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Type them into questions box!

**"Why am I muted?"**
Don't worry. Everyone is muted except the presenter and host. Thank you and enjoy the show.

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## Check out the Archive!

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Hundreds of presentations from the best and brightest minds that chemistry has to offer are available to you on-demand. The Archive is divided into 6 different sections to help you more easily find what you are searching.

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Learn how to write better abstracts, deliver more engaging presentations, and network to your next dream job. Brush up on your soft skills and set a new career path by mastering what can not be taught in the lab.

### Technology & Innovation

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From renewable fuels to creating the materials for the technology of tomorrow, chemistry plays a pivotal role in advancing our world. Meet the chemists that are building a better world and see how their science is making it happen.

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### Culinary Chemistry

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Why does food taste better when it is grilled or what molecular compounds make a great wine? Discover the delectable science of your favorite food and drink and don't forget to come back for a second helping.

### Popular Chemistry

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Feeling burdened by all that molecular weight? Listen to experts expound on the amazing side of current hot science topics. Discover the chemistry of rockets, how viruses have affected human history, or the molecular breakdown of a hangover.

### Business & Entrepreneurship

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How do ideas make it from the lab to the real world? Discover the ins and outs of the chemical industry whether you are looking to start a business or desire a priceless industry-wide perspective.

https://www.acs.org/content/acs/en/acs-webinars/videos.html




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A **collection of the best recordings** from the ACS Webinars Archive will be broadcast on Mondays and Fridays from 2-3pm ET!

www.acs.org/acswebinars

## ACS Green Chemistry Institute

**Engaging you to reimagine chemistry and engineering for a sustainable future!**

We believe sustainable and green chemistry innovation holds the key to solving most environmental and human health issues facing our world today.

- Advancing Science
- Advocating for Education
- Accelerating Industry

ACS GCI convenes **companies in the chemical industries to advance the implementation of sustainable and green chemistry and engineering.**

https://www.acs.org/gciroundtables.html gciroundtables@acs.org



## 15 YEARS of Advancing GC&E *in Pharma and Beyond*

ACS GCI Pharmaceutical Roundtable

**12** Collaboratively developed, high-quality tools & metrics

**$2.4 Million** given in research grant funding

Funding of **28+** research programs around the globe

Leveraged **$1.3 Million** from Federal Agencies

**41** Symposia organized since 2016

Supporting travel of **75** professors & **31** students to present research since 2014

**17** Educational workshops & webinars since 2017

**80+** Publications resulting from funded research, **1700+** unique daughter citations

**49** Roundtable authored papers since 2007

The Peter J. Dunn Award for Green Chemistry & Engineering Impact in the Pharma Established in 2016

- Bridging the gap between academics & industry
- Enabling better decisions about chemical selection process design
- A leading voice for GC&E
- Inspiring and educating the next generation
- Recognizing excellence in GC&E

https://www.acsgcipr.org

**Free ACS Webinars Every Week!**
*Upcoming Broadcasts*

ACS Chemistry for Life®


**Friday, September 18, 2020 at 2-3pm ET**
**Speaker:** Eric Brock, University at Albany
**Moderator:** Bill Courtney, Washington University in St. Louis

Register for Free!

What You Will Learn

- How sulfur role in naturee, in everyday kitchen and garden chemistry, as well as in the laboratory
- How the natural defensive properties of Allium organosulfur compounds have been used to develop a potent environmentally benign pesticide
- How garlic-derived compounds have gone from components of health supplements of questionable value to promising drugs for treatment of deadly cancers


**Miércoles, 23 de Septiembre, 2020 a las 12-1pm CT / 1-2pm ET**
**Ponente:** Maria Escudero Escribano, Universidad de Copenhague
**Moderadora:** Ingrid Montes, Universidad de Puerto Rico, Recinto de Río y American Chemical Society

Registrarse

Lo Que El Público Aprenderá:

- La necesidad de sustituir los combustibles fósiles por procesos limpios, así como la importancia de la electroquímica y la catálisis para descarbonizar la economía
- Algunas aplicaciones de la electrocatálisis en conversión de energía renovable y producción de compuestos químicos y combustibles sostenibles
- La importancia de diseñar y desarrollar catalizadores a escala atómica y combinar investigación básica con investigación en dispositivos electroquímicos reales

**Co-producido con:** Sociedad Química de México y *Chemical & Engineering News*


**Wednesday, September 23, 2020 at 3-4pm ET**
**Speaker:** Christopher McCurdy, College of Pharmacy, University of Florida
**Moderator:** Amy Newman - NIDA-Intramural Research Program, National Institutes of Health

Register for Free!

What You Will Learn

- Understanding of kratom products and their use in the traditional and Western populations
- The pharmacology and pharmacokinetics of the major alkaloid, mitragynine (and others)
- Some insights into the scientific hypotheses for therapeutic benefits as well as negative consequences

**Co-produced with:** ACS Division of Medicinal Chemistry, American Association of Pharmaceutical Scientists, and ACS Publications

www.acs.org/acswebinars

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ACS Green Chemistry Institute
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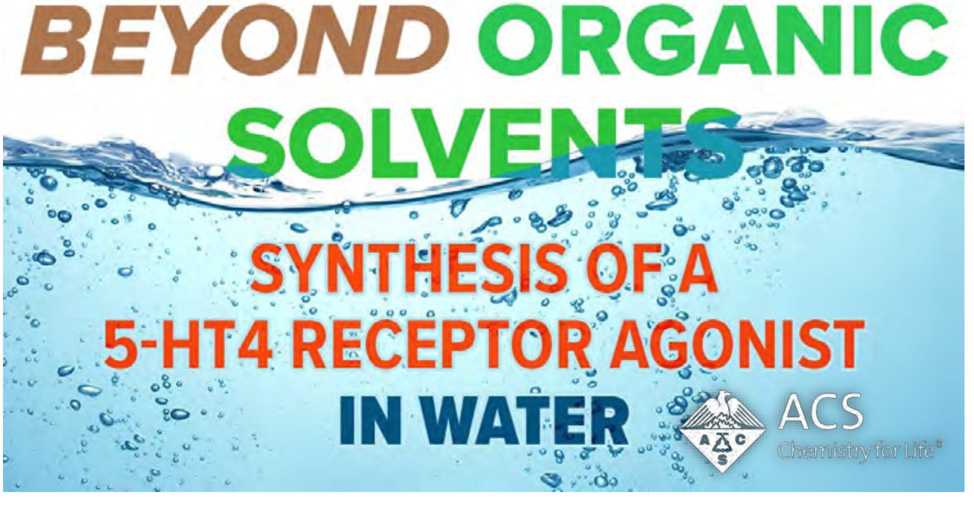
ACS GCI
Pharmaceutical Roundtable




THIS ACS WEBINAR WILL BEGIN SHORTLY...

