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HFA pMDI Manufacturing Techniques

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HFA pMDI Manufacturing Techniques Key Challenges for CFC-HFA Change

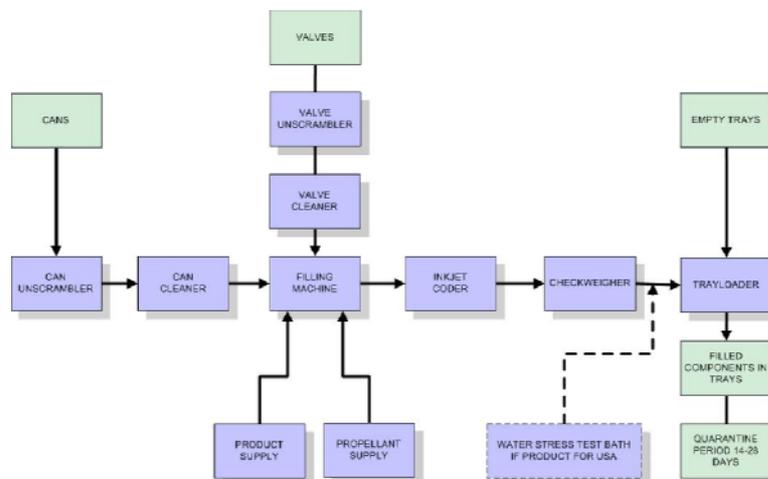
- 1 Typical pMDI filling and packing line configurations
- 2 Typical pMDI formulations and filling techniques
- 3 Mixing and process equipment

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Typical pMDI Filling and Packing Line Configurations

1 Typical pMDI Filling and Packing Line Configurations

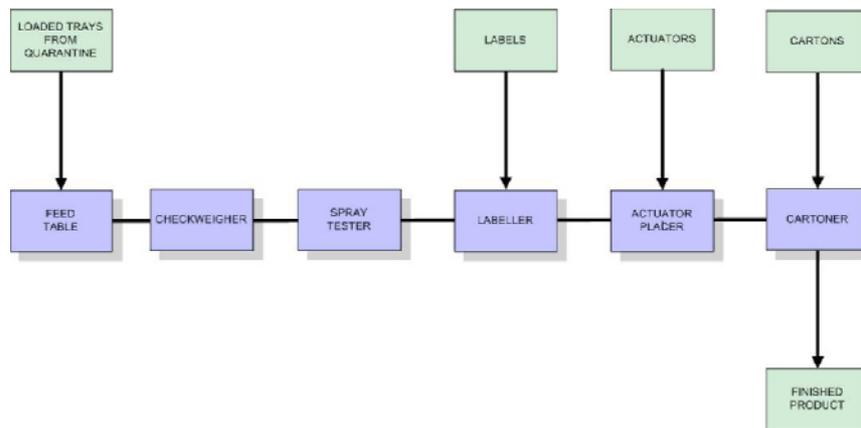
Typical Filling Line Configuration



1 Typical pMDI Filling and Packing Line Configurations

Typical Packing Line Configuration

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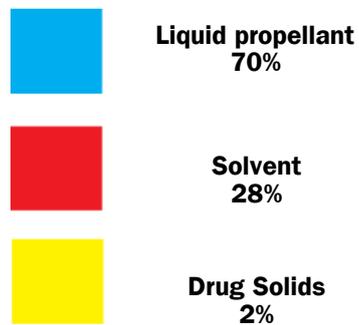
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Typical pMDI Formulations and Filling Techniques

Typical pMDI Formulations

2 Typical pMDI Formulations and Filling Techniques Two stage CFC filling process



2 Typical pMDI Formulations and Filling Techniques

Single or two stage HFA filling process



Liquid propellant
93%



Solvent
5%



Drug Solids
2%

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2 Typical pMDI Formulations and Filling Techniques

