



U.S. Food and Drug Administration

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Reproducibility of Oral Abuse Liability Studies

Primary endpoints drug disliking	Study 102	Study 111	Study 114
Scale	Unipolar: NRS	Bipolar: NRS	Bipolar: VAS
Range	1-29	1-29	0-100
LSMean Differences (SE) 40/240 mg vs. 40/0 mg	5.1 (2.4) p = 0.05	-3.0 (1.4) p = 0.033	-18.7 (3.12) p <0.0001

NRS = Numeric Rating Scale
VAS = Visual Analog Scale