

# GREEN DEAL STRATEGY

## THE AMBITION OF ZERO POLLUTION FOR A NON-TOXIC ENVIRONMENT

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CCUV4 - Green Deal strategies for V4 countries:  
The needs and challenges to reach low-carbon industry.

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# European Green Deal Strategy



# Zero pollution, toxic free environment

- **Topic 1:** Innovative, systemic zero-pollution solutions to protect health, environment and natural resources from persistent and mobile chemicals
- **Topic 2:** Fostering regulatory science to address chemical and pharmaceutical mixtures: from science to evidence-based policies



# Topic 2

- Under 'Towards a zero-pollution ambition for a toxic free environment', the European Green Deal will propose a new Chemicals Strategy for Sustainability, aiming at better protection of both **humans** and the **environment** against hazardous chemicals.
- In addition, there is growing concern about the occurrence of pharmaceuticals in the environment and several knowledge gaps are identified in EU Strategic Approach to Pharmaceuticals in the Environment.



# Scope of Topic 2

This topic calls for applied research studies, demonstrating how regulatory science can apply new tools and methodological approaches based on the latest scientific evidence, to quantify and prevent harmful co-exposures to industrial chemicals and pharmaceuticals.



# Areas of research

- Estimations of the degree to which current regulatory practices/approaches underestimate risks related to chemicals exposure.
- Comparisons of different possible regulatory approaches to manage chemical mixtures with current situation, including regarding effectiveness, workability, cost-effective methods and benefits to society and business.
- Improvement of the knowledge base on mixtures and their health and environmental impact, to underpin and support regulatory action.



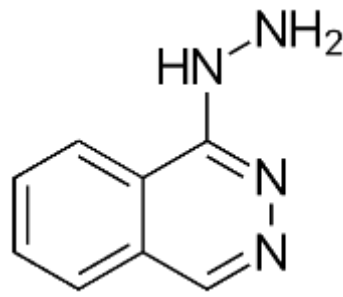
# Example: Application of Wet Granulation Process to Hydralazine Powder Mixture

- Elimination of dustiness and improvement of the flow properties of the pharmaceutical mixture.
- Evaluation of experiments focusing on the properties of granules and tablets.





# Hydralazine



- Antihypertensive drug
- Used to treat high blood pressure and heart failure
- Patented in 1949
- Discovered when scientists were looking for a drug to fight malaria
- It is included in the list of essential medicines of the WHO



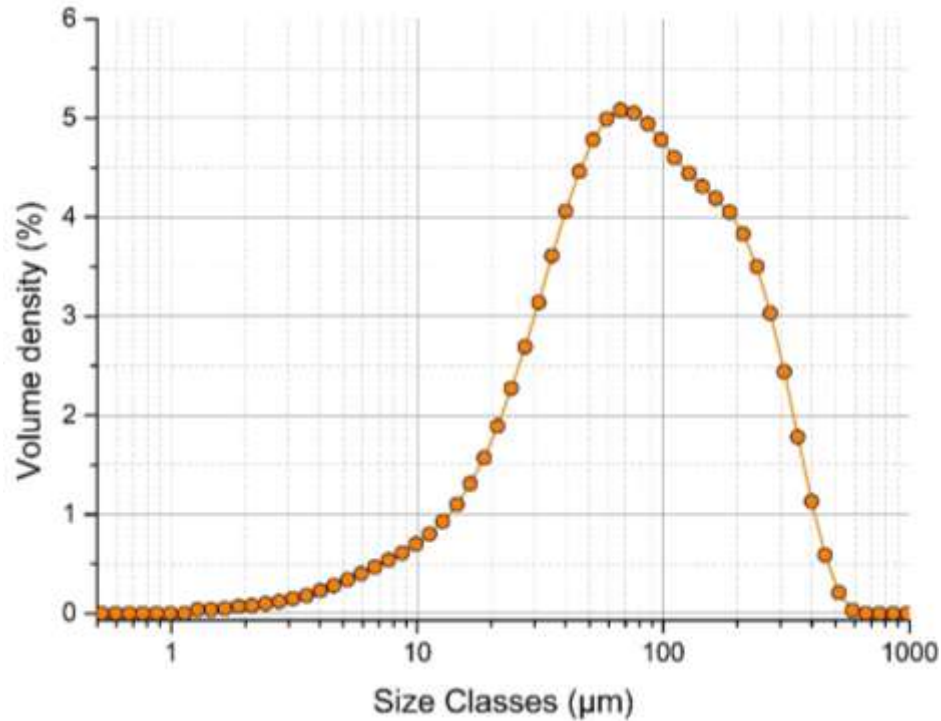
World Health  
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# Powder mixture

