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# REVOLUTIONIZING ABUSE DETERRENCE: HARNESSING CAFFEINE AS A MODEL FOR INNOVATIVE FORMULATION TECHNOLOGY

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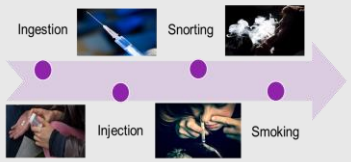
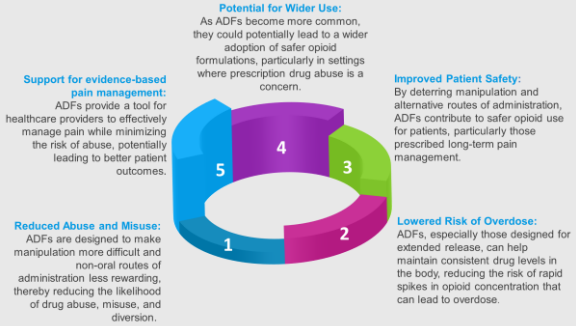
## INTRODUCTION

### Common Routes of Abuse:

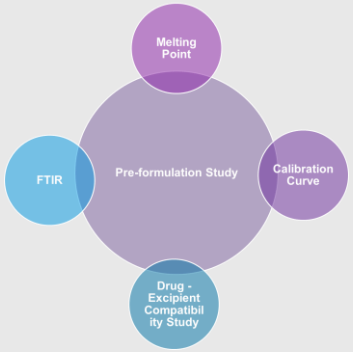



### Need for ADFs : Caffeine


## WHY ABUSE DETERENT FORMULAS




## PREFORMULATION STUDIES




## PROPOSED FORMULATION

| Sr. No | Ingredient | % w/w |
|---|---|---|
| 1 | Caffeine Anhydrous | 48.54 |
| 2 | Kollidon® SR (Polyvinyl acetate, Polyvinylpyrrolidone, Povidone / PVP, PVAc, Silica) | 29.12 |
| 3 | Anhydrous dibasic calcium phosphate | 19.44 |
| 4 | Aerosil® 200 Colloidal Silicon Dioxide | 0.48 |
| 5 | Roquette Magnesium stearate | 2.42 |
| | **Total** | **100 %** |

## PREPARATION

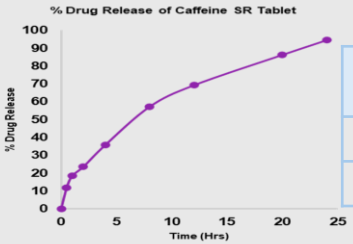
- **Step 1** • Co-sift all the ingredient except magnesium stearate through ASTM 30 # sieve and blend using blender at 15 rpm for 10 mins
- **Step 2** • Sift magnesium stearate through ASTM 60 # sieve and lubricate above mixture using blender at 15 rpm for 3 mins
- **Step 3** • Compress the lubricated blend using suitable punches

| Blend Parameter | Result |
|---|---|
| Bulk Density (g/mL) | 0.581 |
| Tapped Density (g/mL) | 0.755 |
| Compressibility (%) | 20.93 |
| Hausner's ratio | 1.265 |
| Angle of Repose (°) | 14.17 |

## EVALUATION TABLETS

| Tablet Parameters | Result |
|---|---|
| Appearance | White to off white, round, FFBE, Uncoated tablet plain on both sides |
| Tablet weight (mg) | 412.00 |
| Weight variation | Average weight ± 3 % |
| Tablet Hardness (N) | 150-160 |
| Tablet Thickness (mm) | 2.8 ± 0.3 |
| Compression Force (kN) | 1.265 |
| Ejection Force (kN) | 14.17 |
| Friability (%) | 0.176 |
| Assay (%) | 99.50 |

## IN VITRO DISSOLUTION




| Time (Hrs.) | Optimized Product |
|---|---|
| t50 | 6.52 Hrs |
| t90 | 22.98 Hrs |

| Parameters | Specification |
|---|---|
| Apparatus | USP Type II |
| Media | Water |
| Volume | 900 mL |
| RPM | 50 |
| Temperature | 37°C ± 0.5°C |
| Time interval | 30 min, 1,2,4,8,12,16,20, and 24 h |

## EVALUATION ABUSE DETERENCE

### EXTRACTION

| Time(min) | Trial 1(%) |
|---|---|
| **Intact** | |
| 5 | 1.72 |
| 30 | 19.62 |
| **Manipulated** | |
| 5 | 3.26 |
| 30 | 24.75 |

### SYRINGEABILITY

| Time(min) | Trial 1(%) |
|---|---|
| **Intact** | |
| 30 | 5.7 |
| **Manipulated** | |
| 30 | 8.8 |

## CONCLUSION

- The developed formulation successfully limited caffeine extraction, indicating strong potential as an abuse-deterrent solid oral dosage form.
- The formulation can be manufactured using conventional pharmaceutical processing techniques without the need for specialized equipment or infrastructure.
- Not only reduces production complexity and costs but also enhances scalability, making it a practical and economically viable approach for future implementation in abuse-deterrent drug development.

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**REFERENCES:**

https://www.fda.gov/files/drugs/published/Abuse-Deterrent-Opioids-Evaluation-and-Labeling.pdf

*Carinci AJ. Abuse-deterrent opioid analgesics: a guide for clinicians. Pain Management. 2020 Jan 1;10(1):55-62. https://doi.org/10.2217/pmt-2019-0052*