

“The synthesis and certification of three human metabolites of 7-methyl-19-nortestosterone (MENT)”

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Project Overview

In 2002 7 α -methyl-19-nortestosterone was shown to demonstrate advantageous hormone replacement therapeutic properties compared to testosterone and its 17 esters. It was also demonstrated to be a potent inhibitor of spermatogenesis and received considerable interest as a male contraceptive. Despite the commercial potential of this androgenic anabolic steroid it was never officially approved for clinical use. A recent seizure of 1 by law enforcement agencies in Germany has alerted the doping control community to its availability on the black market and raised concerns of potential abuse by athletes wishing to take advantage of the performance enhancing properties. To ensure the WADA accredited anti-doping laboratories can readily identify the abuse of 7 α -methyl-19-nortestosterone scientists at the National Measurement Institute Australia will synthesise three major metabolites detected in human urine. Each compound will be certified to the highest level ensuring unequivocal confirmation of structure using a range of techniques, including mass and NMR spectroscopy. The purity of each calibration standard will be assigned as a mass fraction and a suitable quantity (e.g. 1-5 mg) of each certified reference material will be provided to each WADA accredited laboratory accompanied with a certificate of analysis.

Results and Conclusions:

Scientists at the National Measurement Institute Australia have synthesised a sample of 7 α -methyl-19-nortestosterone and two metabolites observed in human urine post administration. Each compound underwent comprehensive certification confirming the identification and mass fraction of the main component. Upon certification all three calibration standards were made available to the WADA accredited sports doping laboratories, accompanied with a certificate of analysis.

Calibration standards of 7 α -methylnandrolone (NMI collection number S048), 7 α -methyl-4-estren-3 α -ol-17-one (S050) and 7 α -methyl-5 β -estran-3 α -ol-17-one (S047) and associated certificates of analysis have been made available to the WADA accredited laboratories. The certification of each candidate material was performed in accordance with ISO 17034 accreditation as a reference material producer. Each material been certified for identity and purity as a mass fraction and can be considered to be a primary calibrator. The certification, identification and purity assessment, will be reviewed by a panel of experts comprising staff within NMI and academics from local university chemistry departments. NMI's external review committee was

established to ensure the quality of NMI certified reference materials is maintained.