

Analytical Reference Standards

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Highly characterized, highly purified specimens

The United States Food and Drug Administration requires reference-standard materials to be of the highest quality, and thoroughly characterized, to assure identity, strength, and quality. Noramco offers well-characterized, highly purified analytical reference standards for routine analysis, method validation and development, commercial investigations, stability studies and other product development activities.

Noramco's reference standards program is focused on the synthesis of compounds of complex chemistry. Review our catalog of more than 175 reference standards. All reference materials may be ordered in a variety of quantities to meet your project requirements.

Reference standard qualifications

Noramco utilizes various sophisticated spectroscopic techniques to characterize each reference standard. Overall purity, or "Purity Factor," is typically derived from 100% less the summation of inorganic, organic and solvent impurities.

Table 1. Typical Certificate of Analysis includes:

- 1.0 Appearance
- 2.0 Identification
- 3.0 Inorganic impurities
- 4.0 Organic impurities
- 5.0 Solvent impurities
- 6.0 Purity factor

All analytical reference standards include a signed certificate of analysis (CoA) and safety data sheet. The data within the CoA is based on information we believe to be highly accurate and reliable. Reference standards supplied by Noramco is intended only for analytical and research purposes and may not be used for human consumption.

For reference standards technical support, contact our R&D department.


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Certificate of Analysis
Certificate Number: 2016-SA-128

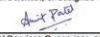
Material Name: Norbuprenorphine Hydrochloride
NDC #: 51634-1048-11
Reference Standard #: NQS1202
Date of Manufacture: March 2012
Requalification Date: December 31, 2019

Test	Limit	Result
Appearance	Report Results	Off-white powder
Infrared Spectroscopy ¹	Consistent With Structure	Complies
Mass Spectrometry ²	Consistent With Structure	Complies
Residue on Ignition (ROI)	Report Results	<0.05%
Karl Fischer (KF)	Report Results	0.35%
Residual Solvents (ROS)	Report Results	1.74%
Total Impurity by HPLC	Report Results	2.23%
Purity Factor ³	Report Results	95.7%

¹ See Figure 1
² See Figure 2
³ Purity Factor is derived from 100% less summation of ROI, KF, ROS and HPLC impurities (utilizing Noramco's internal methods). Values less than 0.05% are not included in the Purity Factor.

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: 
Analytical Services Supervisor, or designee

Authorized By: 
Quality Assurance, or designee

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Certificate Number: 2016-SA-128
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Figure 1: Norbuprenorphine Hydrochloride (NQS1202) FT-IR Spectrum in ATR

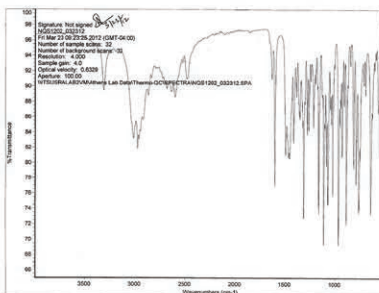
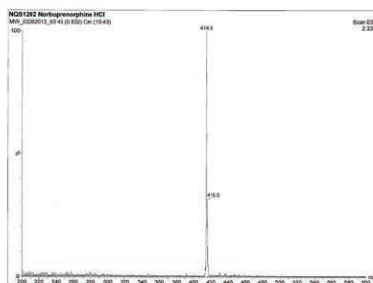


