

UCI Technical Rules on Tramadol

Part I Introduction

In order to protect each rider's health and physical integrity and to ensure the safety of the competitions, tramadol is prohibited in-competition under the UCI Medical Rules as of 1st March 2019.

The UCI Technical Rules on Tramadol ("UCI TRT") are supplementing Chapter III §6 of the UCI Medical Rules (Part XIII) in particular Article 13.3.067. More specifically, the purpose of the UCI TRT is to describe the general steps of a tramadol control from the notification of the rider to the report of the results to the UCI Medical Director.

Departures from the UCI TRT or any other rules set forth in the UCI Regulations does not invalidate the tramadol control or the results of such control, unless it is established by a balance of probability that such departure did cause the positive results.

The UCI Medical Director may delegate some of its tasks or activities under these regulations to a third-party entity.

The UCI TRT comes into effect on 1 March 2019.

Part II Testing

Chapter 1 General

Article 1 Tramadol Control Officer

1. The UCI Medical Director shall appoint and authorise Tramadol Control Officer (TCO) to conduct tramadol controls.
2. Each TCO shall have been trained for his/her assigned responsibilities, shall not have a conflict of interest in the outcome of the sample collection, and shall not be a minor.

Article 2 In Competition Prohibition of Tramadol

For the purpose of the In-Competition Prohibition of Tramadol, “in-competition” is the period starting 12 hours before the beginning of the event the rider is scheduled to participate through the end of such event and through the end of the Tramadol Sample collection process related to such event.

Article 3 Tramadol Control Station

Unless otherwise specified, tramadol control organized following an event (i.e. post-finish testing) takes place at the same location as the doping control.

Otherwise, the tramadol control can take place at any suitable place in accordance with Article 7.1 of these regulations.

Chapter 2 Notification of Riders

Article 4 General

Notification of riders starts when the TCO initiates the notification of the selected riders and ends when the riders arrives at the Tramadol Control Station or when the rider’s possible violation of Articles 13.3.068 let b, c and or d of the UCI Regulations is brought to the UCI Medical Director’s attention.

Article 5 Means of Notification and the Riders’ Obligations

1. In the scope of post-finish testing (i.e. testing organized following an event), the riders who are selected to undergo a tramadol control are notified via a List posted at the entrance of the Tramadol Control Station and at the finish line.
2. The riders shall be identified on the List by either their name, race number or place in the ranking.
3. The absence of the rider’s name, race number or placing from the List shall not be deemed an excuse if the rider is identified in another manner or if it is established that he/she had become aware in another way that he was required to appear for sample collection.
4. Any rider participating in an event, including any rider who has abandoned or did not otherwise finish the event, shall be responsible for ensuring whether he/she has been selected to undergo a tramadol control.
5. Outside the scope of post finish testing, the rider is notified in person or through the rider support personnel.

Article 6 Time-limit and Permissible Delays

1. The rider shall report as soon as possible to the Tramadol Control Station, but in any case within 30 (thirty) minutes of finishing the event, unless compelling justification exists (e.g. obtaining

necessary medical treatment, participation in official protocols, fulfilment of media commitment, doping control or bike checks)

2. If a rider foresees that he/she might be prevented from reporting within the time-limit above, he/she shall try, by all available means, to inform the TCO.

Chapter 3 Sample Collection Session

Article 7 General

1. The sample collection session will be conducted in a manner that ensures the integrity, security and identity of the Sample and respects the privacy and dignity of the rider.
2. The TCO shall ensure that the rider has been informed of his/her rights and responsibilities and shall provide the necessary explanations on the sample collection process.
3. The rider shall only leave the Tramadol Control Station with the approval of the TCO and once the sample collection is terminated.

Article 8 Athlete Rights and Responsibilities

1. The riders selected to undergo a tramadol control shall have the rights to :
 - a. Have a representative and, if available, an interpreter accompany him/her,
 - b. See official and valid proof of identity as well as accreditation of the TCO,
 - c. Ask for additional information on the tramadol sample collection process,
 - d. Request a delay in reporting to the Tramadol Control Station for valid reasons (as provided under 6.2 of these regulations),
 - e. To document any concerns he/she may have about how the sample collection session was conducted,
 - f. Check that the sampling kits comprising, among others, the Dried-Blood devices (DB-devices) are correctly sealed.
2. The riders selected to undergo a tramadol control shall be responsible to :
 - a. Report in time to the Tramadol Control Station
 - b. Produce an official and valid ID.
 - c. Comply with the sample collection process and the TCO's instructions.

