

A Novel Nicotine Sublingual Tablet which Mimics Cigarette Smoking Pharmacokinetics

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TSRC

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IntraTab™ Thanks TSRC



Rob Stevens
James Murphy

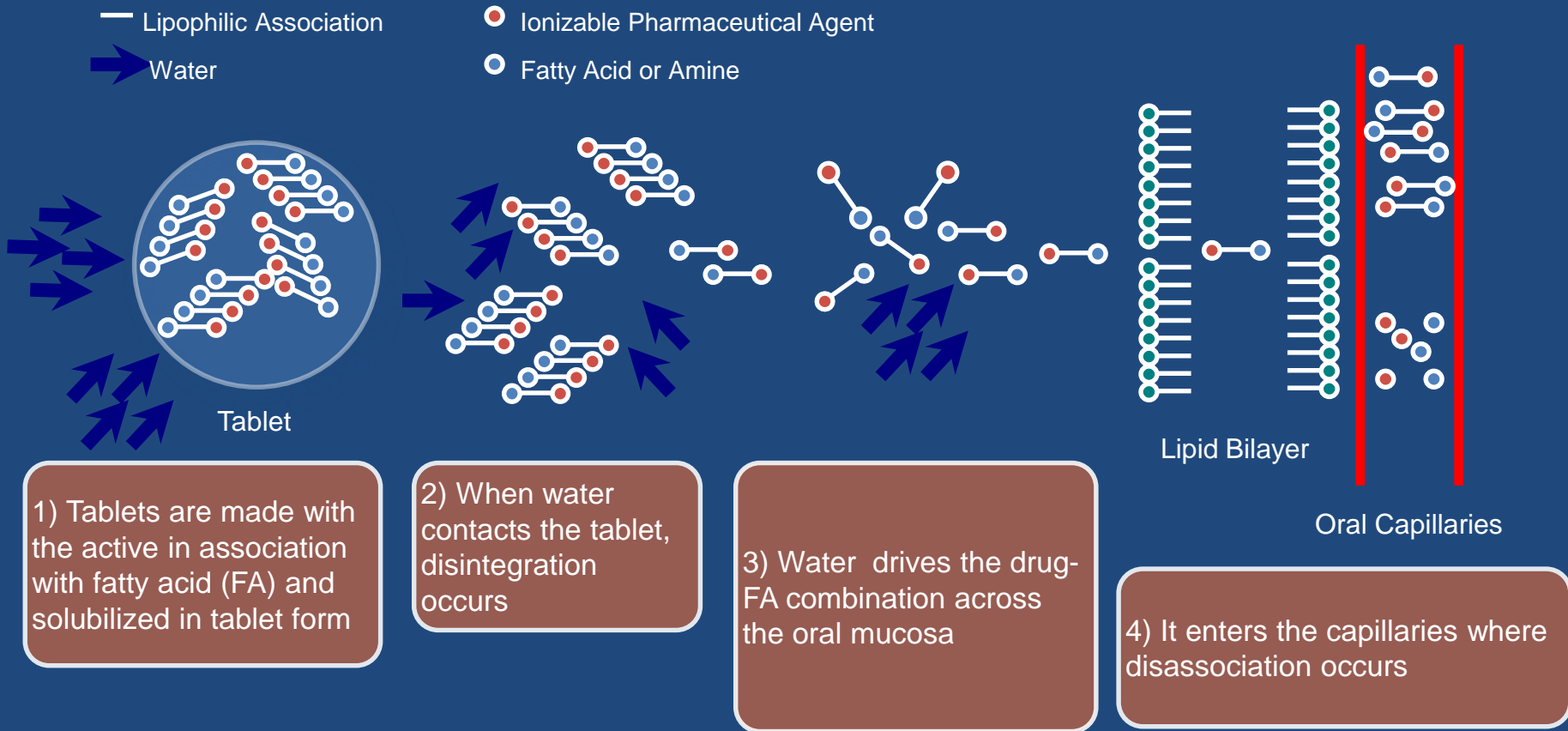
IntraTab's Harm Reduction & Risk Mitigation

- Lowest Harm Product for Nicotine Delivery
 - IntraTab is a convenient pill placed under the tongue
 - Not an NRT – Just Pure Nicotine in a pill form.
 - Pharmacokinetics closest to a cigarette
 - Reduces health risks beyond all inhaled products
 - Combustible, Heated, Low Nicotine or otherwise
 - Bridges the gap between Consumer Tobacco & Pharma NRT's.
 - Fast like a cigarette, safer than current alternatives.

