



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

ADDENDUM

DATE: March 23rd, 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, April 5, 2017 AADPAC/DSaRM Meeting to Discuss NDA 209-777

1. Page 98.

Figure 2 is to be replaced by the Figure 2 below.

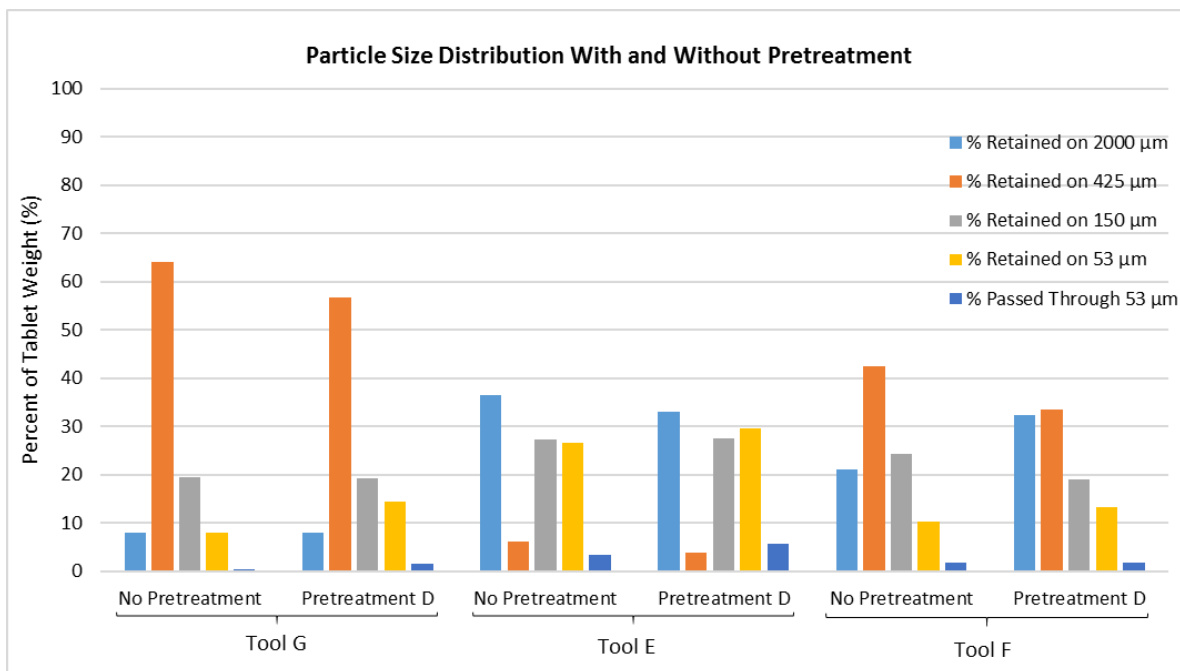


Figure 2. Particle Size Distribution of Manipulated Oxycodone ARIR Tablets With and Without Pretreatment D.

2. Page 98.

“Test 1 – Effect of ... Over Time Course”

is to be replaced with

“Test 1 – Effect of a Solvent Property on Extraction over Time Course”

3. Page 100.

Figure 3 is to be replaced by the Figure 3 below.

