



URINE CALIBRATOR LYOPHILIZED FOR ABUSE DRUGS (Morphine, Dihydrocodeine, Codeine, Ethylmorphine)

Code CC45016
TO USE WITH THE KITS CODE GC45010, LC74010

OBJECTIVE

These urinary calibrators are used to calibrate the analytical system in the quantitative determination of drugs of abuse contained in them. Each analyte has a concentration that allows the construction of a 5-point calibration curve.

RECONSTITUTION

Remove the metal seal and rubber stopper from the vial. Add exactly 5 ml of HPLC-grade water through the tube. Replace the rubber stopper, shake and let stand for 5 to 10 minutes. Before use, mix by inverting the vial to dissolve the material until a homogeneous clear solution. Each analyte has a concentration that allows the construction of a 5-point calibration curve.

STORAGE AND STABILITY

The calibrators are stable for 36 months from the date of preparation if stored at 2-8 ° C. After reconstitution are stable for 2 days at 2-8 ° C and 2 months at -20 ° C. Do not use after the expiry date.

PRECAUTIONS

These calibrators in human matrix should be treated with care and treated as potentially infectious.

LOT		
009	Nov 2016	Nov 2019

PACKAGING AVAILABLE:

- CC45016 URINE CALIBRATOR FOR ABUSE DRUGS
- Morphine, Dihydrocodeine, Codeine, Ethylmorphine-

2 x 5 x 5 ml

Release N° 003	July 2019
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CONCENTRATIONS

CODE

CC45016

		
009	Nov 2016	Nov 2019

Calibrator

<i>ANALYTE</i>	<i>UNIT OF MEASUREMENT</i>	<i>VALUES</i>	<i>MEDIUM VALUE OBTAINED $\pm$ DS*</i>
Morphine -1-	ng/ml	0	0
Morphine -2-	ng/ml	120	117,4 $\pm$ 3,8
Morphine -3-	ng/ml	250	250,6 $\pm$ 18,1
Morphine -4-	ng/ml	450	486,1 $\pm$ 16,3
Morphine -5-	ng/ml	1000	1023,8 $\pm$ 46,0

<i>ANALYTE</i>	<i>UNIT OF MEASUREMENT</i>	<i>VALUES</i>	<i>MEDIUM VALUE OBTAINED $\pm$ DS*</i>
Dihydrocodeine -1-	ng/ml	0	0
Dihydrocodeine -2-	ng/ml	100	94,9 $\pm$ 1,8
Dihydrocodeine -3-	ng/ml	200	180,5 $\pm$ 2,6
Dihydrocodeine -4-	ng/ml	400	371,4 $\pm$ 5,3
Dihydrocodeine -5-	ng/ml	1000	891,1 $\pm$ 8,6

<i>ANALYTE</i>	<i>UNIT OF MEASUREMENT</i>	<i>VALUES</i>	<i>MEDIUM VALUE OBTAINED $\pm$ DS*</i>
Codeine -1-	ng/ml	0	0
Codeine -2-	ng/ml	150	159,9 $\pm$ 4,6
Codeine -3-	ng/ml	300	314,4 $\pm$ 9,1
Codeine -4-	ng/ml	600	638,4 $\pm$ 18,2
Codeine -5-	ng/ml	1500	1544,1 $\pm$ 50,6

<i>ANALYTE</i>	<i>UNIT OF MEASUREMENT</i>	<i>VALUES</i>	<i>MEDIUM VALUE OBTAINED $\pm$ DS*</i>
Ethylmorphine -1-	ng/ml	0	0
Ethylmorphine -2-	ng/ml	150	152,4 $\pm$ 7,1
Ethylmorphine -3-	ng/ml	250	284,2 $\pm$ 7,1
Ethylmorphine -4-	ng/ml	500	572,6 $\pm$ 29,4
Ethylmorphine -5-	ng/ml	1200	1297,7 $\pm$ 17,1

* The procedures for production and validation / quality control of every batch shall be performed using the chromatographic method LC / MS / MS validated according to international guidelines of the Food and Drug Administration (FDA-May 2001) and the International Conference of Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH-Q2-R1-Nov 2005). The mean value and standard deviation were obtained during the validation phase of batch processing for level four bottles in duplicate.

This product fulfills all the requirements of Directive 98/79/EC of 27/10/1998 and D.L. n.332 of 08/09/2000 on in vitro diagnostic medical devices (IVD). The declaration of conformity is available upon request.



FOR IN VITRO DIAGNOSTIC USE ONLY

produced by



The ONLY Italian Company that Researches, Develops and Produces
diagnostic KITS for HPLC, GC, GC-MS, LC-MS/MS

COMPANY WITH
MANAGEMENT SYSTEM
CERTIFIED BY DNV
= ISO 9001 =
= ISO 13485 =

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