

Establishment Inspection Report

J.S. Hamilton Poland S.A.
Gdynia, Pomorskie, 81-571 Poland

FEI: **3006438991**

EI Start: 7/15/2016

EI End: 7/19/2016

16 = Year 2016

FGDY = designated for "Pharma Department"

COMPLAINTS

Please refer to Customer Complaints under QUALITY SYSTEM.

RECALL PROCEDURES

The firm operates as a contract lab and not as a manufacturer of drug product. Recall of product is not part of their operations.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**Observations listed on form FDA 483**

There were no objectionable conditions observed during the inspection and no FDA-483 issued to the firm.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

There were no objectionable conditions observed during the inspection and no FDA-483 issued to the firm.

ADDITIONAL INFORMATION

None

SAMPLES COLLECTED

There were no samples collected during this inspection.

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VOLUNTARY CORRECTIONS

None

EXHIBITS COLLECTED

- 1 Exhibit 1, 27 pages
- 2 Exhibit 2, 1 page
- 3 Exhibit 3, 1 page
- 4 Exhibit 4, 1 page
- 5 Exhibit 5, 1 page
- 6 Exhibit 6, 14 pages
- 7 Exhibit 7, 10 pages
- 8 Exhibit 8, 12 pages

ATTACHMENTS

 Unverified

X Truong X Nguyen

Truong X Nguyen
Investigator
Signed by: Truong X. Nguyen -S