4
The batch production and control records are deficient in that they are not an accurate reproduction of the appropriate master production or control record.

Specifically,
A) The production batch records for the APIs (b) (4) do not include a description and documentation of the accomplishment of each process step in the manufacturing of the finished API.
B) A non-conformance was not opened by the Chemical Production regarding holding of a drug product in the production of (b) (4) Lot (b) (4)

OBSERVATION 5
Laboratory controls do not include the establishment of scientifically sound and appropriate standards, sampling plans, and test procedures designed to assure that in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,
A) The limit of the product residuals stated in the cleaning validation protocol l PVL – EP, Protocolo de Validacion de Limpieza de Equipos, Rev. 1, effective date 7-Mar-2018, was not based on scientifically sound evidence. A justification for the limit of (b) (4) ppm was not provided upon request.
B) The decisions to perform (b) (4) calibrations on the analytical balance (S/N 15103151) and (b) (4) calibrations on the PerkinElmer Clarus 680 GC (S/N 680S14121501) located in the QC Laboratory were not based on scientifically sound and documented evidence.

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	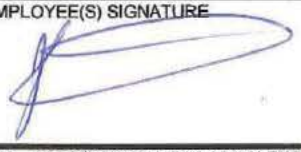	Kara D. Dobbin, Investigator	09/21/2018

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	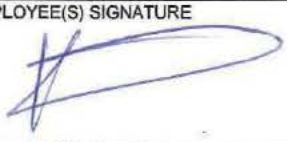	Kara D. Dobbin, Investigator	09/21/2018