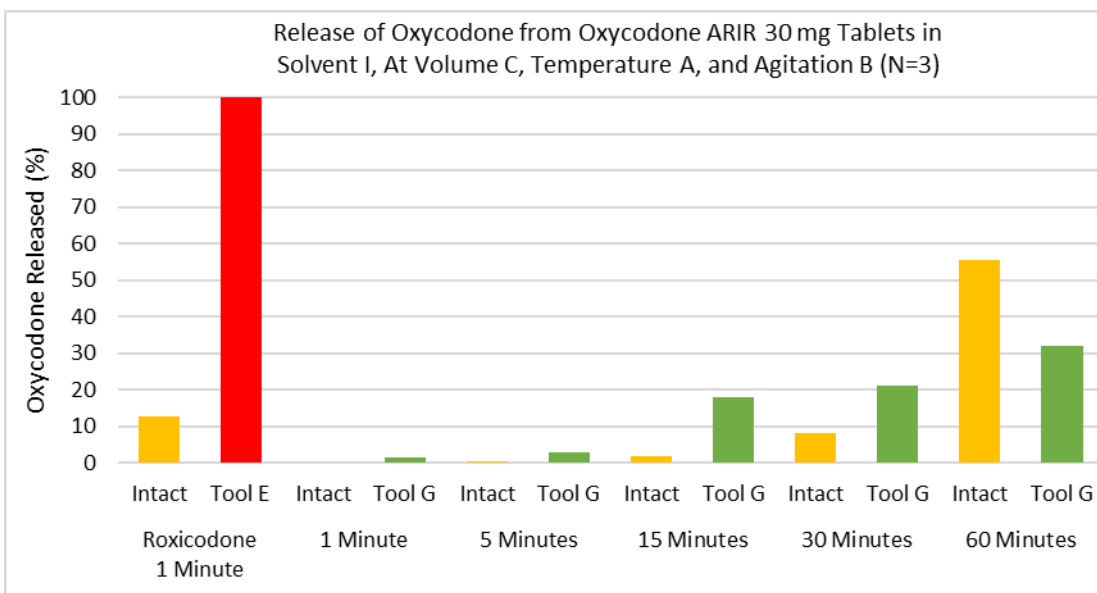
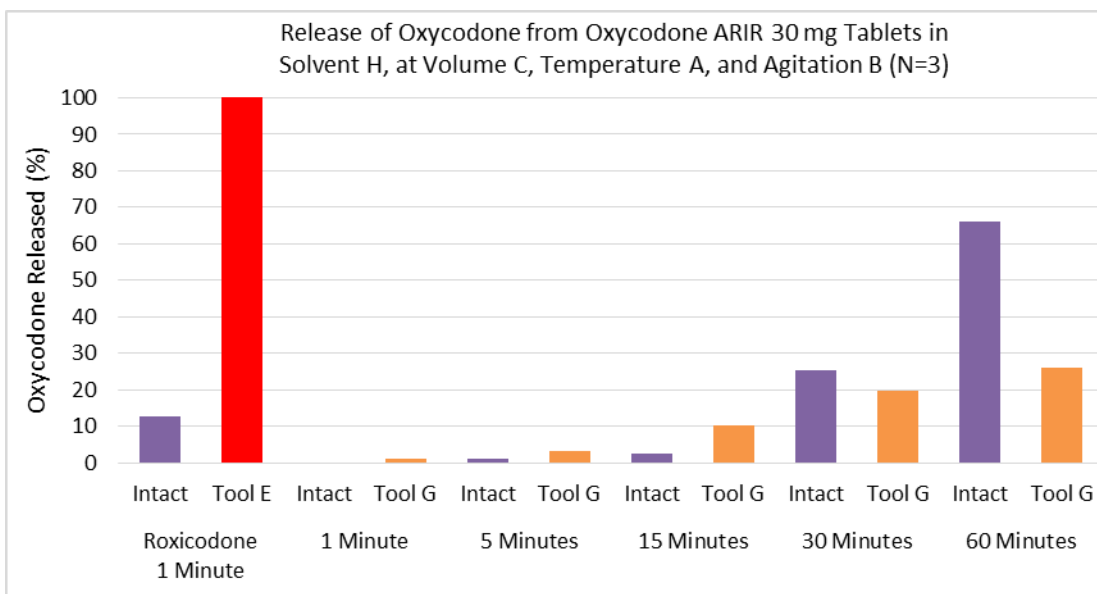


Figure 3. Effect of a solvent property on oxycodone extraction at Temperature A.

Figure 4 is to be replaced by the Figure 4 below.

