

TL24 Diuretics

Summary of Major Modifications

This document summarizes the modifications in the Technical Letter (TL) on the Minimum Reporting Level (MRL) for certain diuretics that are known contaminants of pharmaceutical products (TL24). The TL24 has been revised to enhance clarity by specifying the application of the MRL for six diuretics, namely acetazolamide, bumetanide, furosemide, hydrochlorothiazide, torasemide, and triamterene.

1. Introduction

A minor change was made to improve the readability of the section. It has been also clarified that, in addition to being abused to mask the presence in urine of other prohibited substances, diuretics are also misused to induce weight loss in sports/disciplines where athletes need to meet weight criteria.

2. Reporting Requirements

The structure of this section is maintained.

It has been clarified that, even though the MRL applies only to the six diuretics mentioned above, a finding for chlorothiazide in a sample at levels below 20 ng/mL, in the co-presence of hydrochlorothiazide at less than the MRL of 20 ng/mL, shall be reported as a Negative Finding, since chlorothiazide may have formed from hydrochlorothiazide.

This new version now clarifies in article 2.1 that the MRL of 20 ng/mL for these six diuretics shall be applied to the concentration of the unmodified, free form parent compound only, without considering contributions from any metabolite or degradation product. However, a Comment has been added to clarify that laboratories may monitor the presence of phase-I and/or phase-II metabolites and/or degradation products of these six diuretics to strengthen the interpretation of the test results, but that the concentrations of these additional molecular species shall not be considered for the application of the MRL.

In addition, the Comment dealing with the detection of threshold substances in the presence of diuretics has been removed, because the information is now covered in the effective Technical Document on Decision Limits for the Confirmatory Quantification of Exogenous Threshold Substances by Chromatography-based Analytical Methods (TD DL).

Furthermore, the information about the adjustment of the concentration values based on the Specific Gravity (SG) of the urine sample has also been removed, since it now refers to the Technical Document on Minimum Required Performance Levels and Applicable Minimum Reporting Levels for Non-Threshold Substances Analyzed by Chromatographic-Mass Spectrometric Analytical Methods (TD MRPL), where more detailed information is provided (Reference [1]).

Annex 1

The new version reorganizes the list of sports and disciplines in Annex 1, providing a clearer and more structured presentation. In addition, Mixed Martial Arts (MMA) is added to the list of sports with weight classes.