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Certificate of Analysis

Certificate Number: 2017-SA-029

Material Name: Naloxone Hydrochloride
NDC #: 51634-2018-**
Reference Standard #: NQS1705
Date of Manufacture: March 2017
Requalification Date: March 31, 2018

<u>Test</u>	<u>Limit</u>	<u>Result</u>
Appearance	Report Results	White powder
Infrared Spectroscopy ¹	Consistent with primary standard	Complies
Mass Spectrometry ²	Consistent With Structure	Complies
Residue on Ignition (ROI)	Report Results	<0.05%
Residual Solvents (ROS)	Report Results	<0.05%
Total Impurity by HPLC	Report Results	<0.05%
Purity Factor ³	Report Results	(100%-KF) ⁴

¹ See Figure 1

² See Figure 2

³ Purity Factor is derived from 100% less summation of ROI and HPLC impurities (utilizing Noramco's internal methods). Values less than 0.05% are not included in the Purity Factor.

⁴ For quantitative applications, determine the water content titrimetrically at the time of use and subtract from Purity Factor. Do not dry this material before use.

**Storage Conditions: Store under controlled room temperature conditions.
This material is not intended for sale for human consumption.**

Prepared By: _____
Analytical Scientist, or designee

Approved By: _____
Analytical Services Supervisor, or designee

Authorized By: _____
Quality Assurance, or designee

Figure 1: Naloxone Hydrochloride (NQS1705) FT-IR Spectrum

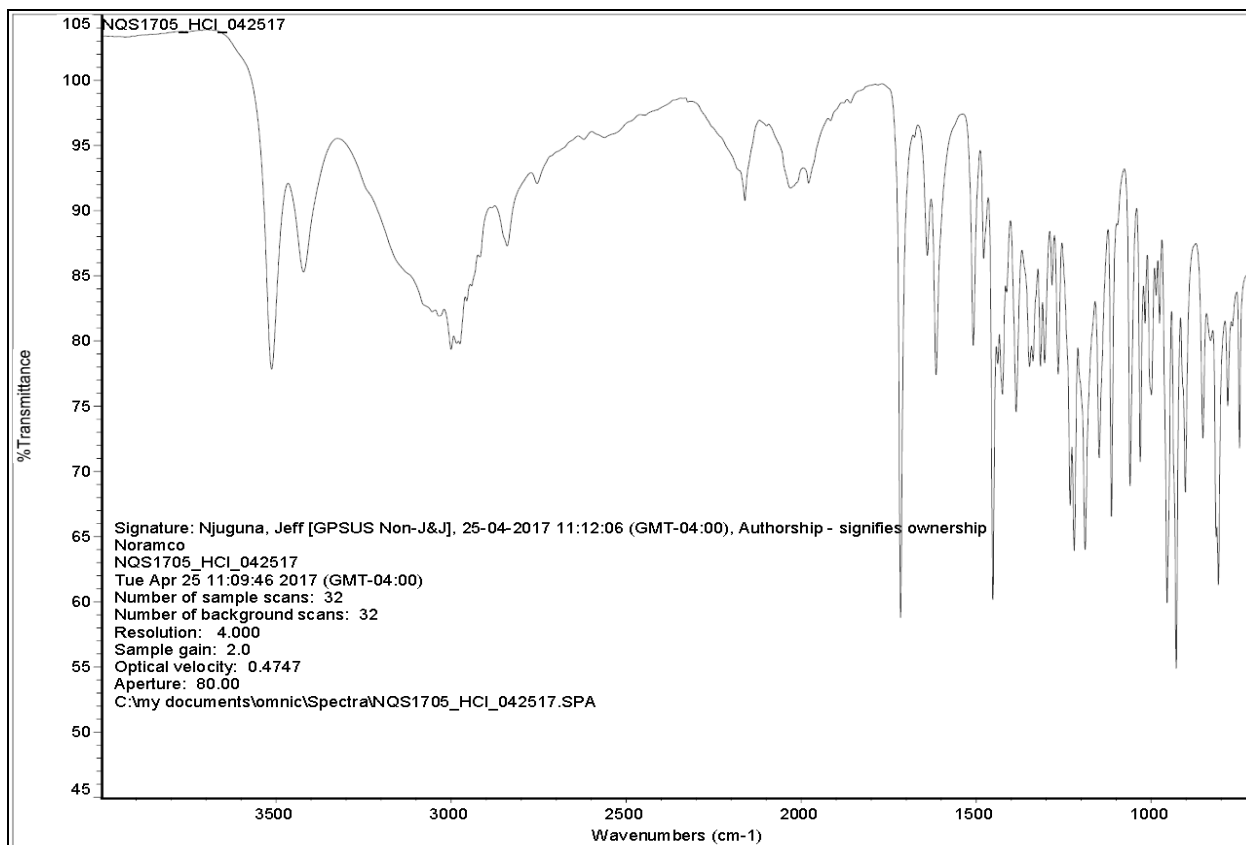


Figure 2: Naloxone Hydrochloride (NQS1705) MS Spectrum