Single stage HFA filling process



Liquid propellant
98%



Drug Solids
2%

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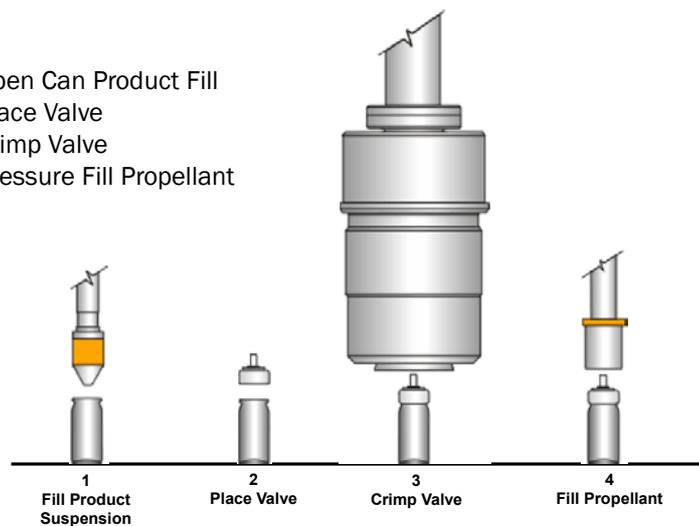


Filling Techniques for different Formulations

2 Typical pMDI Formulations and Filling Techniques

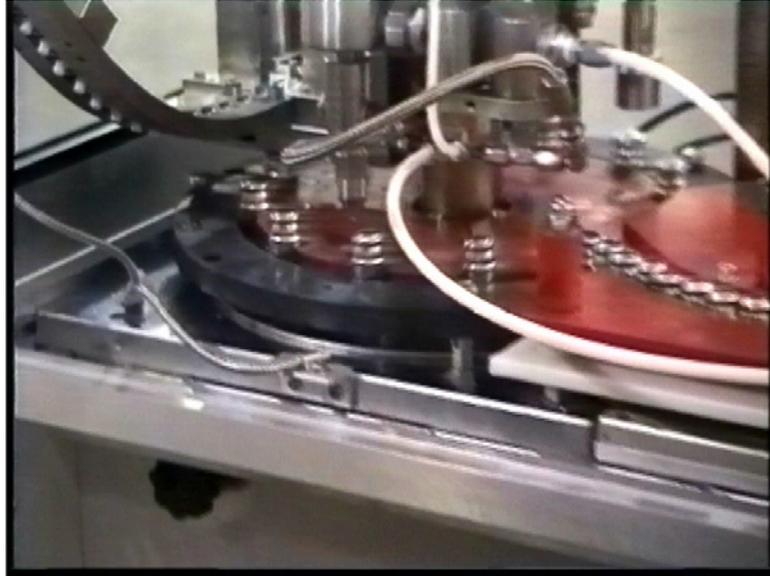
Two Stage CFC Filling

- Open Can Product Fill
- Place Valve
- Crimp Valve
- Pressure Fill Propellant



2 Typical pMDI Formulations and Filling Techniques

CFC MDI Filling on DH Micromat

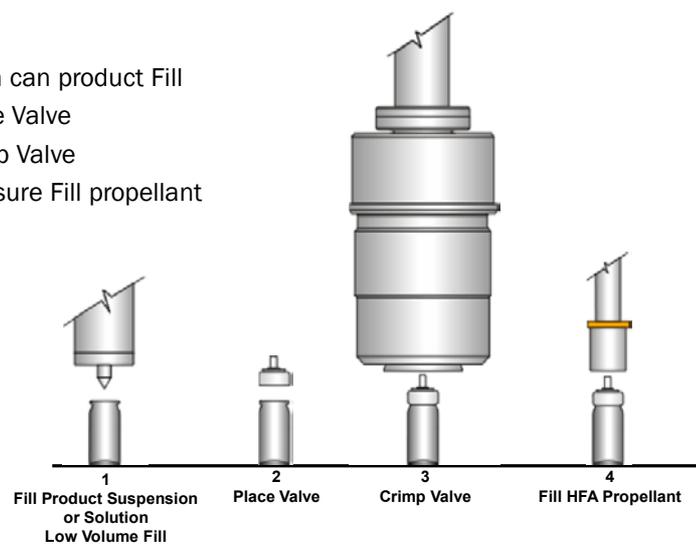


