Metamitron

DOCUMENT L-CA, Section 9

LITERATURE DATA

Version history[1]

Date	Data points containing amendments or additions[1]	Document identifier or version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

Introduction

The reference lists reflect guidance in SANCO/12580/2012-rev. 4, 22 March 2019. Data points are according to the Annex of Com. Reg. (EU) No 283/2013 of 1 March 2013.

List of test and study reports, sorted by data points

(consolidated list including both old and new studies relevant for the renewal approval of metamitron)

Data point	Author(s)	Year	Title Report no., Company Report no. Source (where different from company) GLP/official recognised testing facility[2,3] Published or not	Verte-brate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Previously used[1] (Y/N) If yes, for which data point[4]?
KCA 9/01	Anonymous	2019	Literature Review Report (LRR) - Metamitron and twelve metabolites, *and* Associated documentation - Appendices 1, 2, 3A and 3B Bibra Toxicology Advice and Consulting Ltd, Wallington, UK Not GLP Unpublished	N	N		ADM / [redacted]	N

ADM = Property of ADAMA Agricultural B.V. or affiliate; [redacted] = Property of [redacted] or affiliate

n.a.: not applicable

1 In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.

2 See Art.3 of Annex of Regulation No 283/2013 and 284/2013.

3 The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).

4 In case of studies submitted in the 1st EU review: Old data point according to Annex IIA or Annex IIIA of Annex I of Directive 91/414/EEC, replaced by Commission Regulation (EU) No 544/2011 (former AIIA) and Commission Regulation (EU) No 545/2011 (former AIIIA).