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Beyond Organic Solvents: Synthesis of a 5-$HT_4$ Receptor Agonist in Water

**Dan Bailey**
Process Chemist,
Takeda Pharmaceuticals

**John Tucker**
Executive Director, Chemical Development,
CMC, Neurocrine Biosciences

***Presentation slides are available now! Edited recording will be made available as soon as possible.***

www.acs.org/acswebinars

*This ACS Webinar is co-produced with ACS Green Chemistry Institute and the ACS GCI Pharmaceutical Roundtable.*

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## ACS GCIPR Membership 2020

*Join Our ACS GCI PR Mission*

ACS GCI Pharmaceutical Roundtable

To catalyze the implementation of GC&E in the global pharmaceutical industry.

https://www.acsgcipr.org

Contact: gcipr@acs.org ; and/or Isamir Martinez, i_martinez@acs.org

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## Award Recognition Today

ACS GCI Pharmaceutical Roundtable

- Academic awards are proliferate and significantly focused upon novelty and publication
  - Holistic (process) strategies are often shunned in favor of specific methodology
  - Green Chemistry has yet to fully penetrate academia
  - Process development is not a discipline taught in academia, but is learned on-the-job through mentorship and experience
- Companies may be less likely to share new information (such as advances in chemistry) as the business model does not support publication as a final deliverable
  - There is a risk to any disclosure *i.e.* IP or trade secrets
- Academics drive most public acknowledgement of science
  - Subsequently, there are few opportunities for recognition of green process chemistry https://www.acs.org/content/acs/en/awards.html



## Why a Process Green Chemistry Award?

ACS GCI Pharmaceutical Roundtable

- A phalerist is someone who studies awards
  - Dr. Jana Gallus holds a Ph.D. in Economics from the University of Zurich, is an assistant Professor at the UCLA Anderson School of Management and she's a phalerist of some renown
    - Consider reading her paper entitled "Awards, Honors and Ribbons: Between Fame and Shame."
- There are various reasons why people give awards
  - One reason is that you want to establish a legacy.
    - Alfred Nobel; why did he create or establish Nobel prizes?
  - Another reason is to shape a field and influence the direction that a field takes.
    - The Academy Awards created an award to establish what is considered as high quality in a subjective medium to then influence the production of movies in the future as the award is valuable enough to be something that people seek to achieve, to attain.
- The GCIPR and Peter J. Dunn Award seeks to transform the way Green Process Chemistry is viewed, exemplified, measured and acknowledged…for the inspiration of future science

## An Award for Future Green Chemistry Direction

ACS GCI Pharmaceutical Roundtable

### Peter J. Dunn Award for Green Chemistry and Engineering Impact in the Pharmaceutical Industry

- Established in 2016 to recognize outstanding industrial development or implementation of novel green chemistry and/or engineering in the pharmaceutical industry that demonstrates compelling environmental, safety, cost, and/or efficiency improvements over current technologies at significant scale
- Award consists of a plaque and an invited lecture at the Annual Green Chemistry & Engineering Conference. ACS GCIPR will reimburse travel expenses up to $2,500.
- **Call for Nominations:** Until Dec 31st



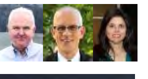
## 2020 Peter J. Dunn Award

for Green Chemistry & Engineering Impact in the Pharmaceutical Industry

ACS GCI Pharmaceutical Roundtable

### Congratulations Dan Bailey!

Dr. Paul Richardson, Pfizer, Co-chair
Dr. Frank Roschangar, BI, Co-chair
Dr. Isamir Martinez, ACS GCI




C&EN Announcement ACS Green Chemistry Nexus Blog Announcement

**2021 Nominations** open Fall 2020: www.acsgcipr.org

# Beyond Organic Solvents

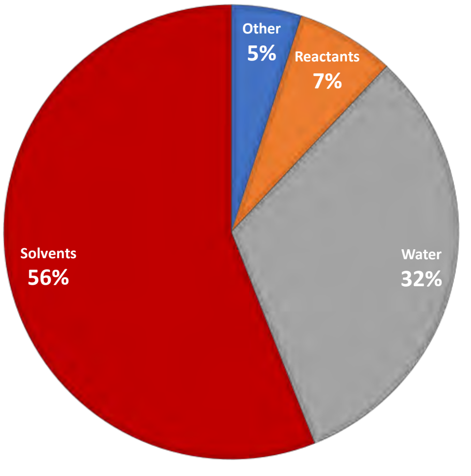
Synthesis of a $5\text{-}HT_4$ Receptor Agonist in Water

ACS Webinar
September 17, 2020
Dan Bailey
Takeda, Process Chemistry Development

## The Solvent Problem

Materials used to manufacture API, by mass, industry-wide (2008)

*Org. Process Res. Dev.* **2011**, *154*, 912-917

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## The Solvent Problem

Many commonly used solvents are hazardous


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## The Solvent Problem

Many commonly used solvents are hazardous



17

## The Solvent Problem

Many commonly used solvents are hazardous




18

## The Solvent Problem

Many commonly used solvents are hazardous





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## The Solvent Problem


“The best solvent is no solvent, but if a solvent is needed, then water has much to offer: it is non-toxic, non-inflammable, abundantly available and inexpensive.”

Roger A. Sheldon, *The E Factor 25 Years On Green Chem.* **2017**, *19*, 18

20 https://pubs.rsc.org/en/content/articlelanding/2017/gc/c6gc02157c

## Audience Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT


### How often have you run organic reactions in water?

- Routinely
- Occasionally
- Rarely
- Once or twice in my career
- Never

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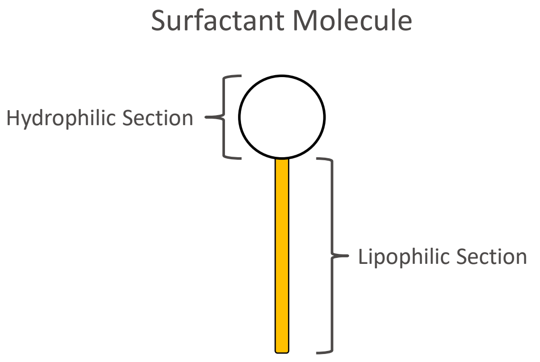
## Aqueous Micelles as “Nano-Reactors”

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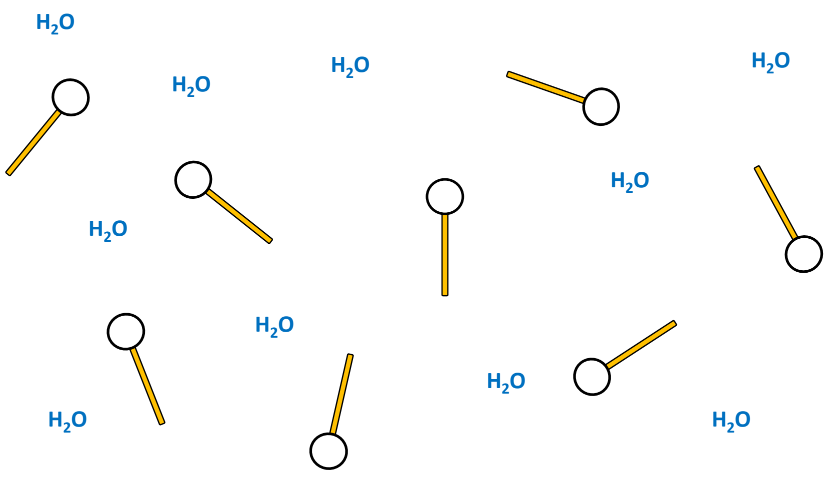
## Aqueous Micelles as “Nano-Reactors”

