

**Syntron Bioresearch, Inc.**  
**Dip DrugScan 5 Test**  
**Catalog No. 30529**  
**Instructions**

**INTENDED USE**

The Dip DrugScan 5 Test is an immunochromatographic assay for rapid, qualitative detection of five drugs and their principal metabolites in urine at specified cut-off concentrations. A five drug combination is composed from any of the following drugs:

DRUG CLASS	SENSITIVITY
COCAINE/BENZOYLECGONINE	300 ng/ml
MARIJUANA	50 ng/ml
METHAMPHETAMINE	1000 ng/ml
OPIATES/MORPHINE	2000 ng/ml
PHENCYCLIDINE	25 ng/ml

*Note: The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.*

**SUMMARY AND EXPLANATION OF THE TEST**

The Syntron Bioresearch Dip DrugScan 5 Test is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of monoclonal and polyclonal antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA). Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the Dip DrugScan 5 Test is set as required for the screening immunoassays of these drugs in the reference guidelines set by SAMHSA and the U.S. Department of Health and Human Services.

**PRINCIPLE OF THE TEST**

The Dip DrugScan 5 Test is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of five drugs from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen- antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose-pink color band is produced in each Control Zone (marked "C") by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.



**REAGENTS AND MATERIALS PROVIDED**

- 1. Test Devices. Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
- 2. Test Instructions. *Cat. # PI-30529*
- Optional:**
- 3. Negative Control I. Contains buffered protein solution with sodium azide. *Cat. # 4010N*
- 4. Cocaine Positive Control. Contains BEG at 1000 ng/ml in a buffered protein solution with sodium azide. *Cat. # 12000-BP*

- 5. Marijuana Positive Control. Contains THC at 150 ng/ml in a buffered solution with sodium azide. *Cat. # 13020P*
- 6. Methamphetamine Positive Control. Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. *Cat. # 11320-BP*
- 7. Opiates Positive Control. Contains MOR at 5000 ng/ml in a buffered protein solution with sodium azide. *Cat. # 11220-BP*
- 8. PCP Positive Control. Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. *Cat. # 14020P*

**MATERIALS REQUIRED BUT NOT PROVIDED**

- 1. Clock or timer.
- 2. Specimen collection containers.

**WARNINGS AND PRECAUTIONS**

- 1. For *in vitro* diagnostic and professional use only.
- 2. Do not use the test device beyond the expiration date.
- 3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
- 4. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the device might be compromised.

**STORAGE AND STABILITY**

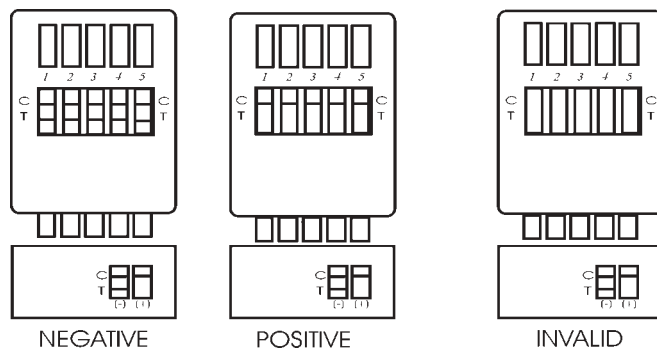
Store test kit below 28°C; **do not freeze**. Refer to the expiration date for stability.

**TEST PROCEDURE**

- 1. Bring a urine sample and a foil test pouch to room temperature (15°-28°C).
- 2. Do not break the seal of the pouch until ready to begin testing.
- 3. Remove a Test Device from the foil pouch.
- 4. Remove the protective cap and place the revealed strips into the urine sample for 10 seconds. Do not allow the urine level to touch the plastic device.
- 5. Read the results at 5 minutes.

**NOTE:** *The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.*

**INTERPRETATION OF RESULTS**



**Positive:** A rose-pink band is visible in each control zone. No color band appearing in the appropriate test zone indicates a positive result for the corresponding drug of that specific test zone.