2 Typical pMDI Formulations and Filling Techniques

Two Stage HFA Filling

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- Open can product Fill
- Place Valve
- Crimp Valve
- Pressure Fill propellant

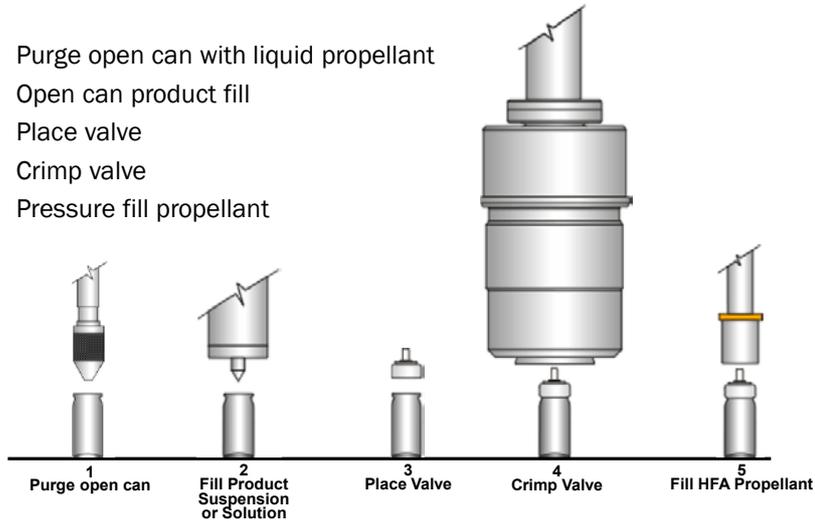


2 Typical pMDI Formulations and Filling Techniques

Two Stage HFA Filling (if purging required)

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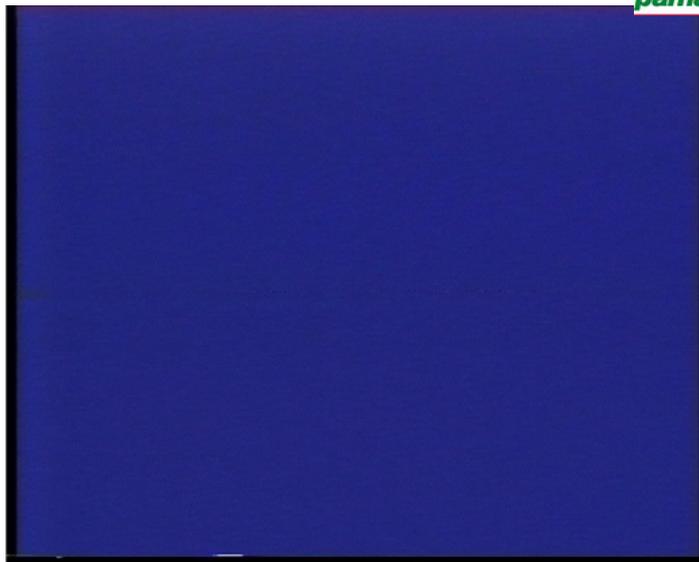
- Purge open can with liquid propellant
- Open can product fill
- Place valve
- Crimp valve
- Pressure fill propellant



