



Pharma Solutions

# Strategies & Solutions for Launching OTC & Rx Gummies

**Presented by  
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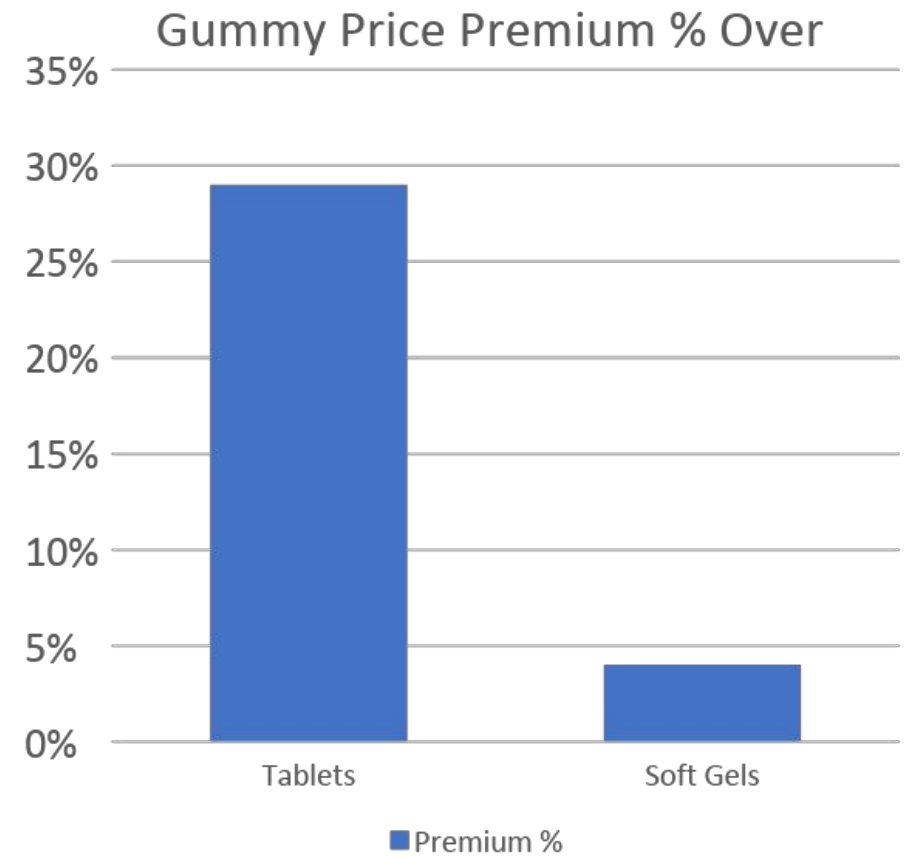
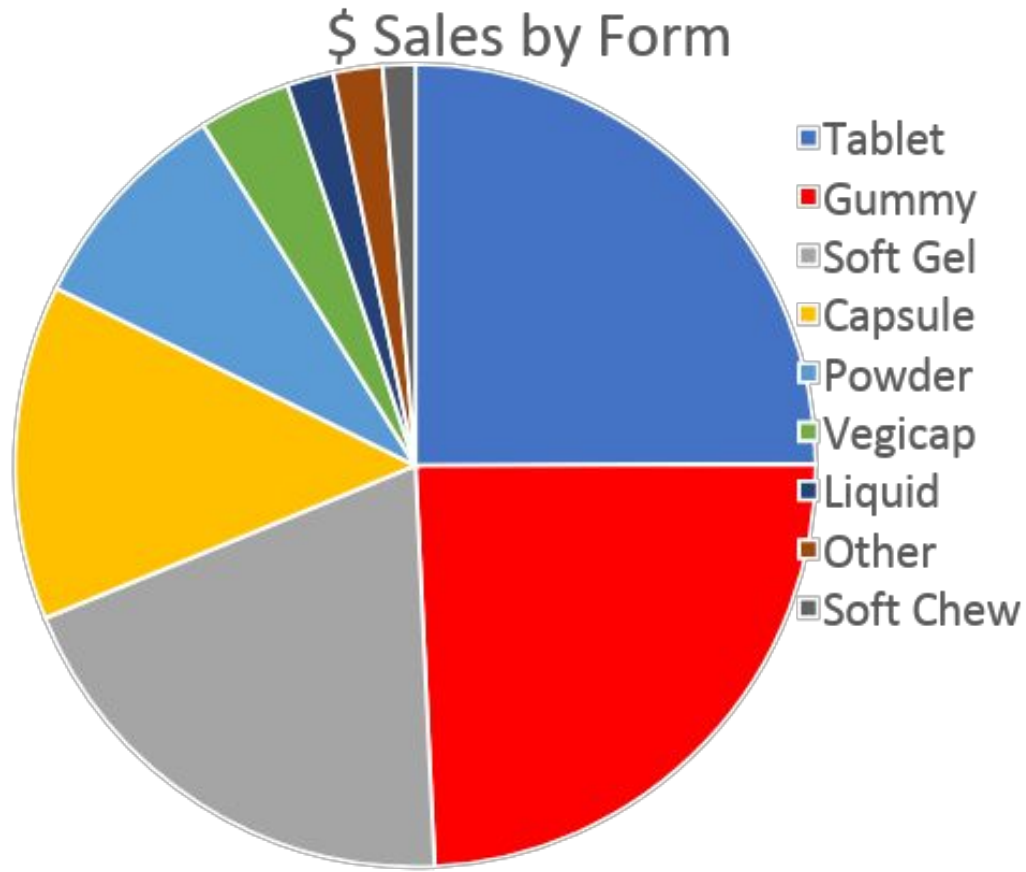
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# Why Gummies? They Drive Compliance