IntraTab™ Nicotine Technology

- IntraTab™ is a unique thermodynamic driven transmucosal drug delivery system where pure nicotine is in solution and capture in a pill
- Pharmacokinetics demonstrate rapid delivery and fast onset of nicotine action with Tmax occurring within as little as 15 minutes
- Only 7 Ingredients (USP Grade).
 - Not 7,000 Constituents

IntraTab™ Technology



Why NRT's Fail

- Over 20 years ago Ovide and Cynthia Pomerleau, pioneers in smoking cessation therapy, defined the necessary attributes for a successful NRT as being:
 - The method should be safe and easy to use
 - Specific doses should be accurately and reproducibly delivered
 - PK should mimic cigarette smoking

IntraTab™ Nicotine Delivery Success

- Mimics smoker's nicotine Pharmacokinetics
 - Tmax within 15 minutes vs. 60 minutes for gum & lozenge
 - Rapid onset satisfies Smoker's nicotine cravings
- Safer nicotine delivery vs. smoking & vaping
- Easy to use like a breath mint
- Low COGS & competitive pricing to cigarettes

Nicofi™ by IntraTab™



Available where Cigarettes are sold but in front of the register in consumer reach.

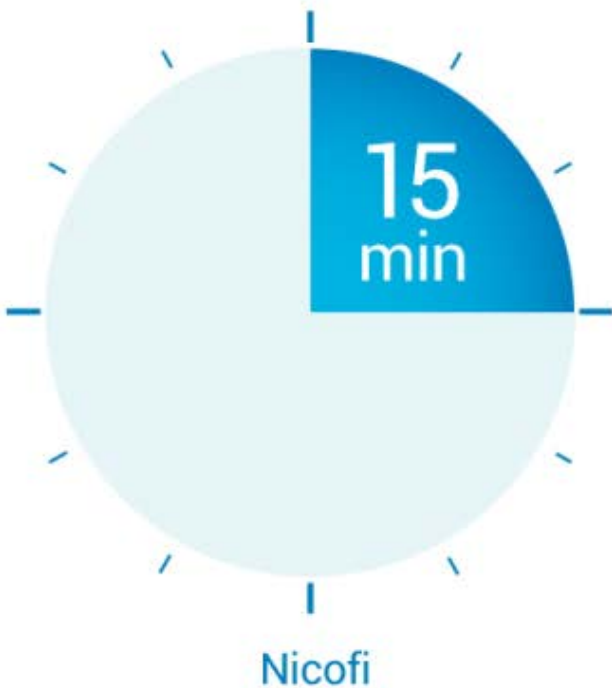
Nicotine Speed of Delivery by IntraTab™ versus Cigarettes & Other Products

Product	T _{max} (min)	C _{max} (ng/ml)
Cigarette*	14	13.4
2mg IntraTab™ (NIH Study)	17	7.7
16mg E-cigarette*	20	1.3
10mg Nicorette Inhalator*	32	2.1
2mg MicroTab#	60	3.8
2mg GSK Lozenge (NIH STUDY)	95	8.6

* Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M (2010), Effect of an electronic nicotine delivery device (e-cigarette) desire to smoke and withdrawal, user preferences and nicotine delivery: randomized cross-over trial. *Tobacco Control*, 19(2), 98-103.