**Negative:** A rose-pink band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

**Invalid:** If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

**Note:** *There is no meaning attributed to line color intensity or width.*



## QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

## LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

## PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The Dip DrugScan 5 Test detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by the SAMHSA and the U.S. Department of Health and Human Services.
2. **Specificity.** A study was conducted with the Dip DrugScan 5 Test to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in **Table II**.

**Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:**

*The following Cocaine-related substances yield positive results for Cocaine*

### at 300 ng/ml Cut-Off Level

Benzoylecgonine	300 ng/ml
Cocaine	300 ng/ml
Isoxsuprine	2,500 ng/ml

*The following Marijuana-related substances yield positive results for Marijuana at 50 ng/ml cut-off:*

11-Nor- $\Delta^8$ -THC-9-COOH	50 ng/ml
11-Nor- $\Delta^9$ -THC-9-COOH	50 ng/ml
$\Delta^8$ -THC	1 $\mu$ g/ml
$\Delta^9$ -THC	4 $\mu$ g/ml
Cannabinol	10 $\mu$ g/ml
11-Hydroxy- $\Delta^8$ -THC	10 $\mu$ g/ml

*The following Opiates-related substances yield a positive result for Opiates at 2000 ng/ml Cut-Off Level:*

Morphine	2,000 ng/ml	Levorphanol	6,000 ng/ml
Morphine-3- $\beta$ -D-Glucuronide	2,000 ng/ml	Naloxone	10,000 ng/ml
Codeine	2,000 ng/ml	Thebaine	15,000 ng/ml
Heroin	2,000 ng/ml	Imipramine	500,000 ng/ml
Norcodeine	20,000 ng/ml	Atropine	1,000,000 ng/ml
Hydrocodone	5,000 ng/ml	Meperidine	1,000,000 ng/ml
Hydromorphone	2,000 ng/ml	Ranitidine	1,000,000 ng/ml
Oxycodone	100,000 ng/ml		

*The following Methamphetamine-related substances yield positive results for Methamphetamine at 1000 ng/ml Cut-Off level:*

( $\pm$ ) 3,4-Methylenedioxyamphetamine (MDMA, Ecstasy)	1250 ng/ml
d-Amphetamine	50,000 ng/ml
( $\pm$ ) 3,4-Methylenedioxyamphetamine (MDA)	250,000 ng/ml
(+) Methamphetamine	1,000 ng/ml
dl-Amphetamine	500,000 ng/ml
Deoxyephedrine	1,000 ng/ml
Pseudoephedrine	2,500 ng/ml
Ephedrine	10,000,000 ng/ml
Phenylpropanolamine	10,000,000 ng/ml

*The following Phencyclidine (PCP)-related substances yield positive results for PCP at 25 ng/ml Cut-Off Level:*

n-Acetylprocainamide	10,000 ng/ml
Codeine	5,000 ng/ml
p-Hydroxymethamphetamine	50,000 ng/ml
Thebaine	10,000 ng/ml
1-(1-Phenylcyclohexyl)morphine	600 ng/ml
N,N-Diethyl-1-phenyl-cyclohexylamine	2.0 ng/ml
1-[1-(2-Thienyl)cyclohexyl]morphine	200 ng/ml
Phencyclidine	25 ng/ml
1-(4-Hydroxypiperidino) phenylcyclohexane	550 ng/ml
1-(1-Phenylcyclohexyl) pyrrolidine	200 ng/ml
4-Phenyl-4-piperidino cyclohexanol	60 ng/ml
1-[1-(2-Thienyl)-cyclohexyl] piperidine	30 ng/ml
1-[1-(2-Thienyl)-cyclohexyl] pyrrolidine	600 ng/ml

**Table II: Compounds tested and found not to cross-react with the test at a specified urine concentration.**

*The following compounds do not cross-react with (300 ng/ml cut-off) Cocaine at a 100  $\mu$ g/ml concentration in urine:*