Article 9 Sample Collection Method

1. Dried blood droplets will be analysed to detect presence of Tramadol and its two main metabolites.
2. The sample will be collected using a specifically designated device for the collection, transportation and storage of human dried blood spot sample.

Article 10 Tramadol Control Form

1. The Tramadol Control Form can be in paper (Appendix A) or electronic format.
2. Any behaviour by the rider and/or persons associated with the rider or anomalies with potential to compromise the sample collection shall be recorded in detail by the TCO
3. The rider shall be granted with the opportunity to document any concerns he/she may have about how the sample collection session was conducted.

Article 11 Sample Collection Process

1. The collection of a sample begins upon the arrival of the rider at the Tramadol Control Station by ensuring the rider is informed of the sample collection requirements.
2. The key steps are then the following:
 - a. The TCO fills in the Tramadol Control Form with the required information.
 - b. The rider chooses the sampling kit of his/her choice among those made available.
 - c. The rider checks that the chosen sampling kit is correctly sealed.
 - d. The TCO proceeds with the sample collection as summarised under Appendix B
 - e. The DB device is sealed in a secured bag.
 - f. The Tramadol Control Form is completed and signed.

Article 12 End of Sample collection

1. At the conclusion of the sample collection session the rider and TCO shall sign the appropriate documentation to indicate their satisfaction that the documentation accurately reflects the details of the rider's sample collection session, including any concerns expressed by the rider. The rider's representative (if any) and the rider shall both sign the documentation if the rider is a Minor.
2. By appending his/her signature on the Tramadol Control Form, the rider confirms that, subject to any concern recorded by the rider:
 - a. the Sample collection was conducted in accordance with applicable regulations;
 - b. any subsequent complaint is excluded;
 - c. he/she received a copy of the records of the sample collection session that have been signed by him/her.

Article 13 Transport of Sample and Documentation

1. The samples are sent to the laboratory designated by the UCI Medical Director through a courier company.
2. Documentation identifying the rider shall not be included with the samples or documentation sent to the laboratory that will be analysing the samples.

Part III Tramadol Sample Analysis

Chapter 1 Introduction

Article 14 Scope

This part outlines the requirements for the production of the analyses of Tramadol and metabolites in DBS (dried blood spots) samples collected in the context of tramadol control as provided under Part XIII of the UCI Cycling Regulations.

Article 15 General

1. The analyses have to be performed in the laboratory designated by the UCI Medical Doctor, using the validated method for the detection of Tramadol in DBS described under these regulations.
2. The results will be then reported by the laboratory to an independent entity for an initial review before being reported to the UCI Medical Director.

Chapter 2 Chain of Custody in the Laboratory

Article 16 Reception of the samples

The sample reception is described in the Appendix C of these regulations (Réception des échantillons DBS pour la détection du tramadol). The document in relation to the reception must at least contain the following items:

- The sample's external chain of custody form as provided by UCI.
- The laboratory's documentation of receipt of the Sample, including a declaration about any condition observed upon Sample receipt that may adversely impact the integrity of the Sample (Appendix C).
- Summary of the chain of custody which is supported by the laboratory's internal chain of custody documentation.

Article 17 Analytical data: Initial Testing Procedure

1. The analyses of Tramadol in DBS are performed by using UHPLC-ESI-MS/MS, after proper extraction of the samples.
2. The initial testing procedure or screening procedure comprises several steps, including the sample preparation, the extraction procedure, followed by the analysis on UHPLC-MS/MS.

The table of the sequence of analyses with the proper controls samples must be part of the documentation provided with the results.

Article 18 Evaluation of the results of the Initial testing Procedure

1. The presence or absence of Tramadol in the DBS will be defined by the analyst on the basis of the presence of the parent compound (the substance tramadol itself), and the two main metabolites (O-desmethyltramadol, N-desmethyltramadol).
2. All samples showing the presence of the parent compound Tramadol and the two main metabolites (O-desmethyltramadol, N-desmethyltramadol) must be submitted to the confirmation procedure. All other samples will be reported as "absence of Tramadol".