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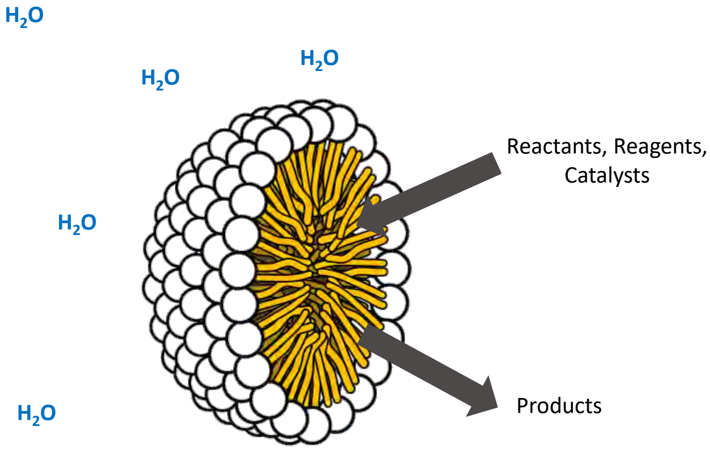
## Aqueous Micelles as "Nano-Reactors"

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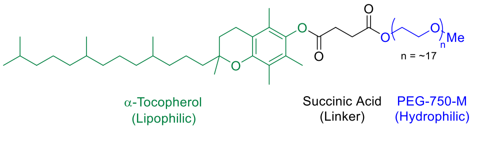
## Organic Synthesis in Micellar Media




- Vitamin E derived surfactant, benign by design
- Developed by the Lipshutz Group at UCSB
- A general surfactant for organic synthesis in water

*J. Org. Chem.* **2011**, 76, 11, 4379-4391

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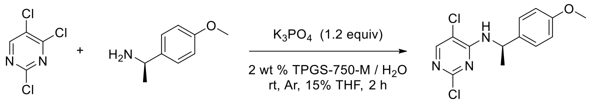
## API Manufacturing in Micellar Media

Use of organic co-solvents in micellar media enables scale-up




No Co-solvent | 10% THF (v/v) | 15% THF (v/v)

*Org. Process Res. Dev.* **2017,** *21*, 218-221

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## Implementing Micellar Media at Takeda

*Goals:*

- Adapt **one chemistry step** of an API process to aqueous media.
- Adapt a **multi-step API synthesis** to aqueous media.
- Conduct an **API manufacturing process** entirely in water, **including isolations.**

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## Implementing Micellar Media at Takeda

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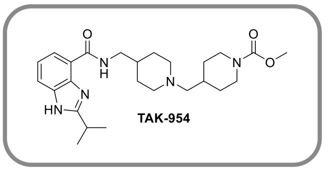
## Implementing Micellar Media at Takeda

*Goals:*

- Adapt **one chemistry step** of an API process to aqueous media.
- Adapt a **multi-step API synthesis** to aqueous media.
- Conduct an **API manufacturing process** entirely in water, **including isolations.**


29

# Implementing Micellar Media at Takeda




5-$HT_4$ Receptor Agonist for Post-Operative GI Dysfunction

- Low complexity molecule
- Opportunity to improve enabling route
- Chemistry seemed likely to work in water
- Basic centers in API and intermediates may provide pH-dependent solubility handle in water

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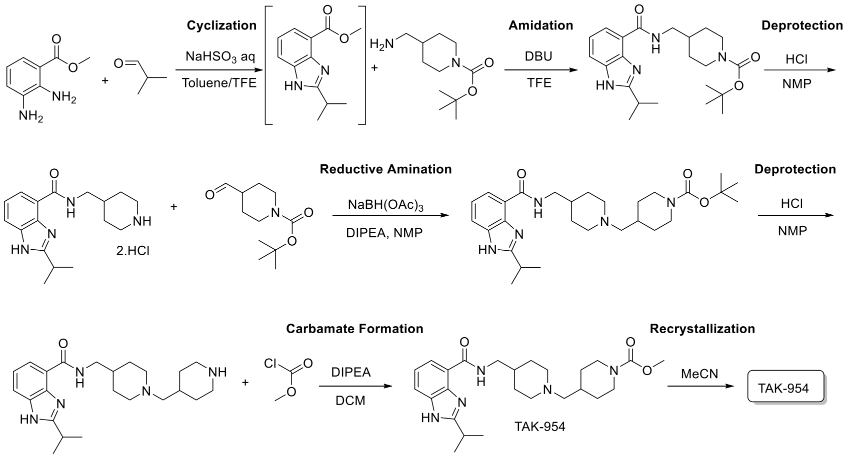
# TAK-954 Enabling Route

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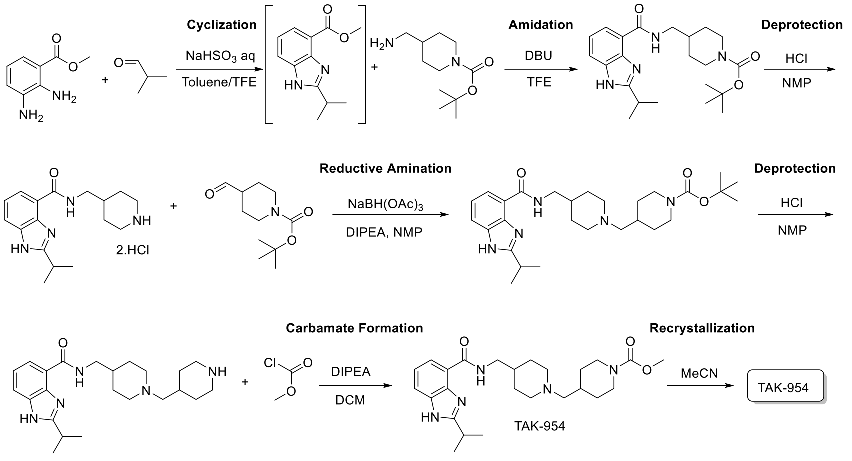
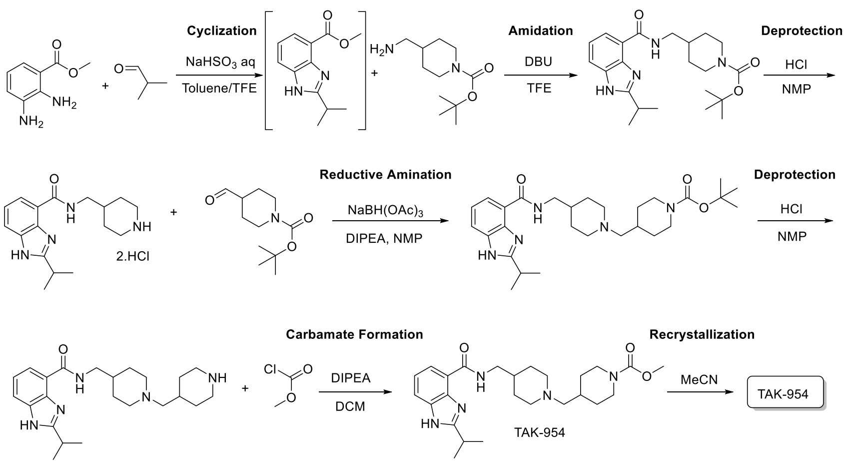
## TAK-954 Enabling Route




