



Health Product Compliance Directorate
GMP Inspection, Central
2301 Midland Avenue
Scarborough, Ontario
M1P 4R7

Dec. 7 2017

Sent by e-mail

File number: HC6-61-4833-1-1

Synthon Chile Ltda.
El Castano N 145 – Valle Grande
Lampa Region Metropolitana (Santiago)
Chile

Attention: Ms. Virginia Faundez

SUBJECT: NOTICE OF COMPLIANT RATED INSPECTION – Synthon Chile Ltda.

This letter is to inform you of the results of the good manufacturing practices (GMP) inspection conducted at your establishment on November 20 2017.

Your establishment has received a compliant (C) rating. This means that at the time of the inspection, its activities were in compliance with the *Food and Drugs Act* and its associated regulations.

However, a compliant rating does not mean there were no observations or corrective actions will not be needed. The attached inspection exit notice summarizes the observations made during the inspection. These observations are categorized based on our guidance document *Risk Classification of GMP Observations* (GUI-0023), which is available at www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0023-eng.php.

A written response describing the corrective actions you will take to address these observations, including timeframes for their implementation, must be sent to Health Canada by January 7 2018.

As part of our internal quality assurance process, any compliant inspection exit notice may be chosen for follow-up review. You will be notified within 60 calendar days if this review results in a change to your inspection rating.





Health
Canada

Santé
Canada

If you disagree with the content of the inspection exit notice, you have 10 calendar days to bring your concerns to our attention. Please note that Health Canada will consider only the information that was presented during the inspection. If you choose to do this, please send a written submission outlining the basis of the dispute, citing the specific sections of the inspection exit notice you disagree with, to:

Hocine Abid, Manager, GMP Inspection
GMP Inspection Central
2301 Midland Avenue
Scarborough, Ontario
M1P 4R7
Phone: 416-973-1466
Email: Hocine.Abid@canada.ca

I would like to thank you and your staff for the cooperation extended throughout the inspection.

Regards,

Digitally signed by Boulton, Jane
DN: c=CA, o=GC, ou=HC-SC,
cn=Boulton, Jane
Date: 2017.12.07 15:37:14 -05'00'

Jane Boulton
GMP Specialist

Magda Joseph
Senior Compliance Officer

Attachment: Inspection exit notice