Acetaminophen	Ecgonine HCl	Oxycodone
Acetylsalicylic Acid	Ecgonine Methyl Ester	Phendimetrazine
Amikacin	Glucose	Penicillin G
Amitriptyline	Histamine	Pentobarbital
Ampicillin	Hydrochlorothiazide	D-Propoxyphene
Arterenol	Hydrocodone	1-Propanol
Aspartame	Hydromorphone	Phencyclidine
Atropine Sulfate	Indomethacin	Phenobarbital
Benzoic Acid	Ketoprofen	Phentermine
Caffeine	Levorphanol	Phenylpropanolamine
Chlorpheniramine	$\Delta^9$ -THC	1-Phenylephrine
Chlorpromazine HCl	11-Nor- $\Delta^9$ -THC-9-COOH	Quinine
Cimetidine	Meperidine	Ranitidine
Codeine	Methylphenidate	Sodium Salicylate
Deoxyephedrine	Methadone	Tetracycline
Dextromethorphan	Methaqualone	Tetrahydrozoline
Diazepam	Morphine-3- $\beta$ -D-Glucuronide	Theophylline
Diethylpropion	Morphine Sulfate	Thioridazine
5,5-Diphenylhydantoin	Oxazepam	Trifluoperazine
Doxylamine		Tryptophan

*The following compounds do not cross-react with (50 ng/ml cut-off) Marijuana at a 100  $\mu$ g/ml concentration in urine:*

Acetaminophen	Digitoxin	Meperidine
4-Acetamidophenol	Digoxin	Methadone
Acetylsalicylic Acid	Ecgonine HCl	Methaqualone
Amikacin	Ecgonine Methyl Ester	Naloxone
Ampicillin	Ephedrine	Neomycin
d,l-Amphetamine	Epinephrine	Niacinamide
Amitriptyline	Genistic Acid	Oxazepam
Arterenol	Glucose	Perphenazine
Aspartame	Guaiacol	Penicillin G
Atropine Sulfate	Glyceryl Ether	Phencyclidine
Benzoic Acid	Histamine	Phenobarbital
Benzoylecgonine	Hydrochlorothiazide	$\alpha$ -Phenylethylamine
Caffeine	Hydrocodone	Phenylpropanolamine
Camphor	Hydromorphone	Promethazine
Chloroquine	Homatropine	Pseudoephedrine
Chlorpheniramine	Imipramine	Ranitidine
Chlorpromazine HCl	Isoproterenol	Salicylic Acid
Cocaine HCl	Ketamine	Secobarbital
Cocaine	Lidocaine	Tetracycline
Cimetidine	Methylphenidate	Tetrahydrozoline
Cortisone	Morphine-3- $\beta$ -D-Glucuronide	Theophylline
Deoxyephedrine	Morphine Sulfate	Thioridazine
Dextromethorphan	d-Methamphetamine	Trifluoperazine
Diazepam		Tryptophan

*The following compounds do not cross-react with (1000 ng/ml cut-off) Methamphetamine at a 100  $\mu$ g/ml concentration in urine:*

Acetaminophen	Ecgonine HCl	Penicillin G
Acetylsalicylic Acid	Ecgonine Methyl Ester	Pentobarbital
Amikacin	Glucose	d-Propoxyphene
Amitriptyline	Histamine	1-Propanol
Ampicillin	Hydrochlorothiazide	Phencyclidine
Arterenol	Hydrocodone	Phenobarbital
Aspartame	Hydromorphone	Phentermine
Atropine Sulfate	Indomethacin	Phenylpropanolamine
Benzoic Acid	Ketoprofen	1-Phenylephrine
Benzoylecgonine HCl	Levorphanol	Quinine
Caffeine	$\Delta^9$ -THC	Ranitidine
Chlorpheniramine	11-Nor- $\Delta^9$ -THC-9-COOH	Sodium Salicylate
Chlorpromazine HCl	Meperidine	Tryptophan
Cimetidine	Methylphenidate	Tetracycline
Codeine	Methadone	Tetrahydrozoline
Deoxyephedrine	Methaqualone	Theophylline
Dextromethorphan	Morphine-3- $\beta$ -D-Glucuronide	Thioridazine
Diazepam	Morphine Sulfate	Trifluoperazine
Diethylpropion	Oxazepam	
5,5-Diphenylhydantoin	Oxycodone	
Doxylamine	Phendimetrazine	

*The following compounds do not cross-react with (2000 ng/ml cut-off) Opiates at a 100 mg/ml concentration in urine:*