Overall Yield = 35%

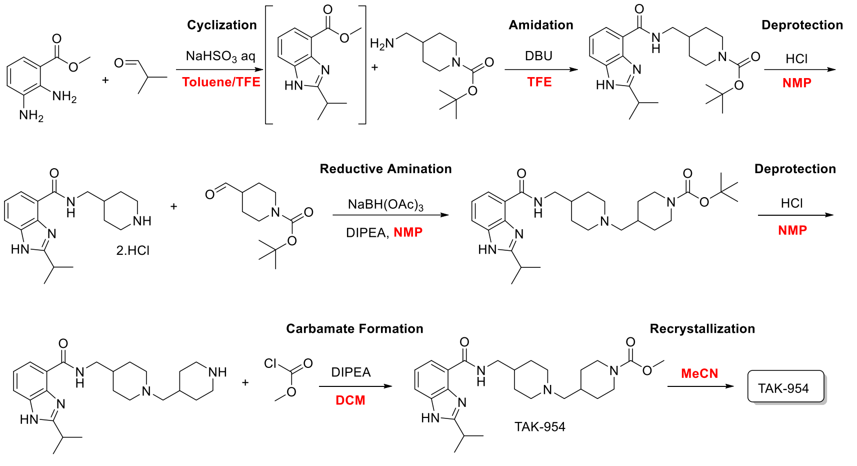


## TAK-954 Enabling Route




$$\text{Cumulative Process Mass Intensity (PMI)} = \frac{\text{mass of all material inputs (kg)}}{\text{mass of API out (kg)}} = \mathbf{350}$$

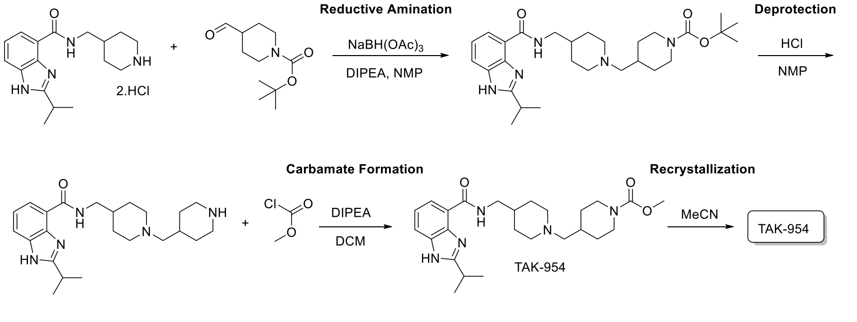
# TAK-954 Enabling Route



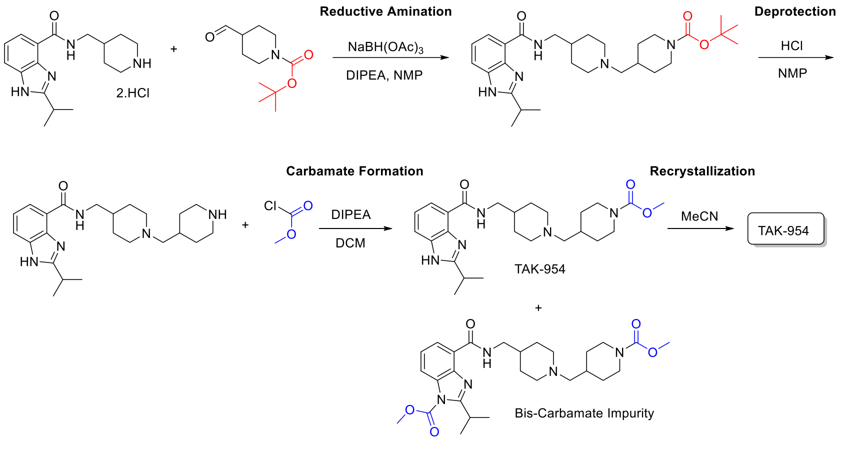

5 Separate Organic Solvents Used



# TAK-954 Enabling Route



# TAK-954 Enabling Route




Opportunity to implement a more efficient route

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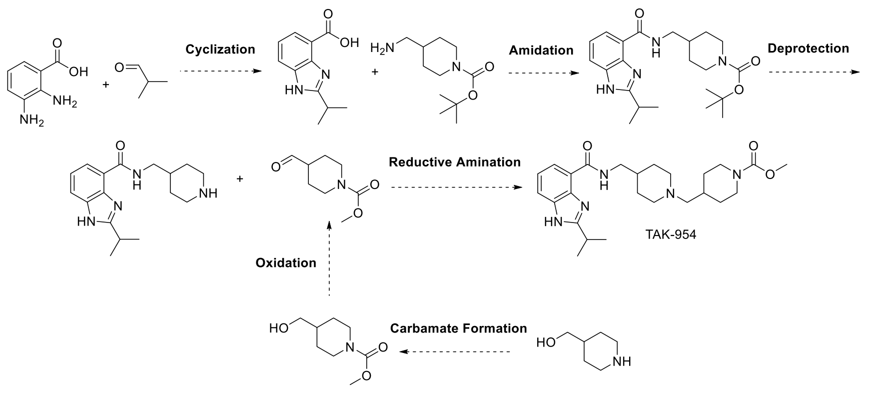
# New Route Proposal

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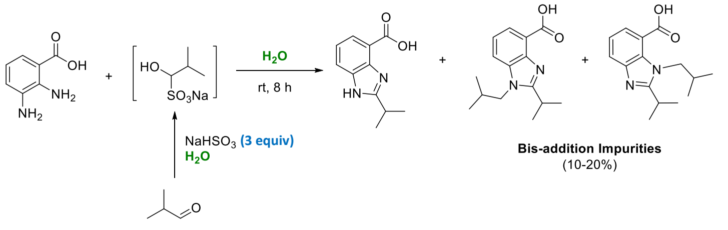
## Step 1: Benzimidazole Cyclization




*Suppression of Bis-Addition Impurities*

- Free aldehyde exclusively gives bis addition
  - Optimized amount of $NaHSO_3$ to ensure full conversion to bisulfite adduct

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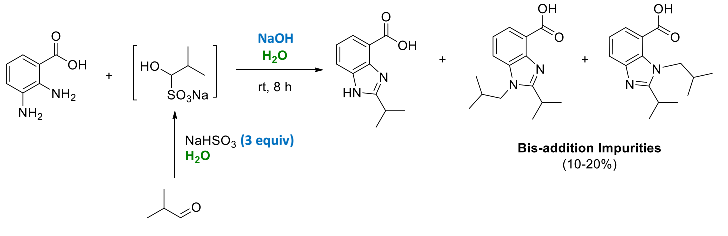
## Step 1: Benzimidazole Cyclization




*Suppression of Bis-Addition Impurities*

- Free aldehyde exclusively gives bis addition
  - Optimized amount of $NaHSO_3$ to ensure full conversion to bisulfite adduct
- Diamine not fully soluble at pH 7
  - Adjusted pH >12 to fully dissolve diamine

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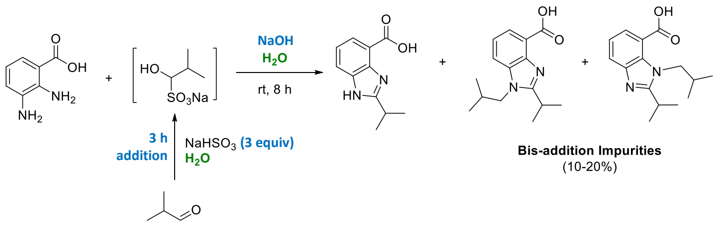
## Step 1: Benzimidazole Cyclization

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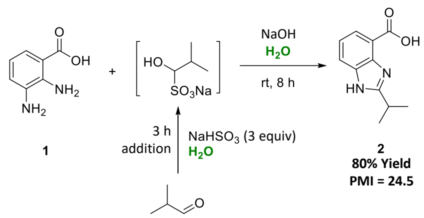
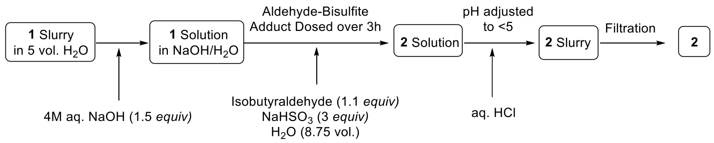
  – Optimized amount of $NaHSO_3$ to ensure full conversion to bisulfite adduct
- Diamine not fully soluble at pH 7
  – Adjusted pH >12 to fully dissolve diamine
- Bisulfite adduct added in a single portion
  – Controlled addition of bisulfite adduct to maintain excess of diamine