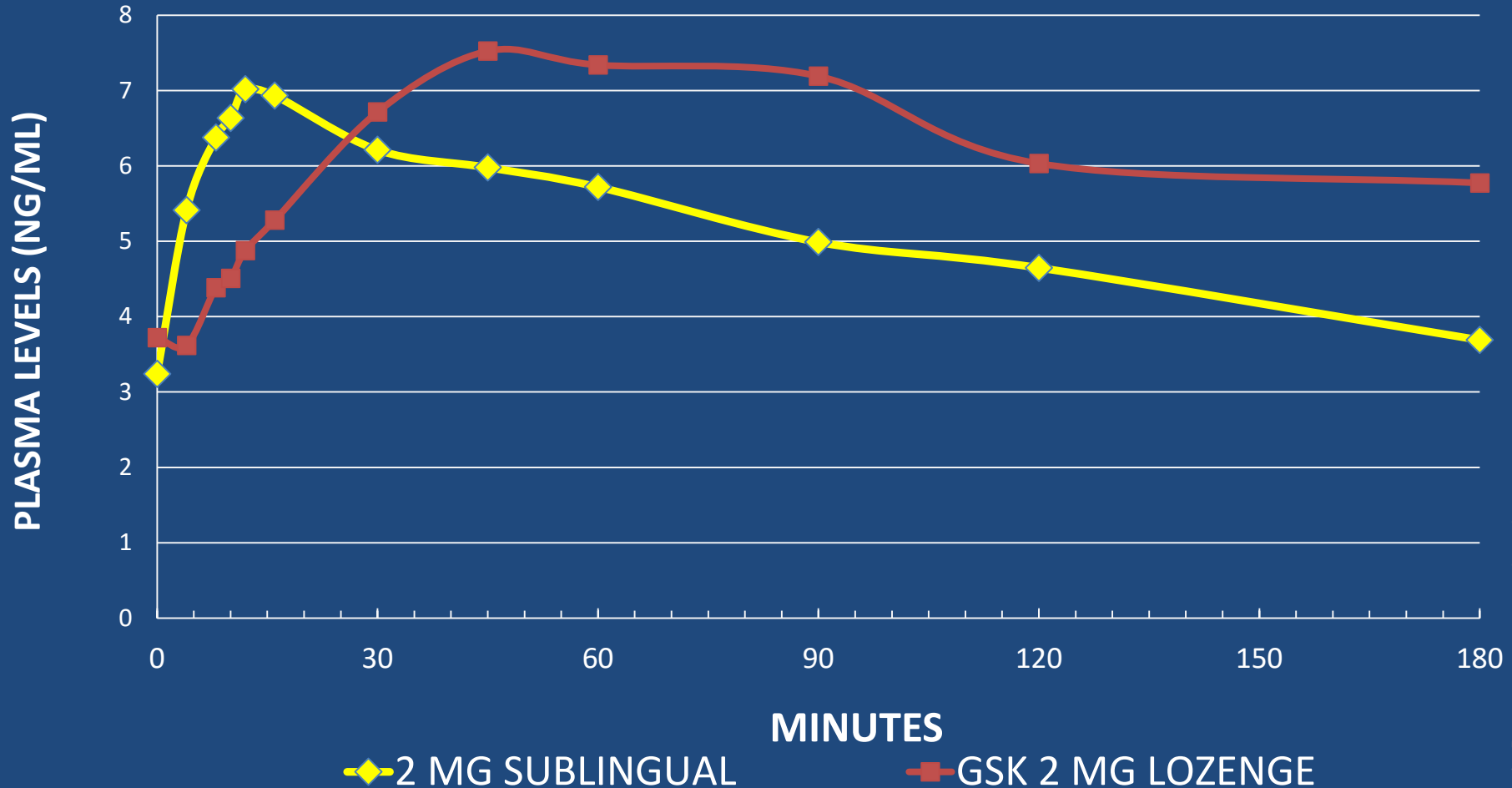
Molander L, Lunell E (2001) Pharmacokinetic investigation of a nicotine sublingual tablet. *Eur J Clin. Pharmacol*, 56 (11), 10 813-819.