Figure 2: Norbuprenorphine Hydrochloride (NQS1202) MS Spectrum



Sample certificate
of analysis



Common Name	Other Names	CAS #	NDC #
Amphetamine Salts			
Amphetamine Aspartate (CII)		N/A	51634-2023-**
Amphetamine Formamide (NC)	N-formylamphetamine	22148-75-0	51634-2040-**
Amphetamine Impurity 251 (NC)		N/A	51634-2039-**
Amphetamine Sulfate (CII)		60-13-9	51634-2024-**
Dextroamphetamine Saccharate (CII)		350708-40-6	51634-2021-**
Dextroamphetamine Sulfate (CII)		51-63-8	51634-2022-**
Dextroamphetamine Sulfate, < 98% EE (CII)	NEW	51-63-8	51634-2022-**
Phenylacetone (CII)	USP Impurity B	103-79-7	51634-2026-**
Buprenorphine Hydrochloride			
15,16-Dehydrobuprenorphine Base (CII)		61577-04-6	51634-1052-**
17,18-Dehydrobuprenorphine Base (CII)	EP Impurity J	155203-05-7	51634-1036-**
19,19' Ethenylbuprenorphine (CII)	NEW	EP Impurity F	97203-04-8
2,2'-Bisbuprenorphine Base (CII)	EP Impurity G	163597-04-4	51634-2119-**
3-Deshydroxybuprenorphine Base (CII)		N/A	51634-1037-**
3-O-Methylbuprenorphine Base (CII)	EP Impurity D	16524-65-5	51634-1044-**
3-O-Methyl-N-cyanonorbuprenorphine Base (CII)	EP Impurity C	16614-60-1	51634-1041-**
3-O-Methyl-N-methylnorbuprenorphine Base (CII)		N/A	51634-1042-**
3-O-Methylnorbuprenorphine Base (CII)		16614-59-8	51634-1043-**
6-O-Desmethylbuprenorphine Base (CII)	EP Impurity E	130668-48-3	51634-1038-**
Buprenorphine Base (CIII)		52485-79-7	51634-1039-**
Buprenorphine Hydrochloride (CIII)		53152-21-9	51634-1040-**
Buprenorphine N-Oxide (CII)		112242-17-8	51634-1045-**
N-But-3-enylnorbuprenorphine Base (CII)	USP Compound A; EP Impurity A	457071-73-7	51634-1046-**
N-But-3-enylnormethylbuprenorphine Base (CII)	3-O-Methyl-N-(But-3-enyl) Norbuprenorphine Base (CII)	N/A	51634-2000-**
N-butylnorbuprenorphine (CII)	NEW	EP Impurity H	N/A
N-Methylnorbuprenorphine Base (CII)		228550-34-3	51634-1047-**
Norbuprenorphine Hydrochloride (CII)	EP Impurity B	209963-02-0	51634-1048-**
Tetramethylfuran Buprenorphine (CII)	NEW	EP Impurity I; THF Buprenorphine	89663-73-0
			51634-2125-**



Common Name	Other Names	CAS #	NDC #
Codeine Phosphate			
10-Hydroxycodone Base (CII)	EP Impurity E	1777-89-5	51634-0940-**. **
14-Hydroxycodone Base (CII)	EP Impurity F	4829-46-3	51634-0923-**. **
α -Codeimethine Base (CII)		23950-06-3	51634-0904-**. **
Codeine Base (CII)		76-57-3	51634-0009-**. **
Codeine-6-methyl Ether Base (CII)	O-Methylcodeine; EP Impurity A	2859-16-7	51634-0903-**. **
Codinone Base (CII)		467-13-0	51634-0998-**. **
Dimethylpseudomorphine Base (CII)	EP Impurity C	121395-47-9	51634-0901-**. **
Morphine Base (CII)	EP Impurity B	57-27-2	51634-0018-**. **
Norcodeine Base (CII)		467-15-2	51634-2046-**. **
Thebaine Alkaloid (CII)	EP Impurity G	115-37-7	51634-0006-**. **
Hydrocodone Bitartrate			
10-Hydroxyhydrocodone Base (CII)		N/A	51634-1020-**. **
10-Ketohydrocodone Base (CII)		1273112-37-0	51634-2016-**. **
6- β -Tetrahydrothebaine Base (CII)	EP Impurity G	41714-53-8	51634-1017-**. **
8,14-dihydrothebaine (CII)	EP Impurity J	561-25-1	51634-0995-**. **
Codeine Base (CII)	EP Impurity C	76-57-3	51634-0009-**. **
Codeine-6-methyl Ether Base (CII)	O-Methylcodeine; EP Impurity F	2859-16-7	51634-0903-**. **
Codinone Base (CII)	EP Impurity E	467-13-0	51634-0998-**. **
Dihydrocodeine Base (CII)	EP Impurity B, USP Impurity	125-28-0	51634-0088-**. **
Dihydrothebainone Base (CII)	USP Compound A	847-86-9	51634-0911-**. **
Hydrocodone Aldol Dimer (CII)	NEW	N/A	51634-2170-**. **
Hydrocodone Base (CII)		125-29-1	51634-0015-**. **
Hydrocodone Bitartrate (CII)		34195-34-1	51634-0104-**. **
Hydrocodone N-Oxide (CII)		909265-05-0	51634-1000-**. **
Hydromorphone Hydrochloride (CII)	EP Impurity K	71-68-1	51634-0057-**. **
Methylene Bridged Hydromorphone Dimer Base (CII)		N/A	51634-0933-**. **
Methylene Bridged Morphine Dimer Base (CII)		N/A	51634-0932-**. **
Morphine Base (CII)	EP Impurity A	57-27-2	51634-0018-**. **
Morphine Sulfate (CII)		64-31-3	51634-0017-**. **
Oxycodone Base (CII)	EP Impurity D	76-42-6	51634-0003-**. **
Oxycodone Hydrochloride (CII)		124-90-3	51634-0102-**. **
Pseudohydrocodone Base (CII)		N/A	51634-0915-**. **
Thebaine Alkaloid (CII)	EP Impurity I	115-37-7	51634-0006-**. **