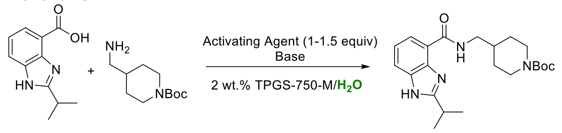
## Step 1: Benzimidazole Cyclization




Direct Isolation Implemented

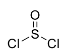


# Step 2: Amidation

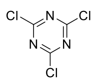



2 3 4

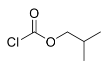
## Activating Agent Screen



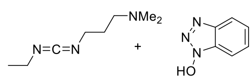
thionyl chloride
59% Conversion



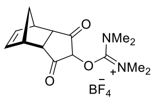
cyanuric chloride
3% Conversion



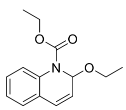
isobutyl chloroformate
13% Conversion



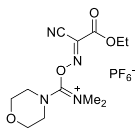
EDCI/HOBt
23% Conversion



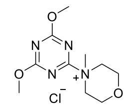
TNTU
16% Conversion



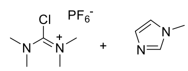
EEDQ
22% Conversion



COMU
47% Conversion



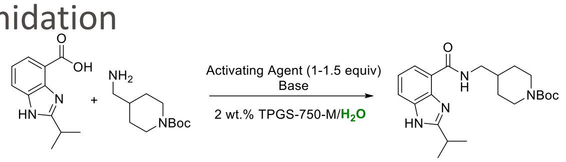
DMTMM
97% Conversion



TCFH/NMI
>98% Conversion

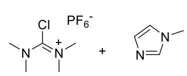
42

# Step 2: Amidation

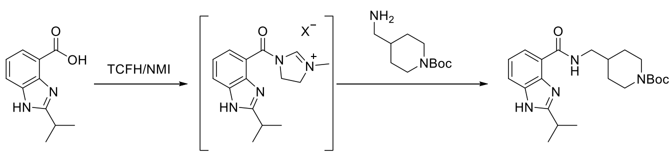



2 3 4

## Activating Agent Screen



TCFH/NMI
>98% Conversion

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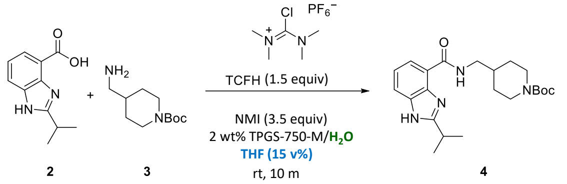
*Org. Lett.* **2018**, *20*, 4218-4222

## Step 2: Amidation




- Reaction is nearly instantaneous upon addition of TCFH
- Product Oiling and Reactor Fouling
  - Added THF co-solvent
  - Added TCFH in 3 portions
  - Removed surfactant

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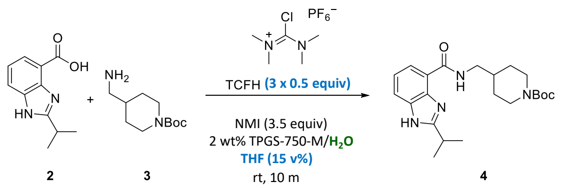
## Step 2: Amidation

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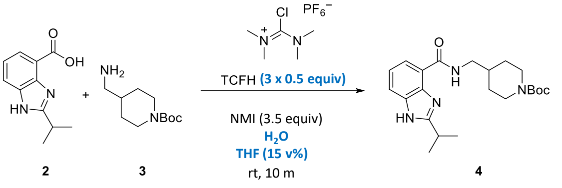
45

## Step 2: Amidation




- Reaction is nearly instantaneous upon addition of TCFH
- Product Oiling and Reactor Fouling
  - Added THF co-solvent
  - Added TCFH in 3 portions
  - Removed surfactant

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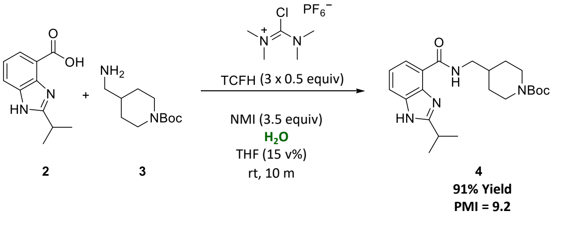
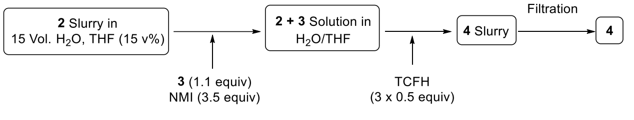
## Step 2: Amidation

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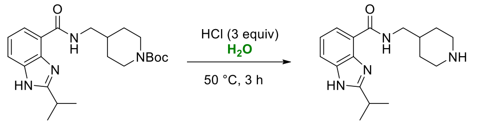
## Step 3: Boc-Deprotection




*Direct Isolation Implemented*

- Starting material & product are soluble at low pH
- Adjusting to pH >12 via slow addition of aq. NaOH leads to precipitation of product **5**

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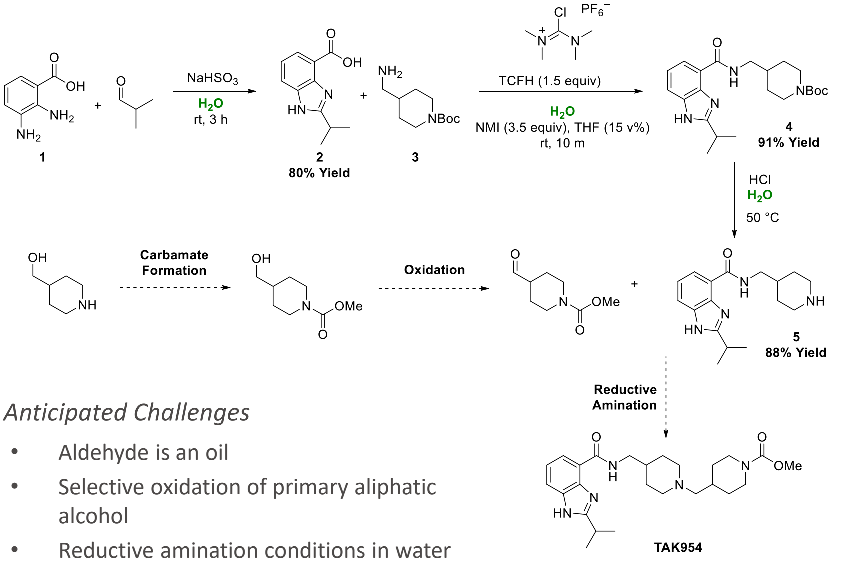
## Steps 1 – 3




*Anticipated Challenges*

- Aldehyde is an oil
- Selective oxidation of primary aliphatic alcohol
- Reductive amination conditions in water