Article 19 Analytical data: Confirmation Procedure (CP)

The confirmation procedure comprises the following items for a proper interpretation of the results:

- Instrument type/identification code;
- A description of the composition of each positive quality control (QC) sample(s) analysed in the same batch;
- The monitored ions/transitions in the method for identification of the target compound(s)
- Each individual's complete signature/initials/name is provided, to assist in the interpretation of the Laboratory Internal Chain of Custody documents.
- Aliquot Laboratory Internal Chain of Custody documentation;
- The analytical instrument sequence file for the CP
- The chromatographic and spectral data (for LC-MSn CP)
- Positive QC sample(s); • Negative QC sample(s); and • Athlete Aliquot(s) analysed to conclude to the presence of tramadol and metabolite(s) in the sample.
- CP data shall be copies of the original data evaluated by the laboratory to support the conclusion of the presence of Tramadol.

Article 20 Evaluation of the Results of the Confirmation Procedure by the Laboratory.

The Identification data: the data must demonstrate the compliance with the WADA technical document for Identification criteria (WADA TD IDCR) including:

- A summary table with relative abundances of diagnostic ions, retention time (RT) data and relevant calculation results;
- The applicable criteria utilized to identify the target substance(s) and report the presence of tramadol;
- The summary table shall include signed statements that the results meet the applicable criteria of the TD IDCR;
- Statement that there was no deviation from the written CP;
- Data shall contain appropriate header information including date and time of analysis, identification code(s), instrument identification, etc.
- Statement that the Instrument meets performance criteria based on the "Laboratory SOP and QC data". This statement shall be signed and dated by the operator performing the evaluation

Article 21 Laboratory report

1. All samples not fulfilling the criteria of identification or presence of tramadol will be reported : "*absence of Tramadol*".
2. All samples with the presence of Tramadol and its two main metabolites (i.e. O-desmethyltramadol and N-desmethyltramadol), which has been confirmed through the applicable confirmation procedure, will be reported: "*presence of Tramadol*". When a sample is reported "*Presence of Tramadol*", it shall be reported on a individual test report, together with the analytical documentation which is described under Articles 17 and 19 of these regulations.

Chapter 3 Initial Review and Final Report

Article 22 Initial review

1. The laboratory will report the results to an independent third entity through a safe electronic platform for review.
2. The review aimed to determine whether there is any apparent departure from the Regulations or circumstances, other than the use of tramadol, that caused the positive results.

Article 23 Final report to UCI Medical Director

Upon the conclusion of the initial review, a final report established as a certificate of analysis will be sent to the UCI Medical Director through a safe electronic platform.

Part IV Appendices

List of Appendices

- Appendix A: Tramadol Control Form
- Appendix B: Sample Collection Summary
- Appendix C: Réception des échantillons DBS UCI pour la detection du Tramadol

Appendix A Tramadol Control Form



TRAMADOL CONTROL FORM
FORMULAIRE CONTRÔLE DU TRAMADOL

1. ATHLETE INFORMATION • INFORMATION CONCERNANT LE SPORTIF

FAMILY NAME NOM DE FAMILLE		GIVEN NAME PRÉNOM		DATE OF BIRTH DATE DE NAISSANCE	
NATIONALITY NATIONALITÉ		COUNTRY OF RESIDENCE PAYS DE RÉSIDENCE		YES - OUI NO - NON ATHLETE ID PROVIDED/ PIÈCE D'IDENTITÉ DU SPORTIF	
ADDRESS ADRESSE		CITY/TOWN • VILLE		DOCUMENT TYPE TYPE DE DOCUMENT	
CONTACT TEL (INCL. COUNTRY CODE) • TÉL CONTACT (INCL. CODE PAYS)		STATE • PROVINCE		DOCUMENT NUMBER NUMÉRO DE DOCUMENT	
E-MAIL • COURRIEL		DOCTOR'S NAME • NOM DU MÉDECIN		SPORT	
				CYCLING • CYCLISME	
				DISCIPLINE	

2. INFORMATION FOR ANALYSIS • INFORMATIONS CONCERNANT L'ANALYSE

ARRIVAL TIME AT CONTROL STATION HEURE D'ARRIVÉE À LA STATION DE CONTRÔLE	DATE OF TEST DATE DU CONTRÔLE	GENDER SEXE	EVENT • ÉVÈNEMENT
TIME SEALED SCÈLLE À HEURE	SAMPLE CODE NUMBER NUMÉRO DE CODE ÉCHANTILLON	TCO NAME NOM DE L'APT	TCO SIGNATURE SIGNATURE DE L'APT
DECLARATION OF MEDICATION USE: LIST ANY PRESCRIPTION / NON-PRESCRIPTION MEDICATIONS TAKEN OVER THE PAST 7 DAYS (INCLUDE DOSAGE AND THE ROUTES OF ADMINISTRATION WHERE POSSIBLE). DÉCLARATION D'USAGE DE MÉDICAMENTS: INDICUER LES MÉDICAMENTS PRÉSCRITS / NON PRÉSCRITS PRIS AU COURS DES 7 DERNIERS JOURS (INDIQUER LA DOSE ET LES VOIES D'ADMINISTRATION SI POSSIBLE).			