Common Name	Other Names	CAS #	NDC #
Hydromorphone Hydrochloride			
6-β-Tetrahydrooripavine Base (CII)	USP Impurity	63732-74-1	51634-0990-**
8,14-Dihydrooripavine Base (CII)	USP Impurity	873087-79-7	51634-0083-**
8-Hydroxyhydromorphone (CII)	USP Impurity	339525-94-9	51634-0988-**
Dihydromorphine Base (CI)	USP Impurity, EP Impurity D	509-60-4	51634-0987-**
Hydromorphone Hydrochloride (CII)		71-68-1	51634-0057-**
Hydromorphone N-Oxide (CII)	EP Impurity B, USP Impurity	109648-80-8	51634-0991-**
Hydromorphone Aldol Dimer (CII)	NEW		51634-2174-**
Morphine Base (CII)	EP Impurity C, USP Impurity	57-27-2	51634-0018-**
Morphinone Perchlorate (CII)	USP Compound A	91265-67-7	51634-1001-**
Norhydromorphone Base (CII)		14696-23-2	51634-0989-**
Pseudodihydrooripavine Base (CII)		N/A	51634-0993-**
Pseudohydromorphone Base (CII)	EP Impurity A, USP Impurity 2,2'-bisdihydromorphone	N/A	51634-0981-**
Methylphenidate Hydrochloride			
Ethylphenidate Hydrochloride (NC)	USP Impurity, EP Impurity E	19716-79-1	51634-1054-**
Methylphenidate Hydrochloride (CII)		298-59-9	51634-0114-**
Methylphenidate Hydrochloride, Erythro Isomer (CII)	USP Impurity, EP Impurity B	23644-60-2	51634-2111-**
Ritalinic Acid (NC)	USP Compound A; EP Impurity A	19395-41-6	51634-1055-**
Morphine Sulfate			
10-Ketomorphine (CII)	NEW		51634-1093-**
14-Hydroxymorphine Base (CII)		3371-56-0	51634-1088-**
Codeine Base (CII)	EP Impurity A	76-57-3	51634-0009-**
Morphine Base (CII)		57-27-2	51634-0018-**
Morphine N-Oxide (CI)	USP Compound A; EP Impurity F	639-46-3	51634-0907-**
Morphine Sulfate (CII)		64-31-3	51634-0017-**
Morphinone Perchlorate (CII)	EP Impurity E	91265-67-7	51634-1001-**
Oripavine Base (CII)	EP Impurity C	467-04-9	51634-0001-**
Pseudomorphine Base (CII)	USP Compound B; EP Impurity B 2,2'-bimorphine	125-24-6	51634-0902-**



Common Name	Other Names	CAS #	NDC #
Naloxone			
10- α -Hydroxynaloxone Base (CII)	EP Impurity C	N/A	51634-2009-**. **
10- β -Hydroxynaloxone Base (CII)	EP Impurity F	N/A	51634-2010-**. **
10-Ketonaloxone Base (CII)		294175-43-2	51634-2042-**. **
3-O-Allylnaloxone Hydrochloride (CII)	EP Impurity B	N/A	51634-2050-**. **
7,8-Didehydronaloxone Base (CII)	EP Impurity D	26451-92-3	51634-2043-**. **
Naloxone Base (NC)		465-65-6	51634-2017-**. **
Naloxone Dimer (CII)	EP Impurity E; 2,2'-bisnaloxone	211738-08-8	51634-2041-**. **
Naloxone Hydrochloride (NC)		357-08-4	51634-2018-**. **
Naloxone N-Oxide (CII)		112242-14-5	51634-2109-**. **
Noroxymorphone Base (CII)	EP Impurity A, USP Impurity	33522-95-1	51634-1022-**. **
Noroxymorphone Carbamate (CII)		144265-46-3	51634-2006-**. **
Naltrexone			
10-Hydroxynaltrexone Base (CII)		60767-82-0	51634-2052-**. **
10-Ketonalnaltrexone Base (CII)	EP Impurity I	96445-14-6	51634-2011-**. **
14-Hydroxy-17-Cyclopropylmethylnormorphinone Base (CII)		123086-68-0	51634-2012-**. **
2,2'-Bisnaltrexone Base (CII)	EP Impurity D; Pseudonaltrexone	607732-61-6	51634-1061-**. **
3-(Cyclopropylmethyl) Naltrexone Base (CII)	EP Impurity E	767615-69-0	51634-1062-**. **
3-O-Methylnaltrexone Base (CII)	EP Impurity J	16617-07-5	51634-2104-**. **
8-Hydroxynaltrexone Base (CII)		N/A	51634-2007-**. **
N-(3-Butenyl)-Noroxymorphone Base (CII)	USP Compound A; EP Impurity C	189016-90-8	51634-2013-**. **
Naltrexone Aldol Dimer Base (CII)		N/A	51634-1063-**. **
Naltrexone Base (NC)		16590-41-3	51634-1060-**. **
Naltrexone Hydrochloride (NC)		16676-29-2	51634-1064-**. **
Noroxymorphone Base (CII)	EP Impurity B	33522-95-1	51634-1022-**. **
Noroxymorphone Carbamate (CII)		144265-46-3	51634-2006-**. **
Oxymorphone Base (CII)		76-41-5	51634-0913-**. **
Oxymorphone Hydrochloride (CII)		357-07-3	51634-0095-**. **