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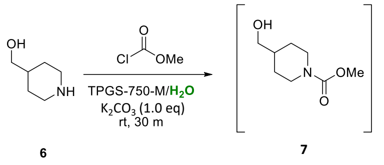
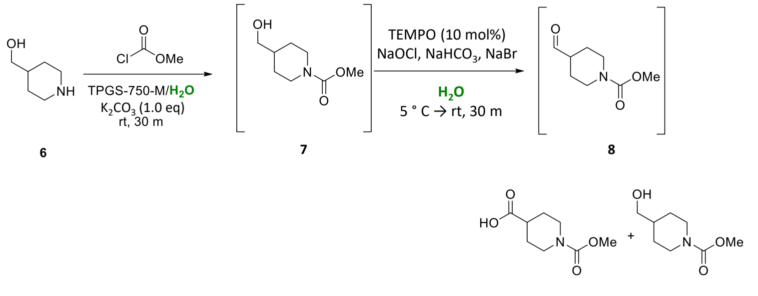
## Step 1A – 3A Telescoped Process




- **6** reacts cleanly and rapidly with ClCOOMe to give carbamate **7** in quantitative conversion
- Carbamate is an oil (not isolated)

50

## Step 1A – 3A Telescoped Process

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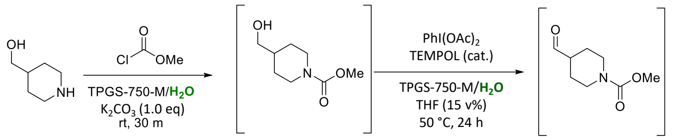
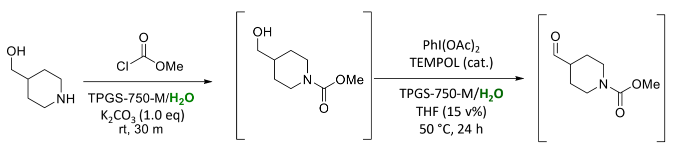
## Step 1A – 3A Telescoped Process




6 7 8

52

## Step 1A – 3A Telescoped Process

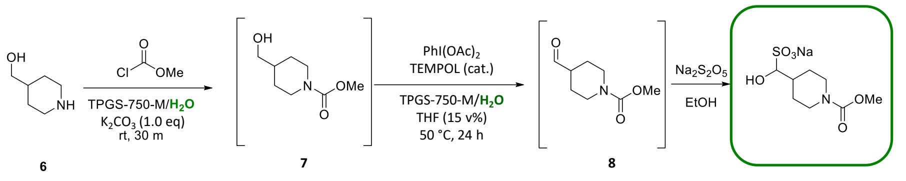



6 7 8

- **Full conversion** to aldehyde **8** in 24 h at 50 °C.
- **No over-oxidation** observed
- **Surfactant and co-solvent** needed to solubilize $PhI(OAc)_2$

53

# Step 1A – 3A Telescoped Process

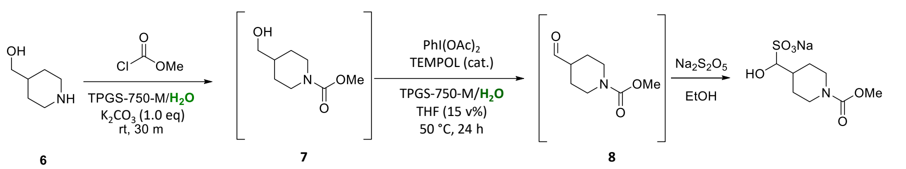



- *Aldehyde-Bisulfite Adduct*
  - Allows for isolation as a **crystalline solid**
  - Known to be **more stable** than free aldehydes
    (*J. Org. Chem.* **2013**, *78*, 1655–1659)

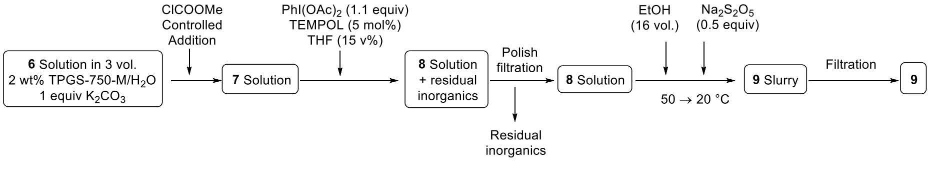
- *Challenges in Isolating Aldehyde-Bisulfite Adduct* ***9***
  - Adduct **9** is highly **water soluble**
  - **EtOH antisolvent** required for crystallization
  - **Residual $Na_2S_2O_5$ + Acetate Salts** co-precipitate with adduct **9**



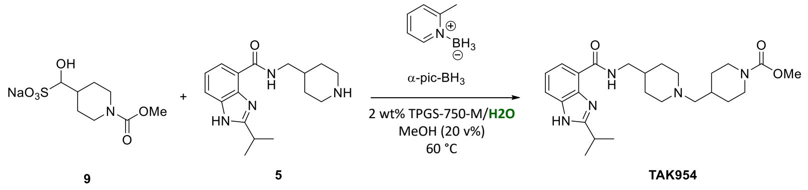
# Step 1A – 3A Telescoped Process




**50% Yield**
**70-80% w/w assay**
**PMI = 27.1**



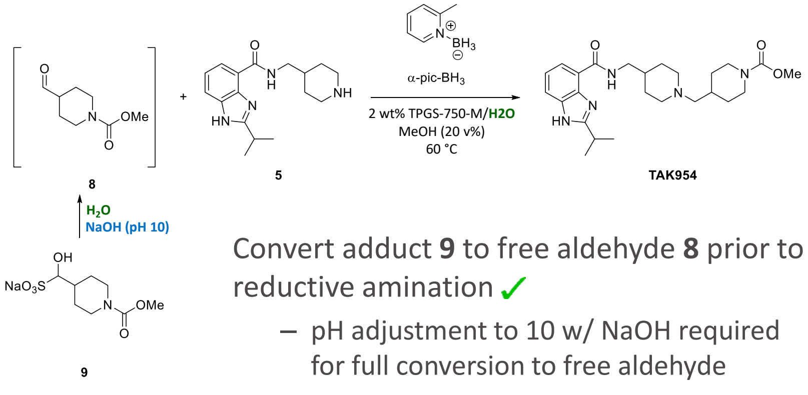
## Step 4: Reductive Amination




- α-picoline-$BH_3$: water-stable reductant
  (*Tetrahedron* **2004**, *60*, 7899-7906)
- Surfactant/Co-solvent needed for workable reaction mixture & full conversion
- Conversion of bisulfite adduct to free aldehyde required?

56

## Step 4: Reductive Amination




Convert adduct **9** to free aldehyde **8** prior to reductive amination ✓

- pH adjustment to 10 w/ NaOH required for full conversion to free aldehyde
- 1.5 *equiv* α-pic-$BH_3$, and 1.5 *equiv* **8** required for full conversion in reductive amination
- No reduction of aldehyde **8** observed

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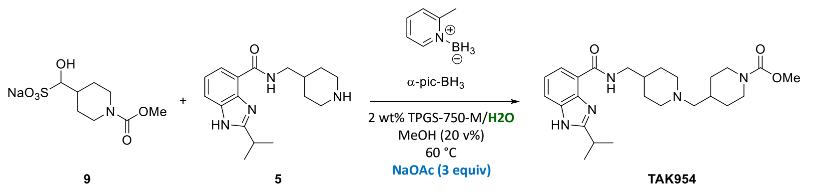
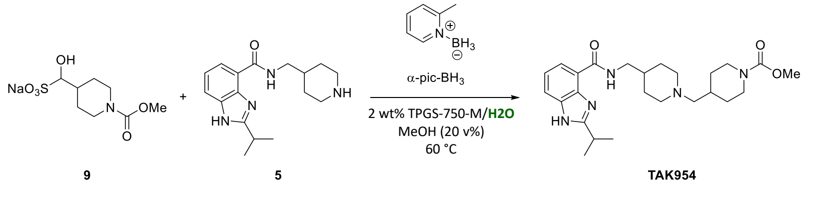
## Step 4: Reductive Amination