2 Typical pMDI Formulations and Filling Techniques

Two stage HFA Filling on DH Macromat

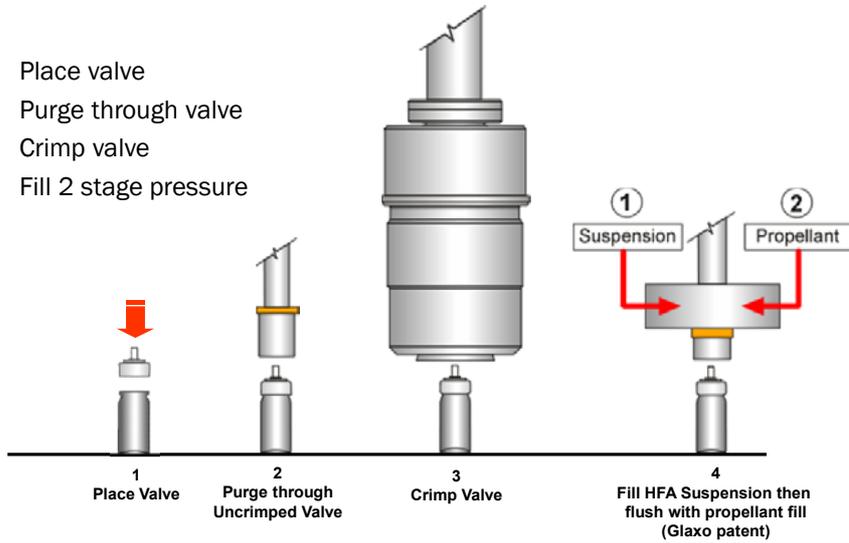
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2 Typical pMDI Formulations and Filling Techniques GSK Patented Dual Filling

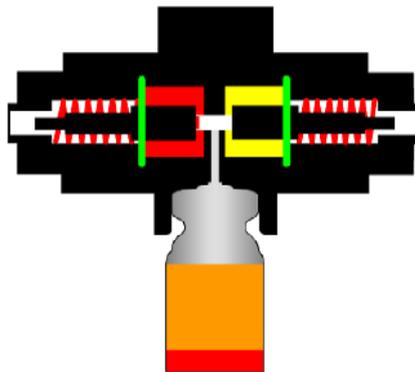
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- Place valve
- Purge through valve
- Crimp valve
- Fill 2 stage pressure



2 Typical pMDI Formulations and Filling Techniques GSK Patented Dual Filling Nozzle

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2 Typical pMDI Formulations and Filling Techniques

Dual Filling on DH MacroElcomat

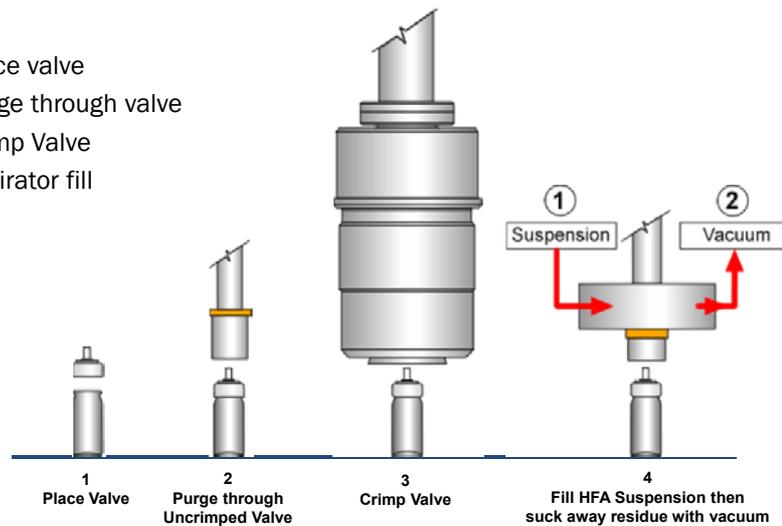


2 Typical pMDI Formulations and Filling Techniques

Single Stage HFA Filling (trough valve purge)

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- Place valve
- Purge through valve
- Crimp Valve
- Aspirator fill