Acetaminophen	5,5-Diphenylhydantoin	Pentobarbital
Acetylsalicylic Acid	Doxylamine	d-Propoxyphene
Amikacin	Ecgonine HCl	1-Propanol
Amitriptyline	Ecgonine Methyl Ester	Phencyclidine
Ampicillin	Glucose	Phenobarbital
Arterenol	Histamine	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Benzoic Acid	Indomethacin	1-Phenylephrine
Benzoylecgonine HCl	Ketoprofen	Quinine
Caffeine	$\Delta^9$ -THC	Sodium Salicylate
Chlorpheniramine	11-Nor- $\Delta^9$ -THC-9-COOH	Tryptophan
Chlorpromazine HCl	Methylphenidate	Tetracycline
Cimetidine	Methadone	Tetrahydrozoline
Deoxyephedrine	Methaqualone	Theophylline
Dextromethorphan	Oxazepam	Thioridazine
Diazepam	Phendimetrazine	Trifluoperazine
Diethylpropion	Penicillin G	



The following compounds do not cross-react with (25 ng/ml cut-off) Phencyclidine at a 100 µg/ml concentration:

Acetaminophen	Egonine -HCl	Phendimetrazine
Acetylsalicylic Acid	Egonine Methyl Ester	Penicillin G
Amikacin	Glucose	d-Propoxyphene
Amitriptyline	Histamine	l-Propranol
Ampicillin	Hydrocodone	Phenobarbital
Arteranol	Hydromorphone	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Atropine Sulfate	Indomethacin	l-Phenylephrine
Benzoic Acid	Ketoprofen	Quinine
Benzoyllecgonine ·HCl	Levorphanol	Ranitidine
Caffeine	Δ <sup>9</sup> -THC	Sodium Salicylate
Chlorpheniramine	11-Nor-Δ <sup>9</sup> -THC-9-COOH	Tryptophan
Chlorpromazine ·HCl	Meperidine	Tetracycline
Cimetidine	Methylphenidate	Tetrahydrozoline
Deoxyephedrine	Methadone	Theophylline
Dextromethorphan	Methaqualone	Thioridazine
Diazepam	Morphine-3-β-D-Glucuronide	Trifluoperazine
Diethylpropion	Morphine Sulfate	
5,5-Diphenylhydantoin	Oxazepam	
Doxylamine	Oxycodone	

3. **Accuracy:** The accuracy of the Dip DrugScan 5 Test was first tested in urine samples by Synttron and subsequently in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. In both cases the laboratories used EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The data was combined and the results are summarized as follows:

3.1 COCAINE (BEG) 300 ng/ml Cut-Off Level

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
DrugScan 5 Positive	147	0
DrugScan 5 Negative	0	291

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

3.2 MARIJUANA (THC) 50 ng/ml Cut-Off Level

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
DrugScan 5 Positive	190	4
DrugScan 5 Negative	3	268

When compared to EMIT II the relative sensitivity between positive samples was 98.45%. The relative specificity between negative samples was 98.53%. The concordance of the combined data with respect to EMIT II was 98.49%.

3.3 METHAMPHETAMINE (MET) 1000ng/ml Cut-Off Level

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
DrugScan Positive	232	0
DrugScan Negative	8	277

When compared to EMIT II the relative sensitivity between positive samples was 96.67%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 98.45%.

3.4 OPIATES (OPI) 2000 ng/ml Cut-Off Level

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
DrugScan 5 Positive	209	0
DrugScan 5 Negative	0	620

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

3.5 PHENCYCLIDINE (PCP) 25 ng/ml Cut-Off Level

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
DrugScan 5 Positive	223	0
DrugScan 5 Negative	0	290

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

**BIBLIOGRAPHY**

**General**

- Baselt, R.C., *Disposition of Toxic Drugs and Chemicals in Man*, 2nd Ed., Biomedical Publ., Davis, CA, p.488 (1982).
- Cody, J.T., Schwarzhoff, R., *J. Anal. Toxicol.*, 17: 2630 (1993).
- Urine Testing for Drugs of Abuse*, NIDA Research Monograph 73, (1986).
- Dasguspta, A., Saldana, S., Kinnaman, G., Smith M., Johansen, K., *Clin. Chem.*, 39(1):104-108 (1993).
- Department of Health and Human Services, *Fed. Regist.*, 53(69): 11970-11989 (1988), (1989).
- FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing*, Kshitij Mohan, 7/21/1987.
- Blum, K., *Handbook of Abusable Drugs*, Gardner Press, Inc., New York, 1st Ed., (1984).
- Tietz, N.W.: *Clinical Guide to Laboratory Tests*; W.B. Saunders Company, (1976).

