DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 18, 2015

GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
LSI INTERNATIONAL
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20878

Re: K150602
Trade/Device Name: CR3 Keyless Split Sample Cup Morphine - Methamphetamine
Regulation Number: 21 CFR 862.3640
Regulation Name: Morphine test system
Regulatory Class: II
Product Code: DNK, LAF
Dated: March 3, 2015
Received: March 10, 2015

Dear Mr. Joe Shia:

This letter corrects our substantially equivalent letter of April 7, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CR3 Keyless Split Sample Cup Morphine – Methamphetamine

Indications for Use *(Describe)*
CR3 Keyless Split Sample Cup Morphine–Methamphetamine is a rapid test for the qualitative detection of Morphine and Methamphetamine in human urine at a cutoff concentration of 300 ng/mL and 1000 ng/mL, respectively. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained. The test is intended for over-the-counter and for prescription use.

The CR3 Keyless Split Sample Cup Morphine–Methamphetamine test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

1. Date: March 31, 2015

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, Guangzhou, P.R. China 510663

3. Contact person: Joe Shia
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4. Device Name: CR^3 Keyless Split Sample Cup Morphine – Methamphetamine

Classification: Class II

Product Code	CFR #	Panel
DNK	21 CFR, 862.3640 Morphine Test System	Toxicology
LAF	21 CFR, 862.3610 Methamphetamine Test System	Toxicology

5. Predicate Devices: K142580
Chemtrue Multi-Panel DOA DipCard Tests

6. Intended Use:
CR3 Keyless Split Sample Cup Morphine–Methamphetamine is a rapid test for the qualitative detection of Morphine and Methamphetamine in human urine at a cutoff concentration of 300 ng/mL and 1000 ng/mL, respectively. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained. The test is intended for over-the-counter and for prescription use.

The CR3 Keyless Split Sample Cup Morphine–Methamphetamine test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only.

7. Device Description:

The CR3 Keyless Split Sample Cup Morphine–Methamphetamine test uses immunochromatographic assays for Morphine and Methamphetamine. The test is a lateral flow system for the qualitative detection of Morphine and Methamphetamine in human urine. The test is the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

8. Substantial Equivalence Information

Item	Device	Predicate – K142580
Indication(s) for use	For the qualitative determination of drugs of abuse in human urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Morphine: 300ng/ml Methamphetamine: 1000ng/ml	Same for Morphine and Methamphetamine
Configurations	Cup	Dipcard
Conditions for Use	Over-the-Counter & Prescription Use	Same

9. Test Principle

The CR3 Keyless Split Sample Cup Morphine–Methamphetamine test is a rapid test for the qualitative detection of Morphine and Methamphetamine in urine samples and contains lateral flow chromatographic immunoassays for Morphine and Methamphetamine. Each assay uses a mouse monoclonal anti-drug antibody-dye conjugate, fixed drug-protein conjugates, and anti-mouse IgG polyclonal antibodies coated on the test membranes. When the absorbent end of the test is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentrations below the target cut-off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cut-off, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a potentially positive result. A band should form in the control region (C) of the device regardless of the presence of drug or metabolite in the sample.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off , +75% cut-off and +100% cut-off. For each concentration, tests were performed two runs per day by three operators for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Morphine (MOP) testing

Result / MOP	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-

B. For Methamphetamine (MET) testing

Result / MET	-100% cut-off	-75% cut-off	-50% cut- off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The CR3 Keyless Split Sample Cup Morphine–Methamphetamine is stable at 4-30^{o}C for 18 months as determined by conducting accelerated and real-time stability testing.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

Cut-off studies were conducted using a total of 125 morphine samples and 125 methamphetamine samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs. These samples were tested using three different lots by three different operators. Results were all positive at +25% and +50% cut-off and all negative at -25% and -50% cut-off for both morphine and methamphetamine. The following cut-off values for the test devices have been verified.