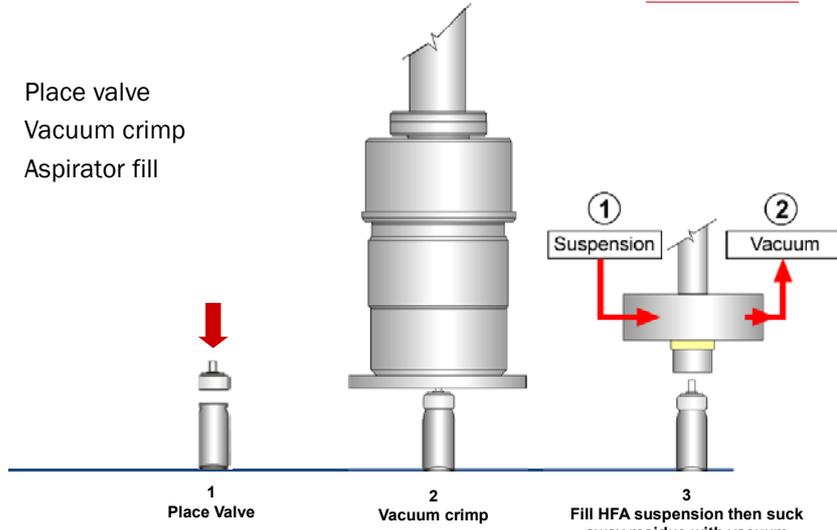


2 Typical pMDI Formulations and Filling Techniques

Single Stage HFA Filling (vacuum purge)

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- Place valve
- Vacuum crimp
- Aspirator fill

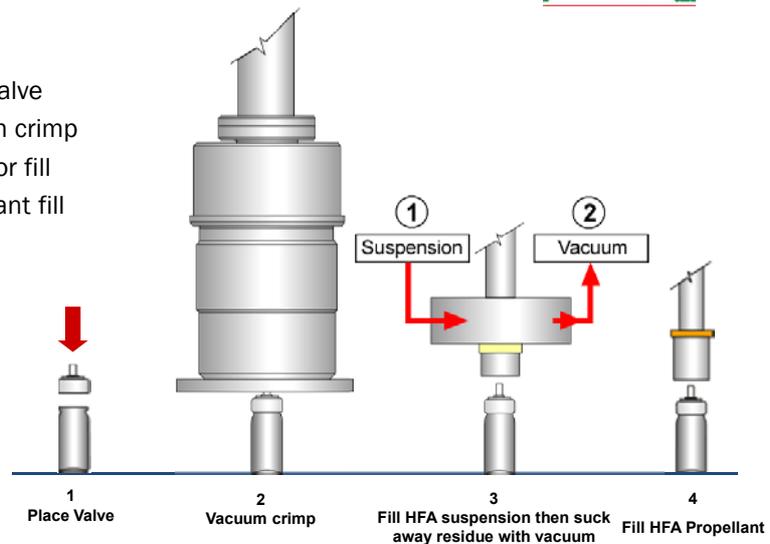


2 Typical pMDI Formulations and Filling Techniques

Two Stage HFA Pressure Filling (vacuum purge)

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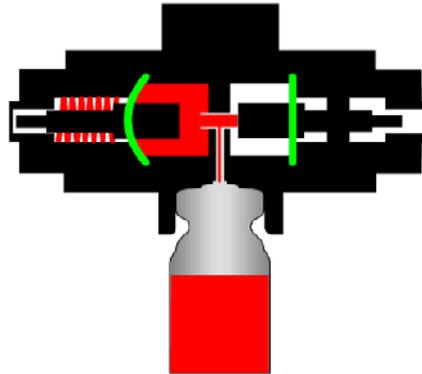
- Place valve
- Vacuum crimp
- Aspirator fill
- Propellant fill



2 Typical pMDI Formulations and Filling Techniques

Single Stage Filling – Aspirator Nozzle

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2 Typical pMDI Formulations and Filling Techniques