- Mixture of API and excipients (cellulose, lactose, dye, lubricant)

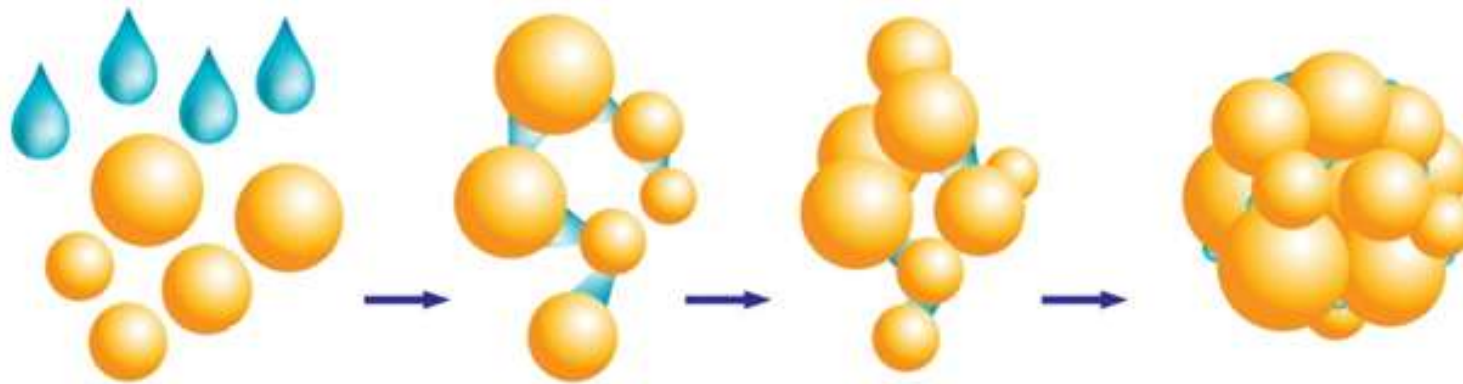


<i>Parameter</i>	<i>Symbol</i>	<i>Value</i>	<i>Unit</i>
Characteristic dimensions	$d_{v10}$	21	(μm)
	$d_{v50}$	81.8	(μm)
	$d_{v90}$	265	(μm)
Bulk density	$\rho$	538	(kg/m <sup>3</sup> )
Compressibility index	$CI$	16.3	(%)
Hausner ratio	$HR$	1.195	(1)



# Wet granulation

- Larger and stronger particles
- Improved flow properties
- Better handling
- Reduction of dustiness
- Dense granules
- Short process duration



# Process parameters

- Two types of binder (PVP, H<sub>2</sub>O)
- Two impeller speeds (500, 700 rpm)
- Two wet massing times (0, 120 s)