Test	**Calibrator**	**Cut-off (ng/ml)**
Morphine (MOP）	Morphine	300
Methamphetamine (MET)	D–Methamphetamine	1000

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to urine containing target drugs (morphine or methamphetamine) at 25% below and 25% above the cut-off. These urine samples were tested using three batches of the CR3Keyless Split Sample Cup Morphine–Methamphetamine by three different operators. Compounds that showed no interference at a concentration of 100µg/mL are summarized below:

Morphine

4-Acetamidophenol	Ecgonine methylester	Oxolinic acid
Acetaminophen	(-)-Y-Ephedrine	Oxycodone
Acetophenetidin	Erythromycin	Oxymetazoline
N-Acetvprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylate	Furosemide	Pentobarbital
Aminopyrine	Gentisic acid	Perphenazine
Amityptyline	Hemoglobin	Phencyclidine
Amorbarbital	Hydralazine	Phenelzine
Amoxicillin	Hydrochlorothiazide	Phenobarbital
Ampicillin	Hydrocortisone	L-Phenylephrine
l-Ascorbic Acid	O-Hydroxyhippuric acid	b-Phenylethylamine
Apormorphine	p-Hydroxy-methamphetamine	Phenylpropanotamine
Aspartame	3-Hydroxytyramine	Prednisone
Atropine	Ibuprofen	Prednisolone
Benzilic acid	Imipramine	Procaine
Benzoic acid	(±)Isoproterenol	D.L-Propanolol
Benzoylecgonine	Isoxsuprine	D-Propoxyphene
Bilirubin	Ketamine	D-Pseudoephedrine
Caffeine	Ketoprofen	Quinine

Cannabidiol	Labetalol	Ranitidine
Chloralhvdrate	Loperamide	Salicylic acid
Chloramphenicol	Loxapine succinate	Secobarbital
Chlordiazepoxide	Maprotiline	Serotonin (5-Hydroxytyramine)
Chlorothiazide	Meperidine	Sulfamethazine
Chlorpromazine	Meprobamate	Sulindac
Chlorquine	Methadone	Temazepam
Cholesterol	Methoxyphenamine	Tetracycline
Clomipramine	(+)3,4-Methylenedioxy-amphetamine	Tetrahydrocortisone,3 Acetate
Clonidine	(+)3,4-Methylenedioxy-methamphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Cocaine hydrochloride	Nalidixic acid	Tetrahydrozoline
(-)cotinine	Nalorphine	Thiamine
Creatinine	Naloxone	Thioridazine
Dextromethlorphan	Naltrexone	D.L-Tyrosine
Deoxycorticosterone	Naproxen	Tolbutamide
Diazepam	Niacinamide	Triamterene
Diclolrfenac	Nifedipine	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Diaoxin	D-Norpropoxyphene	Triyptamine
Diphenhydramine	Noscapine	D.L-Tryptophan
Doxylamine	D.L-Octopamine	Tyramine
Ecgonine hydrochloride	Oxalic acid	Uric acid
β-Estradiol	Oxazepam	Verapamil
Estrone-3-sulfate	Papaverine	Zomepirac

Methamphetamine

4-Acetamidophenol	Estrone-3-sulfate	Oxycodone
Acetaminophen	Erythromycin	Papaverine
Acetophenetidin	Fenoprofen	Penicillin-G
N-Acetvprocainamide	Furosemide	Pentobarbital
Acetylsalicylate	Gentisic acid	Perphenazine
Aminopyrine	Hemoglobin	Phencyclidine
Amityptyline	Hydralazine	Phenelzine
Amorbarbital	Hydrochlorothiazide	Phenobarbital
Amoxicillin	Hydrocodone	L-Phenylephrine
Ampicillin	Hydrocortisone	Phenylpropanotamine
l-Ascorbic Acid	O-Hydroxyhippuric acid	Prednisone
Apormorphine	3-Hydroxytyramine	Prednisolone
Aspartame	Ibuprofen	Procaine