Nicotine Speed of Delivery by IntraTab™ versus Cigarettes & Other Products



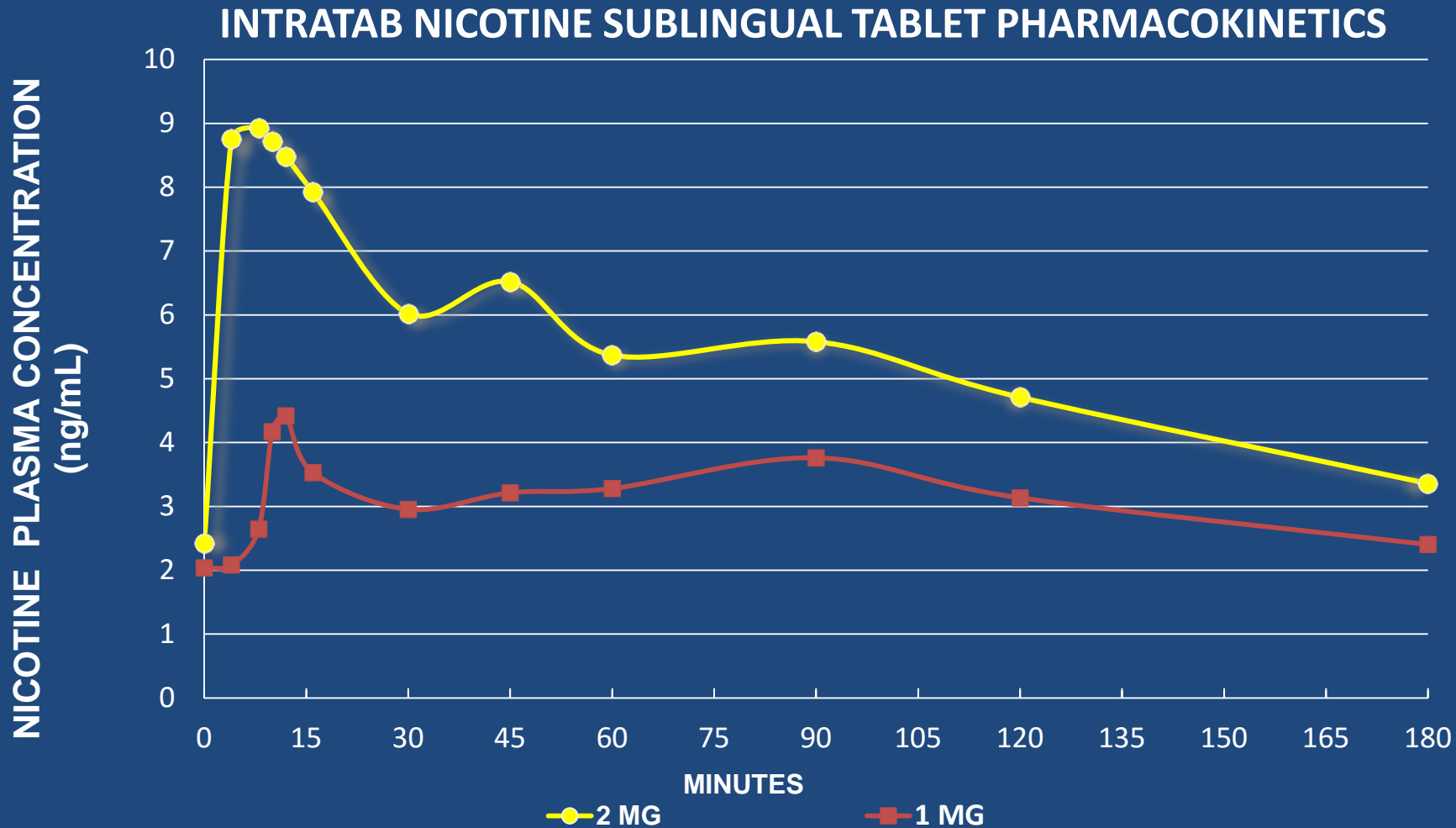
Pharmacokinetics from NIH Study

NICOTINE PK STUDY MEAN PLASMA LEVELS N=6



IntraTab™ Pharmacokinetics

1 and 2 mg Strength



Nicotine IntraTab™ Products

- Nicofi™ 1mg Nicotine Tablet introduced into US market in 2015 www.nicofi.com
- Nicofi™ sold as an unregulated tobacco product
- Nicofi™ seeking CTP Approval for Modified Risk Tobacco Product designation
- FDA has granted IntraTab™ a 505b2 regulatory path for 2mg & 4mg dosages as NRT products
- Innovative and patented

IntraTab™ Intellectual Property

- **Unique Thermodynamic Buccal/Sublingual Drug Delivery Platform for Ionizable Actives, e.g. Nicotine**
 - **Granted in USA, Israel, Russia, Japan, India, Australia, Canada, Mexico, China, Korea, EU, & Indonesia**
 - **Patent life to at least 2030 in USA**

Worldwide IntraTab™ Nicotine Product Commercialization

- Nicotine 1mg, 2mg & 4mg Tablets
 - 1mg Licensed & Commercialized in N. America
 - 1mg Available Rest of World (ROW)
 - 2mg & 4mg strength Worldwide rights available

IntraTab™

- Fast, Safe, Low COGs Nicotine Delivery
- Product Fulfills Lowest Harm in the Risk Continuum
- Novel Sublingual/Buccal Drug Delivery Platform
- Worldwide Patent Exclusivity
- Convenient, Easy to Use Dosage Form
- Worldwide Partnering and Licensing Opportunities

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