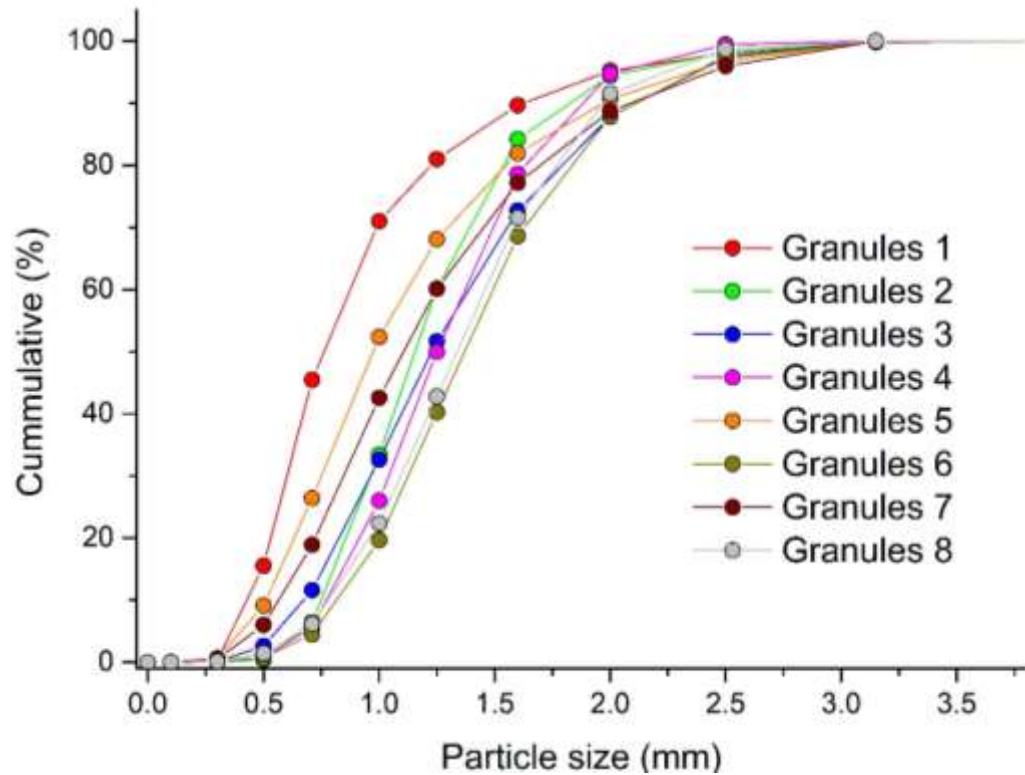


# Summary of experiments

Sample	Impeller speed [rpm]	Wet massing time [s]	Wetting time [s]	Granulation liquid
Granules 1	500	0	180	H <sub>2</sub> O
Granules 2	700	0	180	H <sub>2</sub> O
Granules 3	500	120	180	H <sub>2</sub> O
Granules 4	700	120	180	H <sub>2</sub> O
Granules 5	500	0	180	PVP
Granules 6	700	0	180	PVP
Granules 7	500	120	180	PVP
Granules 8	700	120	180	PVP



# Granule size distribution



Sample	$d_{\text{mean}}$ (mm)	Sphericity (-)
Granules 1	0.92	0.89
Granules 2	1.32	0.87
Granules 3	1.23	0.87
Granules 4	1.30	0.87
Granules 5	1.12	0.86
Granules 6	1.23	0.86
Granules 7	1.43	0.87
Granules 8	1.37	0.86