3. CONFIRMATION OF PROCEDURE FOR TRAMADOL TESTING • CONFIRMATION DE LA PROCÉDURE POUR LE CONTRÔLE DU TRAMADOL

COMMENTS: ANY COMMENTS SHOULD BE NOTED HERE. IF NECESSARY CONTINUE ON A SUPPLEMENTARY REPORT FORM.
 COMMENTAIRES: TOUTS LES COMMENTAIRES DEVRAIENT ÊTRE INSCRITS ICI. AU BESOIN, UTILISER LE FORMULAIRE DE RAPPORT SUPPLÉMENTAIRE.

I CERTIFY THAT SAMPLE COLLECTION WAS CONDUCTED IN ACCORDANCE WITH THE RELEVANT PROCEDURES - JE CERTIFIE PAR LA PRÉSENTE QUE LE PRÉLÈVEMENT D'ÉCHANTILLON S'EST DÉROULÉ EN CONFORMITÉ AVEC LES PROCÉDURES APPLICABLES

ATHLETE REPRESENTATIVE • REPRÉSENTANT DU SPORTIF

NAME • NOM POSITION • FONCTION SIGNATURE

TRAMADOL CONTROL OFFICER • AGENT DE CONTRÔLE DU TRAMADOL

NAME • NOM SIGNATURE

TIME OF COMPLETION • TERMINÉ À (HEURE)

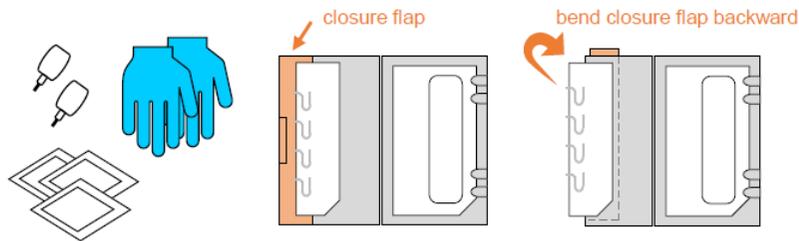
I hereby acknowledge that I have received and read this notice including the athlete rights and responsibilities text on the overleaf of copy 1. I understand that failure or refusal to provide a sample may constitute an infringement of the In-Competition Prohibition of Tramadol. I declare that the information I have given on this document is correct. I declare that, subject to comments made in section 3, samples collection was conducted in accordance with the relevant procedures for sample collection.
 Je reconnais avoir reçu et lu cet avis, y compris les droits et responsabilités du sportif figurant au verso de la copie 1. Je comprends que le refus ou le fait de ne soumettre à fournir un échantillon constitue une violation de l'interdiction du tramadol en compétition. Je déclare que l'information fournie dans ce document est exacte. Je déclare, en tenant compte des commentaires inscrits dans la section 3, que le prélèvement d'échantillons s'est déroulé en conformité avec les procédures applicables.

ATHLETE'S SIGNATURE
SIGNATURE DU SPORTIF

Appendix B Summary of Sample Collection

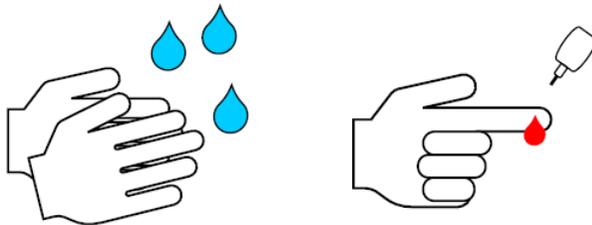
Hemaxis DB device, by DBS System SA, Rte des Avouillons 6, CH-1196 Gland, Switzerland.