Common Name	Other Names	CAS #	NDC #
Oxycodone Hydrochloride			
10-Hydroxyoxycodone Base (CII)	USP Impurity	N/A	51634-2005-**
10-Ketooxycodone Base (CII)		96445-11-3	51634-2126-**
14-Hydroxycodeinone Base (CII)	USP Compound A; EP Impurity D	508-54-3	51634-0906-**
7,8-Dihydro-14-Hydroxycodine Base (CII)	6-a-Oxycodol (USP); EP Impurity B	7183-69-9	51634-0920-**
7,8-Dihydro-8,14-Dihydroxycodine Base (CII)	USP Impurity	23185-97-9	51634-0918-**
7-Methyloxycodone Base (CII)		2859-09-8	51634-1032-**
Codeinone Base (CII)	USP Compound C	467-13-0	51634-0998-**
Hydrocodone Base (CII)	EP Impurity E, USP Impurity	125-29-1	51634-0015-**
Noroxycodone Hydrochloride (CII)	EP Impurity C	52446-25-0	51634-1057-**
Noroxymorphone Base (CII)	USP Impurity	33522-95-1	51634-1022-**
Oxycodone Aldol Dimer (CII)	NEW		51634-2171-**
Oxycodone Base (CII)		76-42-6	51634-0003-**
Oxycodone Ethyl Enolate (CII)		100740-55-4	51634-0919-**
Oxycodone Hydrochloride (CII)		124-90-3	51634-0102-**
Oxycodone N-Oxide (CII)	USP Compound B	71539-52-1	51634-0908-**
Oxymorphone Base (CII)	EP Impurity A, USP Impurity	76-41-5	51634-0913-**
Oxymorphone Hydrochloride (CII)		357-07-3	51634-0095-**
Thebaine Alkaloid (CII)	EP Impurity F	115-37-7	51634-0006-**
Oxymorphone Hydrochloride			
10-Hydroxyoxymorphone Base (CII)		1801682-01-8	51634-2020-**
10-Ketooxymorphone Base (CII)		96445-15-7	51634-2019-**
14- α -Hydroxydihydromorphone Base (CI)		2183-56-4	51634-1053-**
14-Hydroxycodeinone Base (CII)		508-54-3	51634-0906-**
14-Hydroxymorphinone Base (CII)		41135-98-2	51634-1013-**
2,2'-Bisoxymorphone Base (CII)		1426174-64-2	51634-1028-**
4-Hydroxyoxymorphone Base (CII)		N/A	51634-2130-**
4-Hydroxyoxymorphone HCl (CII)	NEW	N/A	51634-2153-**
8-Hydroxyoxymorphone Base (CII)		109440-85-9	51634-1050-**
Hydromorphone Hydrochloride (CII)		71-68-1	51634-0057-**
Noroxymorphone Base (CII)		33522-95-1	51634-1022-**
Oxycodone Base (CII)		76-42-6	51634-0003-**
Oxycodone Hydrochloride (CII)		124-90-3	51634-0102-**
Oxymorphone Aldol Dimer (CII)	NEW		51634-2133-**
Oxymorphone Base (CII)		76-41-5	51634-0913-**
Oxymorphone Hydrochloride (CII)		357-07-3	51634-0095-**
Oxymorphone N-Oxide (CII)		71360-37-7	51634-1049-**
Pyran Bridged Oxymorphone Dimer Base (CII)		N/A	51634-1059-**



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3. Certificate of available procurement quota (if applicable)
4. Copy of DEA license (if ordering schedule 3 compounds)

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2. A non re-export statement

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