



**FDA CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF ANESTHESIA, ANALGESIA, AND ADDICTION PRODUCTS**

ERRATA

DATE: July 12th, 2017

FROM: Xiaobin Shen, Ph.D., Review Chemist
Julia Pinto, Ph.D., Branch Chief

TO: Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

RE: Open Session Study Results Document: In Vitro Studies of Proposed Abuse-Deterrence Properties, July 26th, 2017 AADPAC/DSaRM Meeting to Discuss NDA 209-653

The following are corrections based on the Applicant's reanalysis of their data due to errors in their initial calculations of the in vitro data.

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The 4th paragraph –

Since it was syringeable using a D Ga needle, a C Ga needle was used to test again. This time the syringed liquid had an average of **28.5%** of oxycodone recovery from ...

Table Form B with Pre-treatment D – Prepared in Solvent 1

Solvent Temperature A –

Both samples were syringeable with a D Ga needle at 0.5 min. The oxycodone extended-release tablet samples had ~~negligible~~ oxycodone recoveries at an average of **15.1%** and **29.1%** at 0.5 min and 3 min respectively. ...

Further testing with an A Ga needle also demonstrated syringeability of both samples.

Again, the oxycodone extended-release tablet sample had ~~an low~~ average of 19.7% recovery at 0.5 min. ...

Solvent Temperature B –

Both samples were syringeable with a D Ga needle at 0.5 min. The oxycodone extended-release tablet samples had ~~relatively low~~ oxycodone recoveries at an average of **43.6%**. The OxyContin samples had significantly higher oxycodone recoveries, reaching an average of **57.2%** at 0.5 min. Note that the results were very variable among the three replicates.

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The 1st paragraph –

Similarly, further testing with an A Ga needle also demonstrated syringeability of both samples. The oxycodone extended-release tablet samples had an average oxycodone recovery of **15.4%** and **9.1%**, at 0.5 min and 3 min respectively. ...

Solvent Volume – V2 mL

Solvent Temperature A –

Both samples were syringeable with a D Ga needle at 0.5 min. The oxycodone extended-release tablet samples had oxycodone recoveries at an average of **20.4%**, 14.3% and 15.9% at 0.5 min, 3 min and 5 min respectively. The OxyContin samples had oxycodone recoveries at an average of 85.0% at 0.5 min already.

Solvent Temperature B –

Both samples were syringeable with a D Ga needle at 0.5 min and 3 min. The oxycodone extended-release tablet samples had oxycodone recoveries at an average of **51.2%** and 18.7% at 0.5 min and 3 min respectively. The OxyContin samples had oxycodone recoveries at an average of 47.8% and **20.0%** at 0.5 min and 3 min respectively.

When tested with an A Ga needle, the oxycodone extended-release tablet samples had oxycodone recoveries at an average of 22.8% and 24.9% at 0.5 min and 5 min respectively. The OxyContin samples had oxycodone recoveries at an average of 44.2% and **19.9%** at 0.5 min and 3 min respectively. These results indicate that the samples are also syringeable using B Ga and C Ga needles.

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Solvent Temperature B –

Both samples were syringeable with a D Ga needle at 0.5 min, 3 min and 5 min. The oxycodone extended-release tablet samples had oxycodone recoveries at an average of 18.5%, 24.9% and 16.5% at 0.5 min, 3 min and 5 min respectively. The OxyContin samples had oxycodone recoveries at an average of 25.6%, 25.9% and **23.3%** at 0.5 min, 3 min and 5 min respectively.