Single Stage HFA Filling on DH Macromat



3

Mixing and Process Equipment

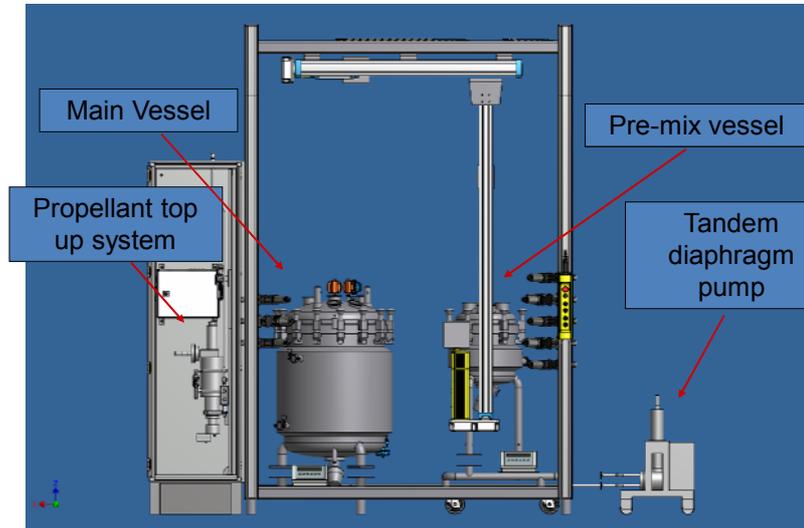
3 Mixing and Process Equipment

HFA Suspension Manufacturing – Single Stage Filling

- Manufacturing and filling carried out at room temperature
- Product kept under pressure at 20°C
- 134a pressure at 20°C – 5.7 bar
- 227 pressure at 20°C – 3.9 bar
- Product suspension pumped to filling heads at 10 bar pressure to keep it in its liquid state
- Recirculation path back to mixing vessel.

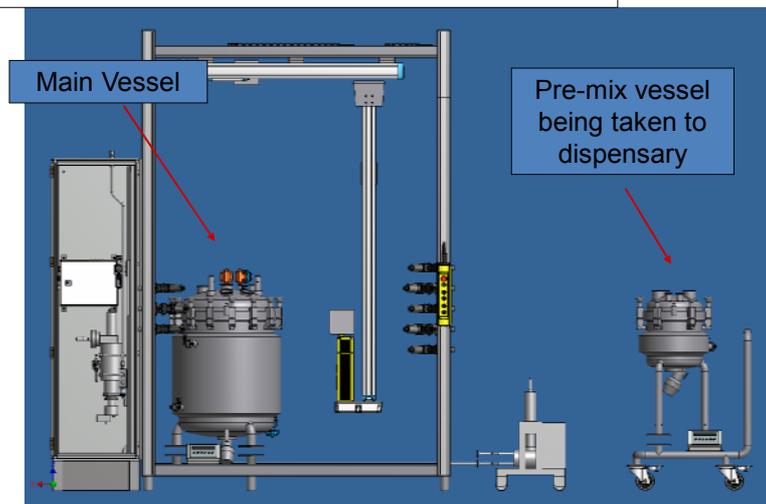
3 Mixing and Process Equipment
HFA Suspension Manufacturing