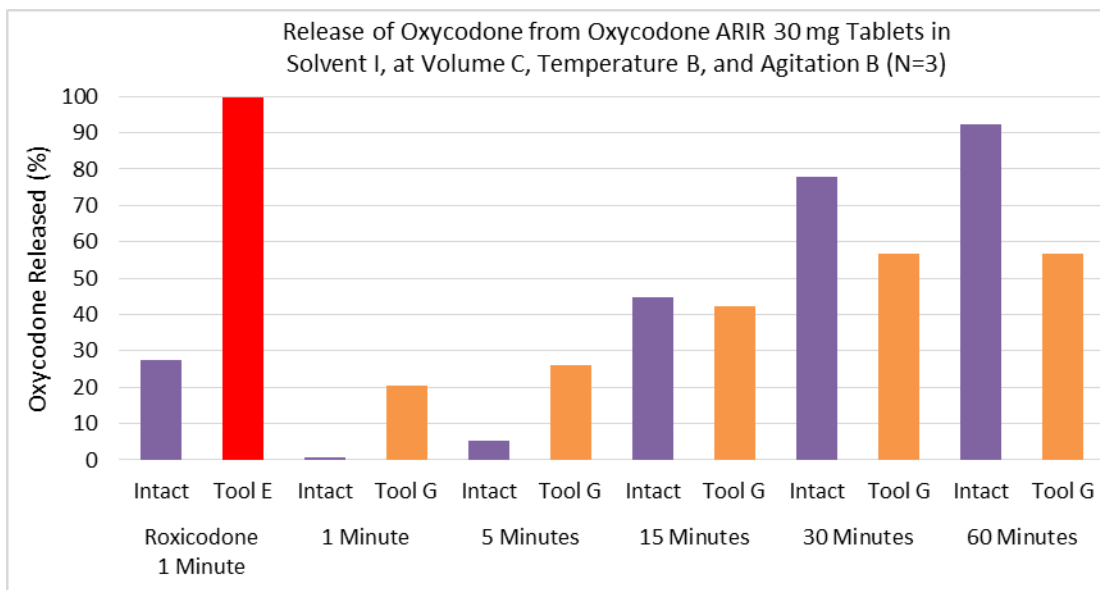
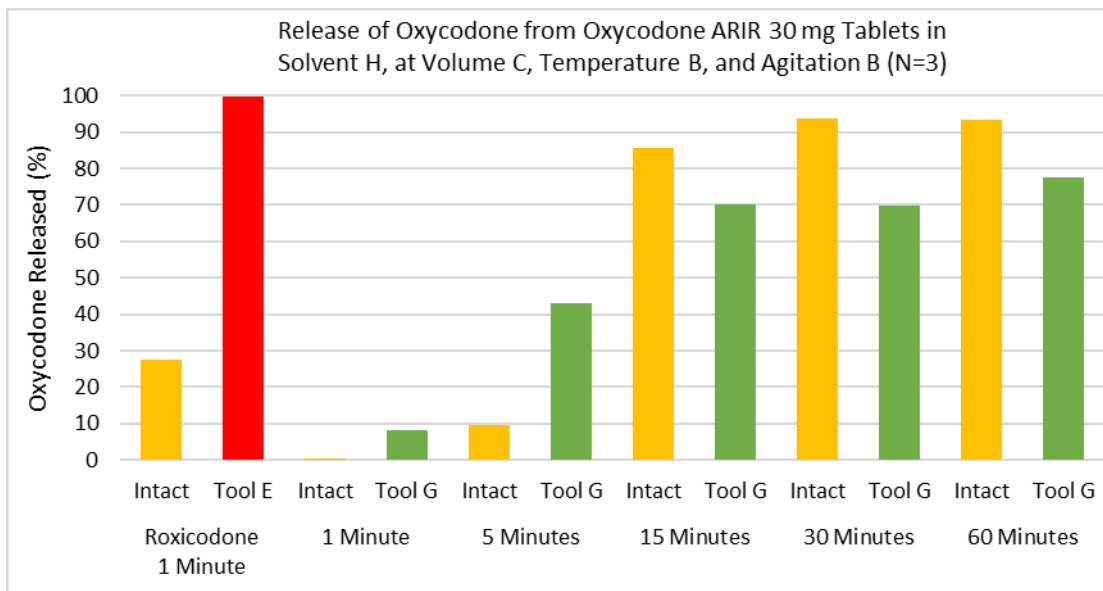


Figure 4. Effect of a solvent property on oxycodone extraction at Temperature B.

5. Page 102.

Figure 5 is to be replaced by the Figure 5 below.

