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Certificate of Analysis

Certificate Number: 2015-SA-099 v 1.0

Material Name: Buprenorphine Base Selectivity Batch
NDC #: 51634-2139-**
Reference Standard #: NQS1213 (Identification Only)
Date of Manufacture: June 2012
Requalification Date: July 31, 2020

Buprenorphine Base Selectivity Batch

Buprenorphine base containing the following impurities of approximately 0.15% w/w: Norbuprenorphine, N-Methylnorbuprenorphine, 6-O-Desmethyl buprenorphine, 5,19-Anhydrobuprenorphine, 15,16-Dehydrobuprenorphine, 17,18-Dehydrobuprenorphine, 3-O-Methyl-N-cyanonorbuprenorphine, N-But-3-enylnorbuprenorphine, 3-O-Methylbuprenorphine.

<u>Test</u>	<u>Limit</u>	<u>Result</u>
Appearance	Report Results	Off-White powder
Mass Spectrometry	Consistent With Structure	Complies
Relative Retention Times by HPLC	Information Only	Complies

Component	RRT*
Norbuprenorphine	0.38
N-Methylnorbuprenorphine	0.50
6-O-Desmethylbuprenorphine	0.59
5,19-Anhydrobuprenorphine	0.61
Buprenorphine	1.00
15,16-Dehydrobuprenorphine	1.16
17,18-Dehydrobuprenorphine	1.20
3-O-Methyl-N-cyano-norbuprenorphine	1.58
N-But-3-enylnorbuprenorphine	1.85
3-O-Methylbuprenorphine	2.02

*Relative retention times (RRT) are based on Noramco's DS-TMD-7091 HPLC1 method.

Storage Conditions: Store under ambient temperature and humidity conditions.

This material is not intended for sale for human consumption.

Prepared By: _____
Analytical Scientist, or designee

Approved By: _____
Reference Standards Program Lead, or designee

Authorized By: _____
Quality Compliance Specialist, or designee

Figure 1: Typical HPLC Chromatogram of Buprenorphine Base Selectivity Batch (NQS1213)