- Direct use of adduct **9** in reductive amination in the presence of exogenous base. ✓
  (*J. Org. Chem.* **2013**, *78*, 1655-1659)

58

## Step 4: Reductive Amination




- Direct use of adduct **9** in reductive amination in the presence of exogenous base. ✓
  (*J. Org. Chem.* **2013**, *78*, 1655-1659)
- Direct use of adduct **9** in reductive amination with **NO** base. ✓

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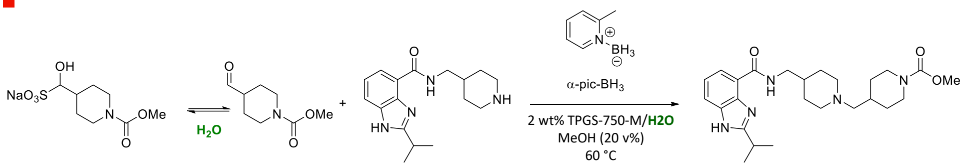
## Step 4: Reductive Amination

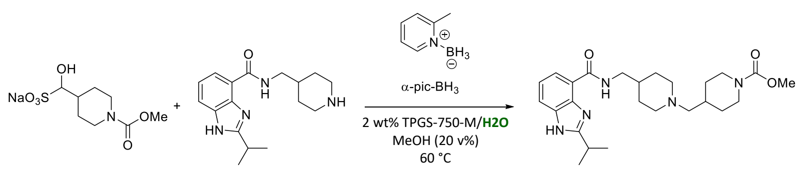



**9** **8** **5** **TAK954**

- Direct use of adduct **9** in reductive amination in the presence of exogenous base. ✓
  (*J. Org. Chem.* **2013**, *78*, 1655-1659)
- Direct use of adduct **9** in reductive amination with **NO** base. ✓

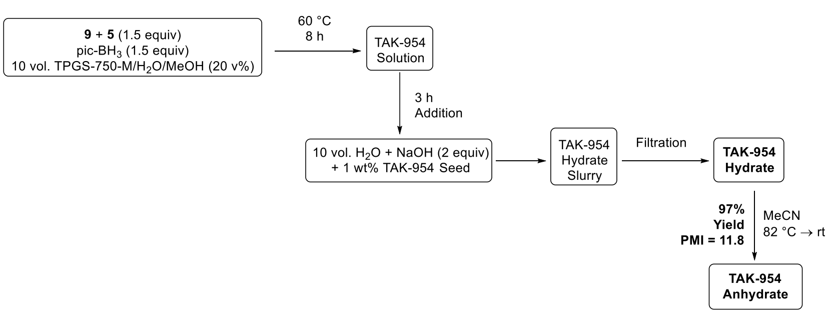
60

## Step 4: Reductive Amination – Isolation




**9** **5**

**TAK954 Hydrate**
**91% Yield**
**PMI = 21.7**

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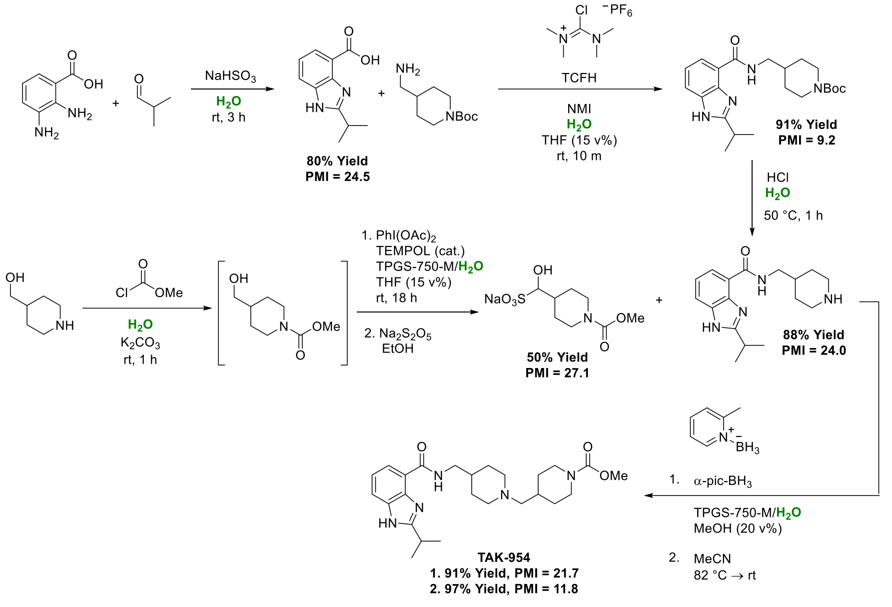
## TAK-954: New Route in Water

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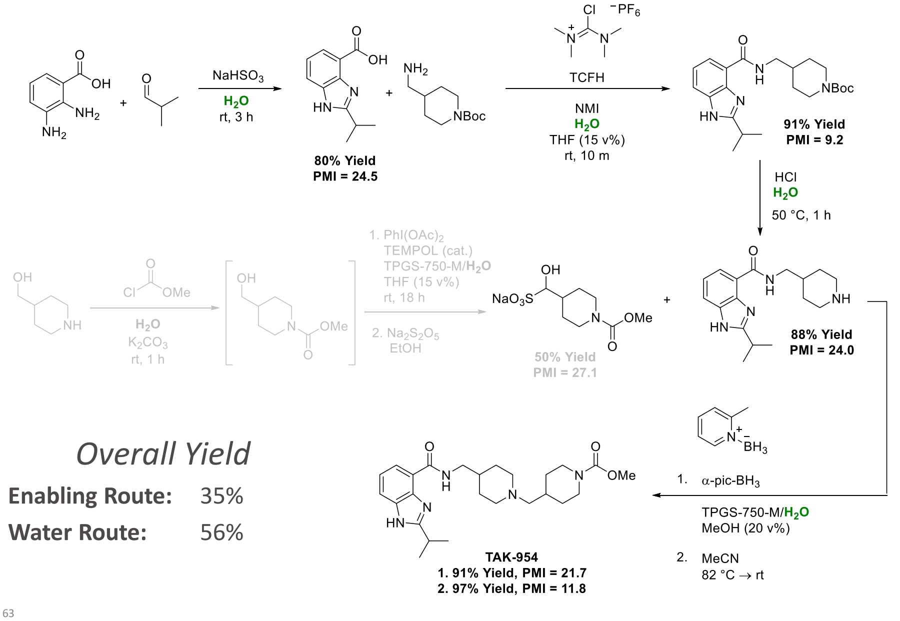
## TAK-954: New Route in Water