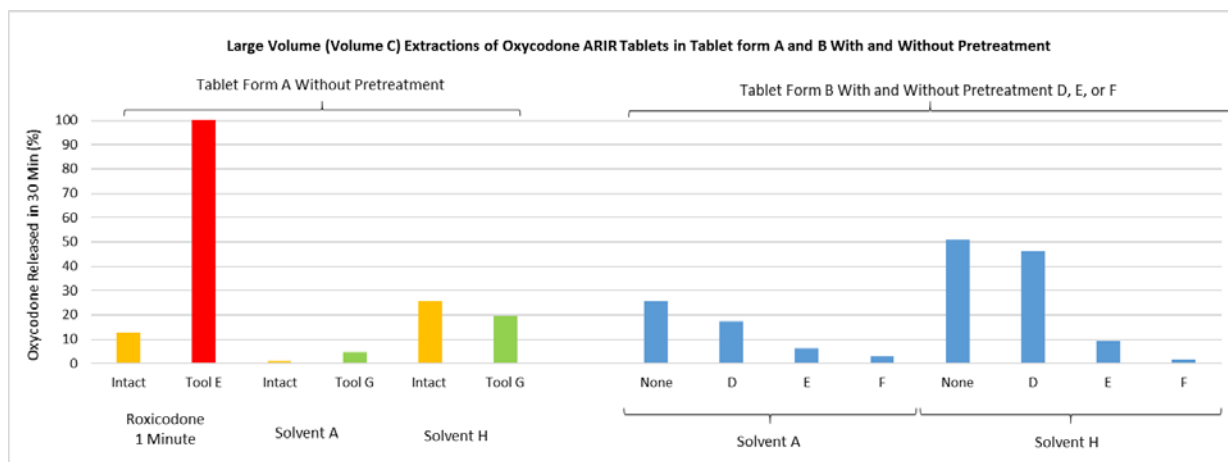


Figure 5. Effect of Tablet Form and Pretreatment on oxycodone extraction from Oxycodone ARIR tablets.

6. Page 102

“Test 2 – Extraction with other Solvents (... ARS-122-01)”

is to be replaced with

“Test 2 – Extraction with other Solvents (Volume C. ARS-122-01)”

7. Page 102

“All tested solvents (Solvents ...) extracted less than Solvent H ... (Figure 6)”

is to be replaced with

“All tested solvents extracted less than Solvent H (Figure 6)”

8. Page 102

Figure 6 is to be replaced by the Figure 6 below.

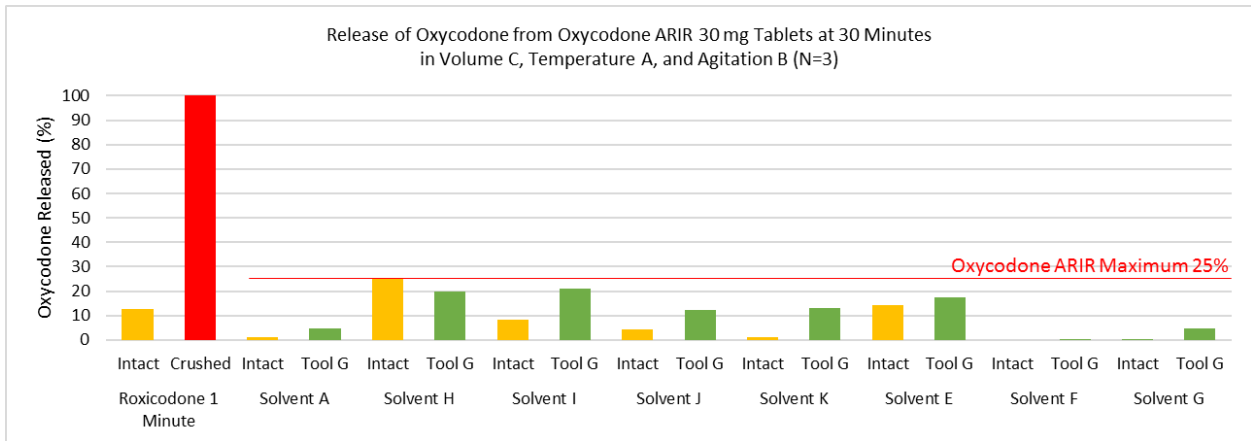
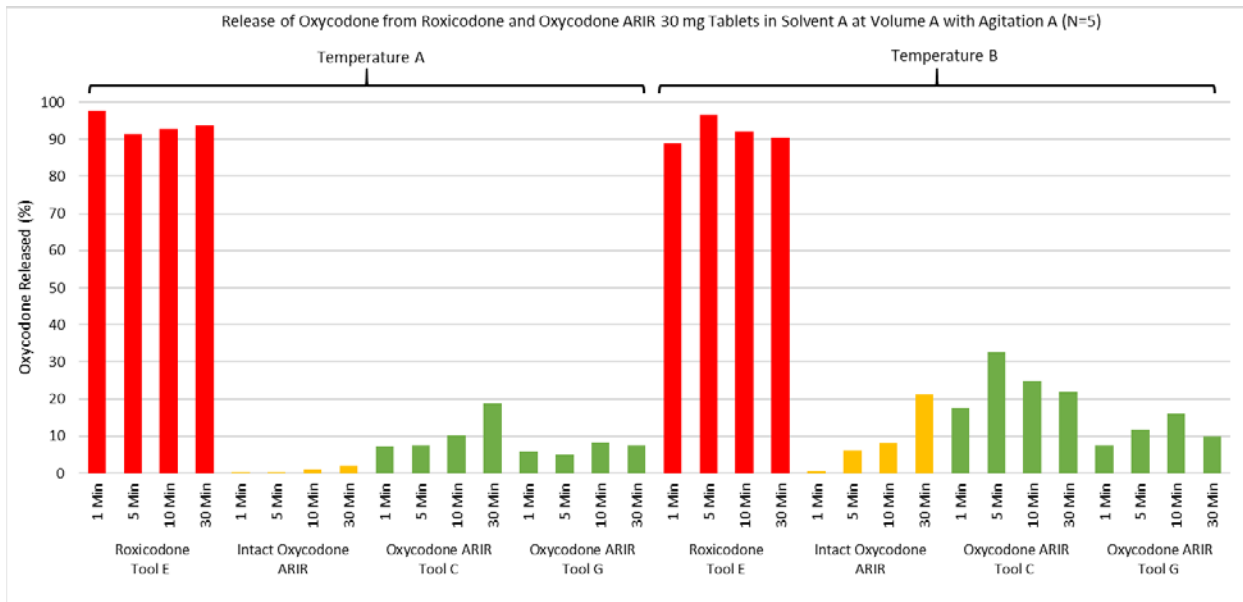