Typical HFA Suspension Manufacturing System



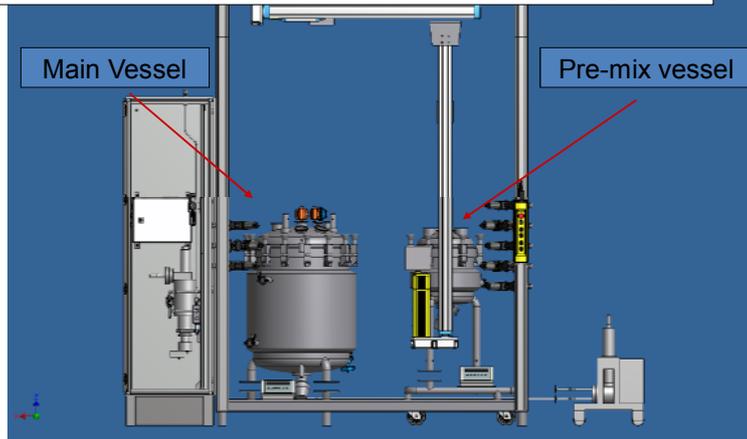
3 Mixing and Process Equipment
HFA Suspension Manufacturing

Mobile pre-mix vessel taken to dispensary to add product/formulation



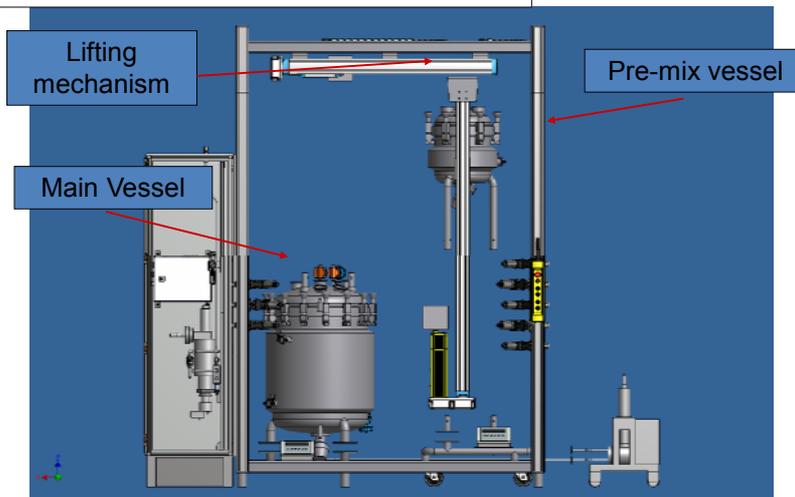
HFA Suspension Manufacturing

Pre-mix vessel connect back to mixing skid
Product/formulation mixed with homogeniser/agitator
depending on manufacturing method
Propellant can be added to concentration prior to mixing



HFA Suspension Manufacturing

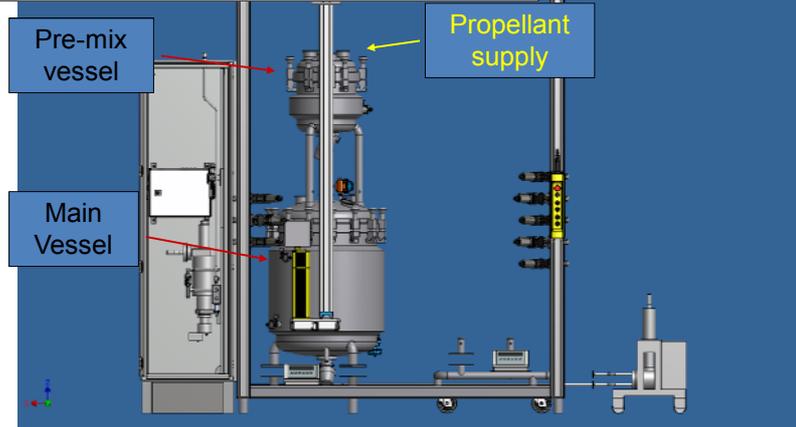
Mobile pre-mix vessel connected to hoist and
elevated above main vessel



HFA Suspension Manufacturing

Pre-mix vessel docked on top of main vessel
Propellant supply connected to pre-mix vessel
Hose connected between pre-mix vessel and main vessel