*Overall Yield*

**Enabling Route:** 35%

**Water Route:** 56%

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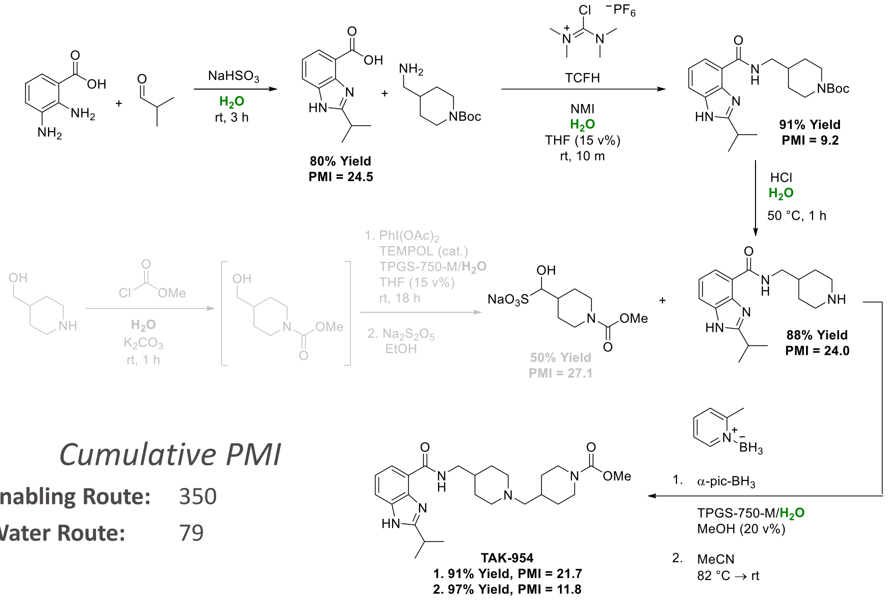
## TAK-954: New Route in Water




*Cumulative PMI*

**Enabling Route:** 350

**Water Route:** 79

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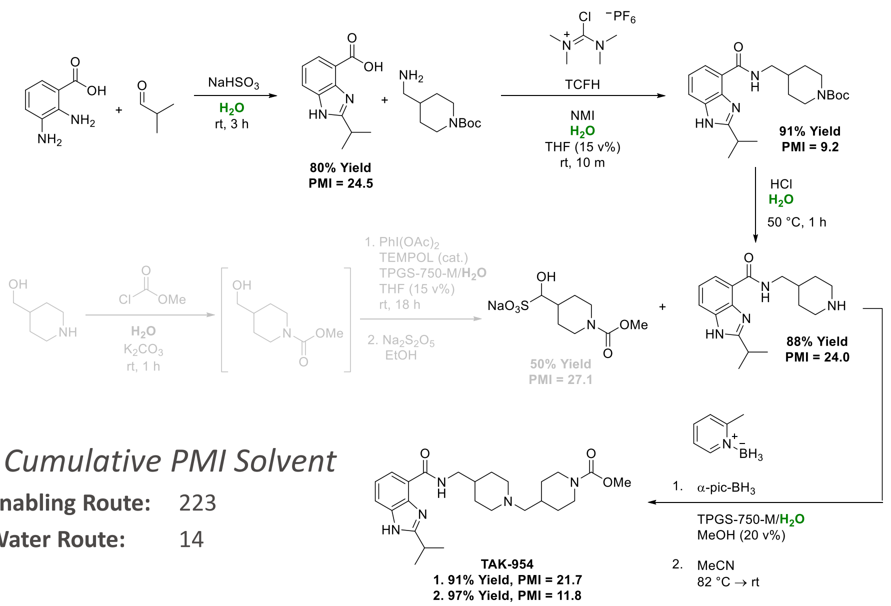
## TAK-954: New Route in Water



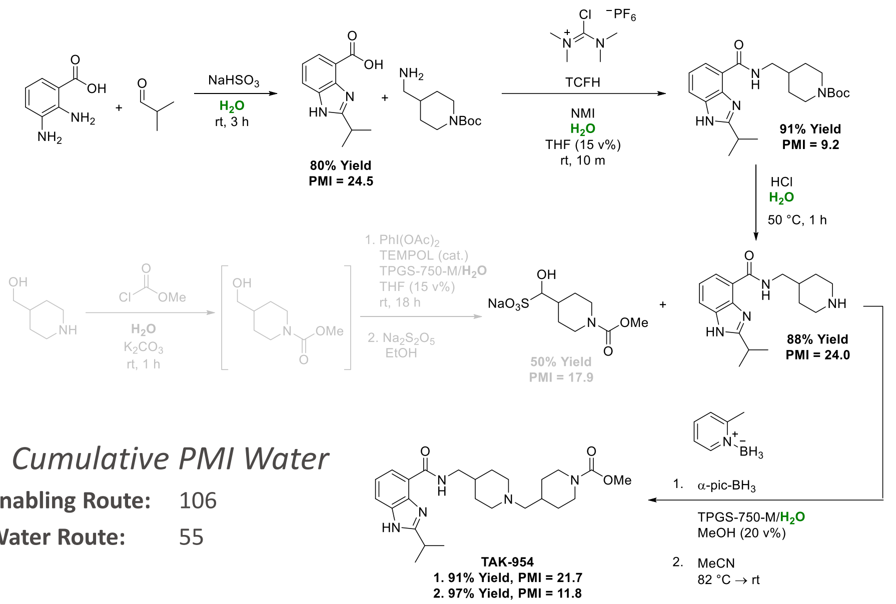

*Cumulative PMI Solvent*

**Enabling Route:** 223

**Water Route:** 14

65

# TAK-954: New Route in Water



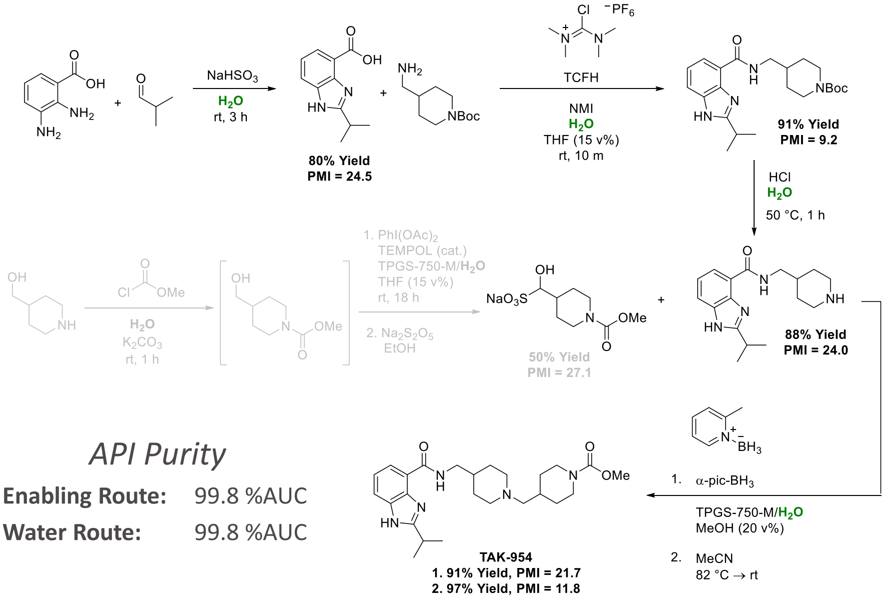

*Cumulative PMI Water*

**Enabling Route:** 106

**Water Route:** 55

66

# TAK-954: New Route in Water




*API Purity*

**Enabling Route:** 99.8 %AUC

**Water Route:** 99.8 %AUC

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# Lessons Learned

- When operating in water, pH can provide a solubility handle, allowing for direct isolations
- In some cases, water can function as a solvent without any additives
- More chemistry works in water than you might expect
- Swapping an organic solvent for water is no substitute for good process design



# Acknowledgments

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Northeastern University Co-Op Student

Amey Mankar
Northeastern University Co-Op Student

## Acknowledgments


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- **Yumin Dai** – Senior Scientist, Analytical Development
- **Takeda Process Chemistry Development Group**


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