# Angle of Repose

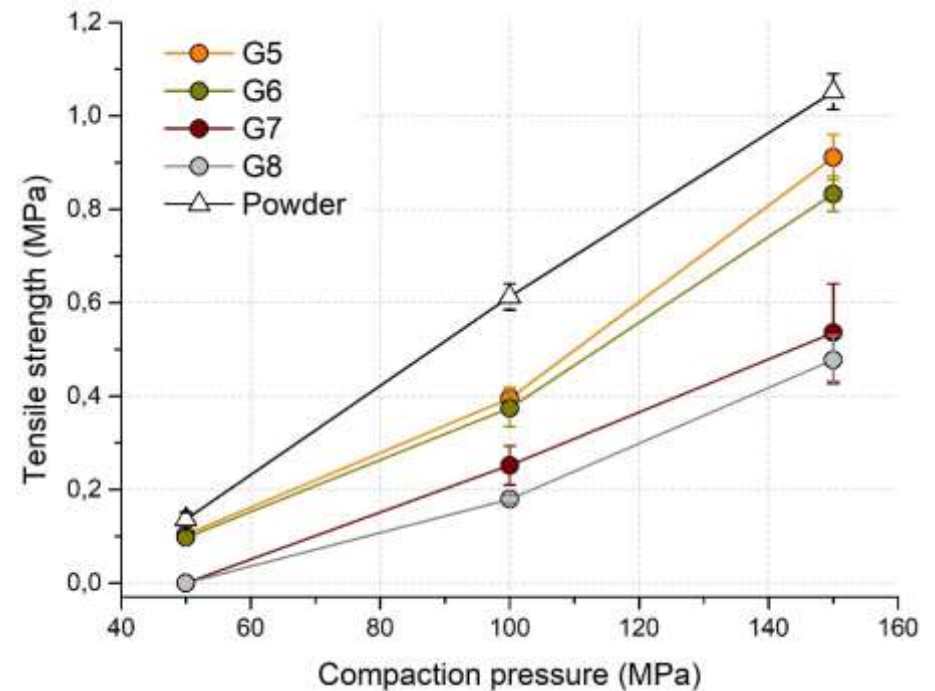
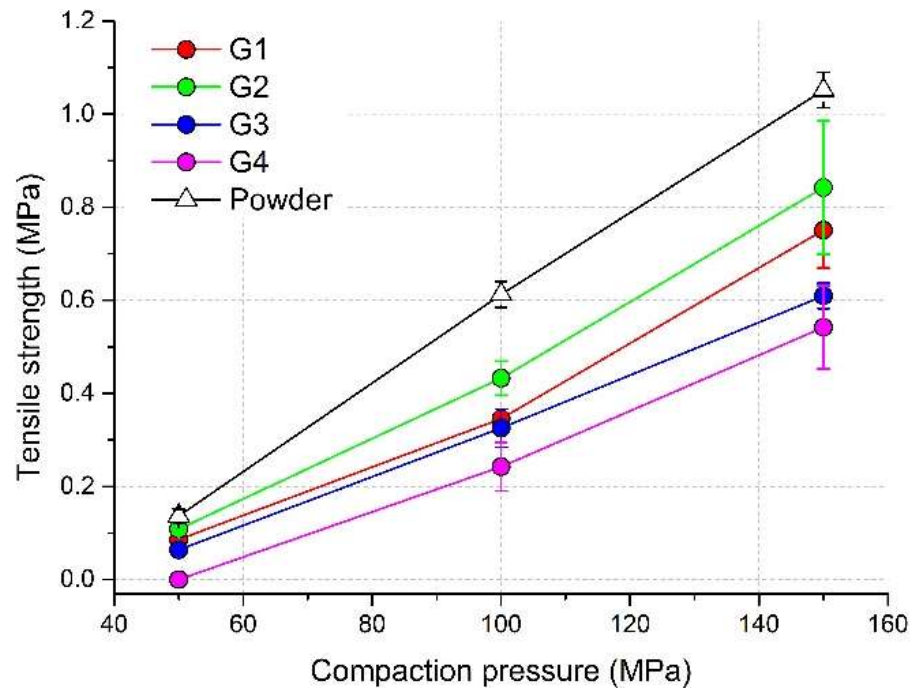
Sample	AoR (°)
Pure API	55.305
Powder mixture	35.640
Granules 1	33.425
Granules 2	32.189
Granules 3	31.617
Granules 4	29.365
Granules 5	31.593
Granules 6	32.135
Granules 7	32.461
Granules 8	31.357





# Batch tableting

- 13 mm diameter
- 700 mg weight at pressures 50, 100, 150 MPa





# Conclusion

- Green Deal Strategy - Zero pollution for a non-toxic environment
- Analysis of properties of powders, high shear granulation, tableting
- Elimination of risk of exposure, dustiness, contamination, cost savings



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# Thank you for your attention