Atropine	Imipramine	D.L-Propanolol
Benzilic acid	(±)Isoproterenol	D-Propoxyphene
Benzoic acid	Isoxsuprine	D-Pseudoephedrine
Benzoylecgonine	Ketamine	Quinine
Bilirubin	Ketoprofen	Ranitidine
Caffeine	Labetalol	Salicylic acid
Cannabidiol	Loperamide	Secobarbital
Chloralhvdrate	Loxapine succinate	Serotonin (5-Hydroxytyramine)
Chloramphenicol	Maprotiline	Sulfamethazine
Chlordiazepoxide	Meperidine	Sulindac
Chlorothiazide	Meprobamate	Temazepam
Chlorpromazine	Methadone	Tetracycline
Cholesterol	Methoxyphenamine	Tetrahydrocortisone,3 Acetate
Clomipramine	Morphine-3-β-Dglucuronide	Tetrahydrocortisone 3 (β-D glucuronide)
Clonidine	Nalidixic acid	Tetrahydrozoline
Cocaine hydrochloride	Nalorphine	Thebaine
Codeine	Naloxone	Thiamine
(-)cotinine	Naltrexone	Thioridazine
Creatinine	Naproxen	D.L-Tyrosine
Dextromethlorphan	Niacinamide	Tolbutamide
Deoxycorticosterone	Nifedipine	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclolrfenac	D-Norpropoxyphene	Trimethoprim
Diflunisal	Noscapine	Triyptamine
Diaoxin	D.L-Octopamine	D.L-Tryptophan
Diphenhydramine	Oxalic acid	Tyramine
Doxylamine	Oxazepam	Uric acid
Ecgonine hydrochloride	Oxolinic acid	Verapamil
β-Estradiol	Oxymetazoline	Zomepirac
Ecgonine methylester		

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. The target drug (Morphine or Methamphetamine), its drug metabolites and the related compounds were studied. These samples were tested using three batches of the CR3Keyless Split Sample Cup Morphine–Methamphetamine by three different operators. The drug metabolites and other components were tested at different concentrations. The obtained lowest detectable concentration was used to calculate the cross-reactivity. Results are shown in the following tables.

MOP (Morphine**, Cut-off=300 ng/mL)**	**Result**	**% Cross-Reactivity**
Morphine	Positive at 300 ng/mL	100%
Normorphine	Positive at 300 ng/mL	100%
6-Monoacetylmorphine	Positive at 300 ng/mL	100%
Codeine	Positive at 300 ng/mL	100%
Ethyl Morphine	Positive at 300 ng/mL	100%
Heroine	Positive at 300 ng/mL	100%
Hydrocodone	Positive at 5,000 ng/mL	6%
Hydromorphone	Positive at 5,000 ng/mL	6%
Morphinie-3-β-d-glucuronide	Positive at 1,000 ng/mL	30%
Thebaine	Positive at 30,000 ng/mL	1%
Oxycodone	Negative at 100,000 ng/mL	Not detected
Oxymorphone	Negative at 100,000 ng/mL	Not detected

MET (D-Methamphetamine**, Cut-off=1000 ng/mL)**	**Result**	**% Cross-Reactivity**
D-Methamphetamine	Positive at 1,000 ng/mL	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	Positive at 1,000 ng/mL	100%
D/L-Methamphetamine	Positive at 1,000 ng/mL	100%
p-Hydroxymethamphetamine	Positive at 1,000 ng/mL	100%
D-Amphetamine	Positive at 50,000 ng/mL	2%
L-Amphetamine	Positive at 75,000 ng/mL	1.3%
Chloroquine	Positive at 50,000 ng/mL	2%
(+/-)-Ephedrine	Positive at 50,000 ng/mL	2%
L-Methamphetamine	Positive at 25,000 ng/mL	4%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	Positive at 1,000 ng/mL	100%
(+/-)3,4-methylenedioxymethamphetamine(MDMA)	Positive at 2,000 ng/mL	50%
β-Phenylethylamine	Positive at 50,000 ng/mL	2%
Trimethobenzamide	Positive at 10,000 ng/mL	10%

g. Effect of Specific Gravity and Urine pH

Twelve urine samples of normal, high, and low specific gravity ranges (1.000 to 1.035) were collected and spiked with either Morphine or Methamphetamine at 25% below and 25% above

the corresponding cut-off level. These samples were tested using three batches of the CR3 Keyless Split Sample Cup Morphine-Methamphetamine by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with Morphine or Methamphetamine at 25% below and 25% above the corresponding cut-off levels. These samples were tested using three batches of the CR3 Keyless Split Sample Cup Morphine - Methamphetamine by three different operators.