Gummies are the 2<sup>nd</sup> best selling form in VMS

They can help increase compliance and help companies expand their brands.



Source: IRI 52WE4/28/24



# Drug Gummy - Regulatory Challenges

- Companies are moving forward with OTC gummies.
  - At least one Investigational New Drug application has been approved.
  - 505b2s are in progress
- FDA addressed gummies in 2023 - “Candy-Like OTC Drugs” 10/23 (<https://www.fda.gov/media/172272/download>)
  - Safety, efficacy and delivering the right dosage are the big take aways.



Bismuth  
Subsalicylate



Magnesium  
Hydroxide



Calcium Carbonate  
Simethicone



Acetaminophen



Acetaminophen



Diphenhydramine



Sennosides

# What are the Challenges for Commercialization?

- API Suitability
- Stability (heat and moisture)
- Taste masking, mouth feel, chewability
- Dosage accuracy and loading
- Manufacturing cost
- Regulatory approvals



## Which criteria should be considered?

- Dosage considerations.
- Does it have a reasonable taste profile?
- What is the aqueous solubility of the API?
- Does the API exhibit thermal stability issues?
- Is the API stable across a broad pH range?



Stability is an issue with complex gummy matrixes.

- **Heat sensitivity.** A typical gummy process might achieve 130°C which could be problematic for APIs that are heat sensitive.
- **Moisture sensitivity:** A typical gummy contains 15-20% moisture which could cause hydrolyzable drugs to degrade.
- **pH Sensitivity:** Pectin-based gummies are dependent on the addition of acidic excipients which could destabilize pH sensitive drugs.
- **Microbial control:** The high moisture content of gummies can promote microbial growth. Moisture control, preservatives and proper packaging are essential for proper control.



# Achieving Consistency

Dosage consistency is a major challenge with OTC and Rx drugs.

- Poorly soluble or dense powders (e.g., calcium, iron, cannabinoids) tend to settle during manufacturing.
- Insufficient mixing leads to hot spots of concentrated active.
- Use of powder dispersers, high-shear mixers or emulsifiers may be necessary.
- Thicker matrices help suspend active better.
- Cooling has to be optimized: too slow can lead to settling, too fast might cause incomplete dispersion.



# Taste and Texture Issues

- **Taste:** Some API can cause unpleasant tastes that are hard to mask in gummies. Various techniques such as microencapsulation, coating, or ion exchange resins are often investigated.
- **Texture disruption:** High loads of actives can negatively affect chewiness, softness, or cause crystallization.



# Manufacturing Costs

Gummies are the fastest growing delivery system but can incur higher manufacturing costs.

- **Excipients:** Solid dose platforms support higher dosage levels than gummy platforms. This may require higher amounts of excipients.
- **Taste masking:** Raw material costs can vary widely depending upon which technique is required.
- **Process:** APIs in suspension require more robust and expensive equipment to achieve the necessary product quality.



# Applying Rx Standards to Gummies



## What should you be looking for?

- Is the facility FDA approved for drug gummies?
- Does the CDMO have experience developing drug products?
  - Do they have a library of formulations
  - Do they use QbD in Drug development
  - Are they experienced conducting clinical trials and BE studies
  - Regulatory submissions
- Do they have a robust and capable analytical development department?



Find out how our team can help you bring your product to market from concept through commercialization.

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