**Cocaine Test**

- D.W. Hoyt et al. *J. Am. Med. Assoc.*, Vol. 258 (1987), pp. 504-509.
- R.R. MacGregor, J.S. Fowler, and A.P. Wolf. *J. of Chromatography*, Vol. 590 (1992), pp. 354-58.
- E.J. Cone, D. Yousefnejad, and S.L. Dickerson. *J. of Forensic Sciences*, Vol. 35, No.4 (1990), pp. 786-91.
- E.J. Cone et al. *J. of Forensic Sciences*, Vol. 34, No. 1 (1989), pp. 15-31.
- B. Holmstedt and A. Fredga. *J. of Ethnopharmacology*, Vol. 3 (1981), pp. 113-47.
- T. Inaba and J. Can. *Physiol. Pharmacol.*, Vol. 67 (1989), pp. 1154-57
- A.R. Jeffcoat et al. *Drug Metabolism and Disposition*, Vol. 17, No. 2 (1989), pp. 153-59.

**Marijuana Test**

- Johansson, E., Gillespie, H.K., Halldin, M.M. *J. Anal. Toxicol.*, 14: 176-180 (1990).
- El Sohly, M.A., Jones, A.B., El Sohly, H.N. *J. Anal. Toxicol.*, 14: 277-279 (1990); 14: 227-279 (1990).
- Foltz, R.L., Sunshine, I.J. *Anal. Toxicol.*, 14: 375-378 (1990).
- Wimbish, G.H., Johnson, K.D. *J. Anal. Toxicol.*, 14: 292-295 (1990).
- Nakamura, G.R., Meeks, R.D., Stall, W.J. *J. Forensic Sci.*, 35(4): 792-796 (1990).
- Jenkins, A.J., Mills, L.C., Darwin, W.D., Huestis, M.A., Cone, E.J., Mitchell, J.M. *J. Anal. Toxicol.*, 17:6.
- Hollister, L.E., Kanter, S.L., Board, R.D., Green D.E. *Res. Com. Chem. Pathol. Pharmacol.*, 8: 579-584 (1974).

**Methamphetamine**

- Ellerbe, P., Long, T., Welch, M.J., *J. Anal. Toxicol.*, 17: 165-170 (1993).

**Opiate Test**

- Huang, W., Andollo, W., Hearn W.L. *J. Anal. Toxicol.*, 16: 307-310 (1992).
- Cone, E.J., Dickerson, S., Paul, B.D., Mitchell, J.M., *J. Anal. Toxicol.*, 17: 156-164 (1993).
- Glare, P.A., Walsh, T.D., and Pippenger, C.E., *Ther. Drug Monit.*, 13: 226-232 (1991).
- Walsh, T.D., Cheater, F.M., *Pharm. J.*, 10: 525-527 (1983).
- Mitchell, J.M., Paul, B.D., Welch, P., Cone, E.J. *J. Anal. Toxicol.*, 15: 49-53 (1991).

**Phencyclidine Test**

- Froelich, P.E., Gross, G.: Separation and Detection of Phencyclidine in Urine by Gas Chromatography. *J. Chromatograph* 1977;137;135-143.
- Gupta R.C. et al: Determination of Phencyclidine in Urine and Illicit Street Drug Samples. *Clin. Toxicol* 1975; 8:611-621.
- Oellerich, M.: Enzyme Immunoassays In Clinical Chemistry: Present Status and Trends. *J. Clin. Chem. Biochem.*, 1980;18:197-208.
- Anilino, Pitts, F.N.: *Phencyclidine (PCP): A Review and Perspectives. CRC Crit. Rev. Toxicol* 1982;10:145-177.