The device performance was found to not be affected by varying specific gravity and pH.

2. Comparison Studies

The method comparison for the CR^3 Keyless Split Sample Cup Morphine - Methamphetamine was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked and randomized. The obtained test results were compared to GC/MS results. The results are presented in the table below:

Morphine

Group / Operators		**Negative**	**Low Negative by GC/MS (less than -50%)**	**Near Cutoff Negative by GC/MS (Between -50% and cutoff)**	**Near Cutoff Positive by GC/MS (Between the cutoff and +50%)**	**High Positive by GC/MS (greater than +50%)**
Viewer A	Positive	0	0	3	17	20
	Negative	10	18	9	3	0
Viewer B	Positive	0	0	4	16	20
	Negative	10	18	8	4	0
Viewer C	Positive	0	0	3	16	20
	Negative	10	18	9	4	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	MOPC3061	291	positive
Viewer A	MOP3211	289	positive
Viewer A	MOP3224	294	positive
Viewer A	MOP3216	304	negative
Viewer A	MOP3221	311	negative
Viewer A	MOP3228	301	negative
Viewer B	MOPC3061	291	positive
Viewer B	MOP3211	289	positive

Viewer B	MOP3214	267	positive
Viewer B	MOP3224	294	positive
Viewer B	MOP3216	304	negative
Viewer B	MOP3221	311	negative
Viewer B	MOP3223	319	negative
Viewer B	MOP3228	301	negative
Viewer C	MOPC3061	291	positive
Viewer C	MOP3211	289	positive
Viewer C	MOP3224	294	positive
Viewer C	MOP3216	304	negative
Viewer C	MOP3221	311	negative
Viewer C	MOP3223	319	negative
Viewer C	MOP3228	301	negative

Methamphetamine

Group / Operators		**Negative**	**Low Negative by GC/MS (less than -50%)**	**Near Cutoff Negative by GC/MS (Between -50% and cutoff)**	**Near Cutoff Positive by GC/MS (Between the cutoff and +50%)**	**High Positive by GC/MS (greater than +50%)**
Viewer A	Positive	0	0	3	17	19
	Negative	10	10	17	4	0
Viewer B	Positive	0	0	3	18	19
	Negative	10	10	17	3	0
Viewer C	Positive	0	0	3	18	19
	Negative	10	10	17	3	0

Discordant table:

Viewer	Sample number	GC/MS result	viewer results
Viewer A	METC1062	962	positive
Viewer A	MET1208	985	positive
Viewer A	MET1217	978	positive
Viewer A	MET1219	1009	negative
Viewer A	MET1224	1024	negative
Viewer A	MET1226	1012	negative
Viewer A	METC1124	1003	negative
Viewer B	METC1062	962	positive
Viewer B	MET1208	985	positive
Viewer B	MET1217	978	positive
Viewer B	MET1219	1009	negative

Viewer B	MET1226	1024	negative
Viewer B	METC1124	1003	negative
Viewer C	METC1062	962	positive
Viewer C	MET1208	985	positive
Viewer C	MET1217	978	positive
Viewer C	MET1219	1009	negative
Viewer C	MET1226	1024	negative
Viewer C	METC1124	1003	negative

Lay-user study

A lay user study was performed at three intended user sites with 260 lay persons, of which, 20 tested for drug-free samples, 120 for morphine samples, 120 for methamphetamine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
Drug -free	-100%	20	20	0	100%
Morphine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Methamphetamine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that CR^3 Keyless Split Sample Cup Morphine –Methamphetamine is substantially equivalent to the predicate.