1 Prepare material



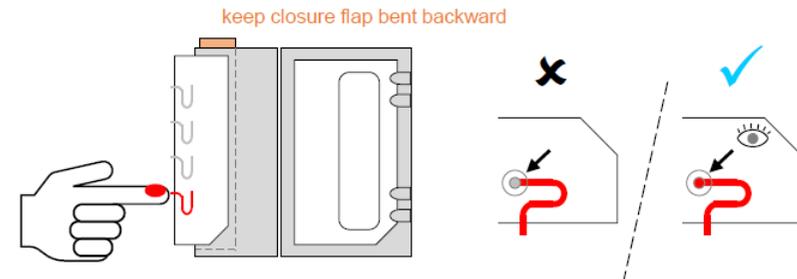
- Prepare material (lancets, disinfectant wipes)
- Wear gloves and remove the device from its packaging
- Open the cover and bend the closure flap backward

2 Generate blood drop



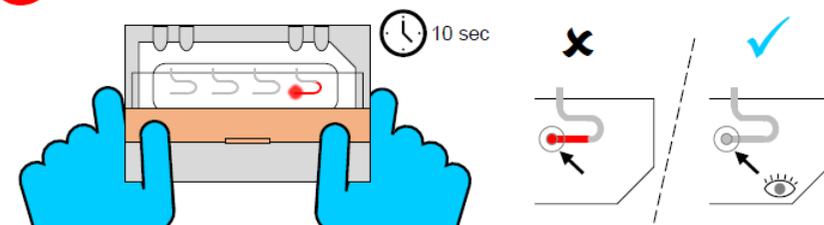
- Wash patient hands and sterilize finger
- Prick fingertip and gently press finger to produce a blood drop
- Wipe off first blood drop with gaze and generate a new drop

3 Fill one collection channel with blood



- Contact blood drop with one channel entrance
- Check channel is completely filled (see 👁)
- If necessary, make several contacts to complete filling

4 Transfer blood to paper card



- Close the cover while maintaining the closure flap bent backward
- Visualize channel emptying until transfer completion (see 👁)
- Repeat steps 3-4 to generate up to 4 samples. Close the closure flap for sample storage or shipping

Appendix C Réception des échantillons DBS pour la détection du Tramadol**Réception des échantillons DBS pour la détection du Tramadol**

Réception des échantillons DBS	
Date et lieu de réception :	
Heure de réception :	
Réceptionné par :	
Ouverture des scellés	
Heure d'ouverture :	
Visa :	
Liste des échantillons DBS	
Code	Non-conformité(s)
Stockage des échantillons DBS	
Heure de stockage :	
Stocké dans l'enceinte réfrigérée :	
Visa :	

Contents

Part I	Introduction.....	2
Part II	Testing.....	3
Chapter 1	General.....	3
Article 1	Tramadol Control Officer.....	3
Article 2	In Competition Prohibition of Tramadol.....	3
Article 3	Tramadol Control Station.....	3
Chapter 2	Notification of Riders.....	3
Article 4	General.....	3
Article 5	Means of Notification and the Riders' Obligations.....	3
Article 6	Time-limit and Permissible Delays.....	3
Chapter 3	Sample Collection Session.....	4
Article 7	General.....	4
Article 8	Athlete Rights and Responsibilities.....	4
Article 9	Sample Collection Method.....	4
Article 10	Tramadol Control Form.....	4
Article 11	Sample Collection Process.....	5
Article 12	End of Sample collection.....	5
Article 13	Transport of Sample and Documentation.....	5
Part III	Tramadol Sample Analysis.....	6
Chapter 1	Introduction.....	6
Article 14	Scope.....	6
Article 15	General.....	6
Chapter 2	Chain of Custody in the Laboratory.....	6
Article 16	Reception of the samples.....	6
Article 17	Analytical data: Initial Testing Procedure.....	6
Article 18	Evaluation of the results of the Initial testing Procedure.....	6
Article 19	Analytical data: Confirmation Procedure (CP).....	7
Article 20	Evaluation of the Results of the Confirmation Procedure by the Laboratory.....	7
Article 21	Laboratory report.....	7
Chapter 3	Initial Review and Final Report.....	8
Article 22	Initial review.....	8
Article 23	Final report to UCI Medical Director.....	8
Part IV	Appendices.....	9
List of Appendices.....		9
Appendix A	Tramadol Control Form.....	10
Appendix B	Summary of Sample Collection.....	11
Appendix C	Réception des échantillons DBS pour la détection du Tramadol.....	12