



Future proofing patient impact with technology

Mark Filosi BS Pharm

Medisca Pharmacy Coaching Services

Success Partner

1



2

Case Study

- Coaching clients across the globe
- Mixing processes commonly used by compounders
- USP <1163> vs homogeneity
- Process development and improvement
- Being credible with technology



3

Planetary Mixer

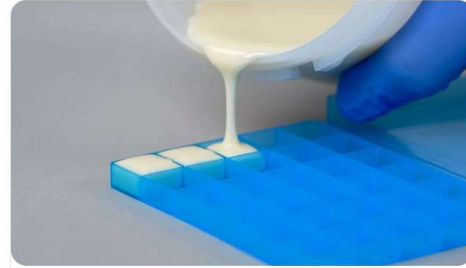
- Definition
- How it works
- Benefits
- Use cases



4

Process, Formulation, and Potency

- Mixing processes
- Particle size reduction
- Formulation w/w or w/v
- Volumetric actuated devices
- Volume expansion
- Delayed de-gassing during product aging
- ADME Pharmacokinetics
- Absorption: Drug – Base – Biology
- Melting



Melting Patent No.: 10,993,876 and 10,231,903



Consistent Potency

- Certificate of Analysis
- Salt form, water content, impurities
- Process Volume due to air incorporation
- Former client processes

CERTIFICATE OF ANALYSIS		
PROGESTERONE, USP (Micronized)		
Batch/Lot Number :	192037	This lot was manufactured by
Manufacturing Date :	03/01/2022	HARIS DESAI/HANMIBELL PHARMACEUTICAL CO. LTD
Expiration Date :	02/28/2027	3520AN ECONOMIC DEVELOPMENT DISTRICT
CAS :	87-83-0	EDMONT, ALBERTA T4N 0N1
TESTS	SPECIFICATIONS	RESULTS
ASSAY ON DRIED BASIS ¹	97.0 - 103.0 %	99.5 %
DESCRIPTION	White or creamy white, crystalline powder, is stable in air.	CONFORMS
IDENTIFICATION A - (157A) ¹	IR: Reference to standard spectrum.	POSITIVE
IDENTIFICATION B - (157A) ¹	IR: Reference to standard spectrum.	POSITIVE
MELTING RANGE - (157) ¹	136° - 137°C	127° - 130°C
SPECIFIC ROTATION - (191B) ¹	+17° to +18°	+18°
LOSS ON DRYING - (731) ¹	→ 0.1 %	0.01 %
ELEMENTAL IMPURITIES - (231) ¹	Meets the requirements.	CONFORMS
RESIDUAL SOLVENTS - (467) ¹	Meets the requirements.	CONFORMS
PARTICLE SIZE	To be reported	95 % → 10 µm
SOURCE	Yam	
SOLUBILITY	Practically insoluble in water, soluble in alcohol, acetone and chloroform, sparingly soluble in vegetable oils.	
"PACKAGING AND STORAGE"	Preserve in light, light-resistant containers. Store at 20°C, excursions permitted between 15° and 30°C.	
TESTED ON 10/17/2022		
Lot number has been changed from 19H172020/001 to 192037		
LOT TESTED BY:	PUBLISHED BY:	PUBLISHED DATE:
DES: HANMIBELL, PH. D. MSc. in Science, BCJURM, GC Hong, TN 7683		10/17/2022
		ISSUE DATE: 10/17/2022
<small>The above mentioned product conforms to the specifications of USP. The above lot was tested with a HPLC method (HPLC method) to determine the purity of the product. The results of the analysis are as follows: Method: Additional testing conducted to determine the purity of the product. The test was conducted by HPLC. Method: The above lot was tested with a HPLC method (HPLC method) to determine the purity of the product. The above lot was tested with a HPLC method (HPLC method) to determine the purity of the product.</small>		



Process Development

- Control
- Consistency
- Reliability
- Quality
- Better for physicians
- Better for patients



7

Process Efficiency

- Labor vs Revenue
- Opportunity cost
- Volumetric actuated devices
- Planetary mixer process time study
- ROI



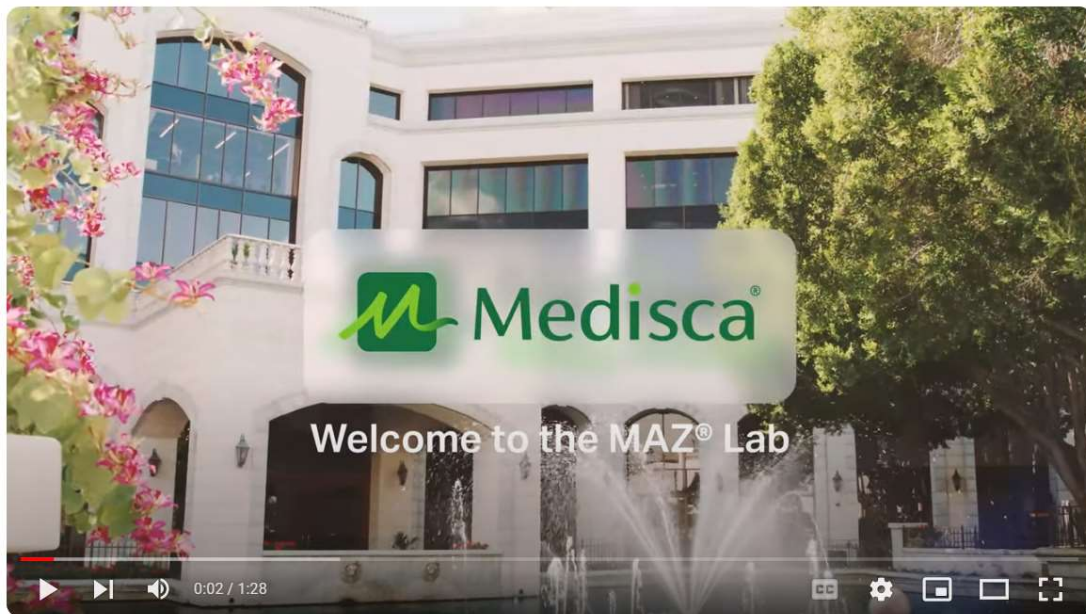
8

Bridging gaps in healthcare with technology

We all have a role in continuing to bring **credibility** to our industry. Technology bring us closer to that mission.



9



<https://www.youtube.com/watch?v=i50QpHveiBE>

10

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