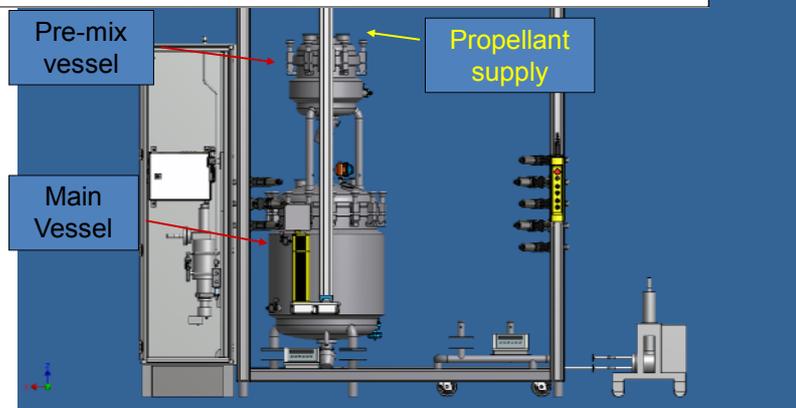
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HFA Suspension Manufacturing

Contents of pre-mix vessel emptied into main vessel
Propellant charged to main vessel through pre-mix vessel
rinsing all product/formulation out of pre-mix vessel
Product kept in suspension by agitator in main vessel

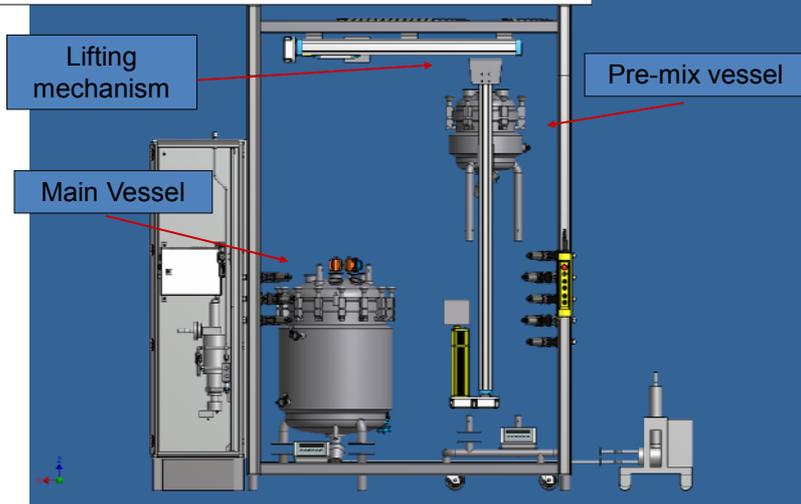
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HFA Suspension Manufacturing

Pre-mix vessel connected to hoist and removed from main vessel

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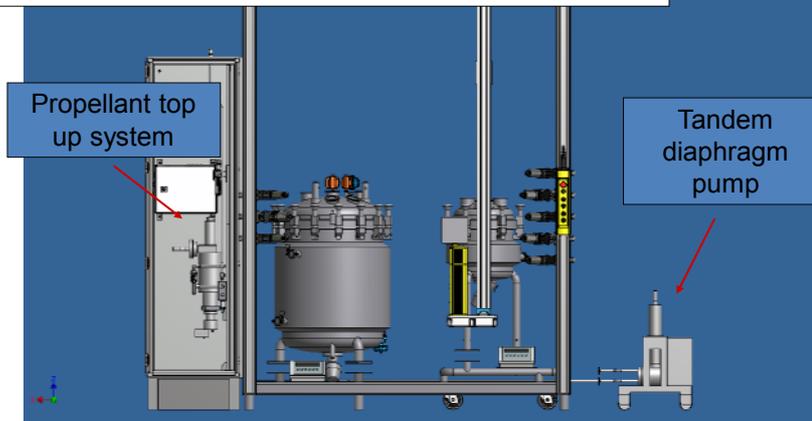


HFA Suspension Manufacturing

Tandem diaphragm pump pumps HFA suspension in recirculation to filling machine

Propellant top up system replaces propellant in main vessel as level descends

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