Figure 6. Effect of solvent type on oxycodone extraction at Temperature A.

9. Page 104.

Figure 7 is to be replaced by the Figure 7 below.



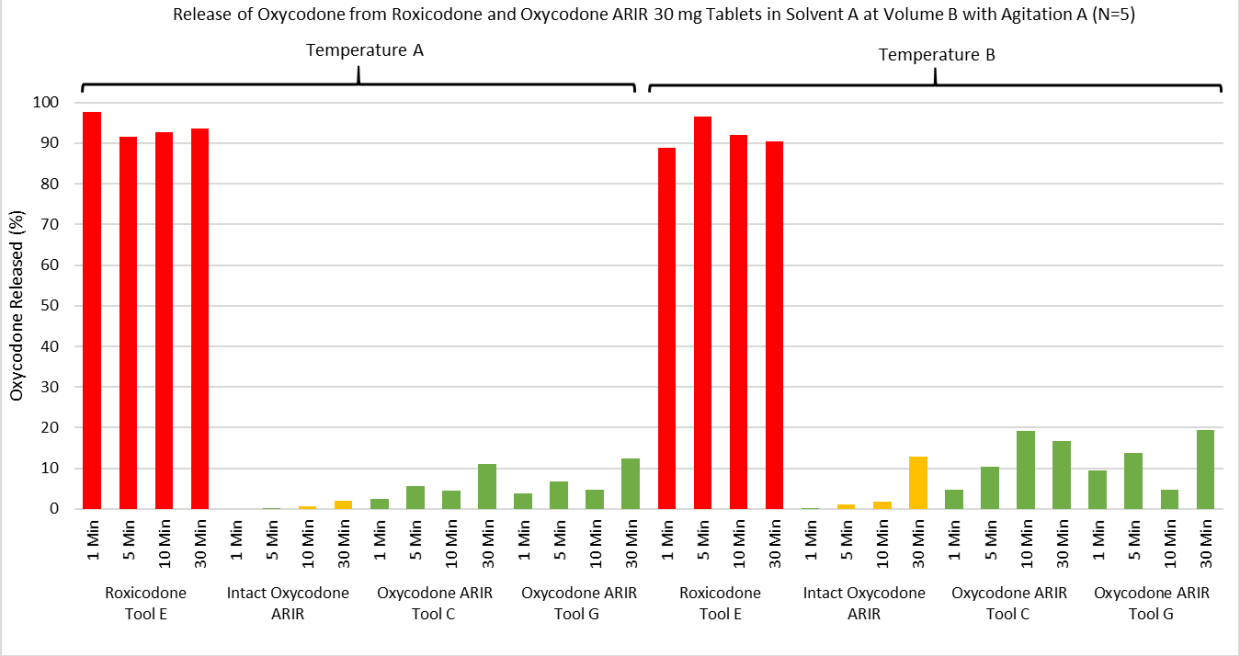


Figure 7. Syringeability of intact and manipulated Oxycodone ARIR vs Roxicodone tablets prepared using Solvent A at different volumes and Temperatures.