



AN ITALIAN COMPANY THAT RESEARCHES, DEVELOPS AND PRODUCES READY TO USE KITS
USING CHROMATOGRAPHIC TECHNIQUES FOR CLINICAL LABORATORIES

URINE CALIBRATOR LYOPHILIZED FOR DRUGS OF ABUSE
(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		



PACKAGING AVAILABLE:

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

2 x 5 x 5 ml

N° 004	06/2024
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CONCENTRATIONS
CODE CC45016

LOT		

<i>ANALYTE</i>	<i>MESUREMENT UNIT</i>	<i>C1</i>	<i>OBTAINED MEDIUM VALUE C1 + DS*</i>	<i>C2</i>	<i>OBTAINED MEDIUM VALUE C2 + DS*</i>	<i>C3</i>	<i>OBTAINED MEDIUM VALUE C3 ± DS*</i>	<i>C4</i>	<i>OBTAINED MEDIUM VALUE C4 ± DS*</i>	<i>C5</i>	<i>OBTAINED MEDIUM VALUE C5 ± DS*</i>
Morphine	ng/ml										
Dihydrocodeine	ng/ml										
Codeine	ng/ml										
Ethylmorphine	ng/ml										

* 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 fulfils all the requirements of Directive 98/79/EC of 27/10/1998 on *in vitro* diagnostic medical devices (IVD). The declaration of conformity is available upon request.



FOR *IN VITRO* DIAGNOSTIC USE ONLY



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