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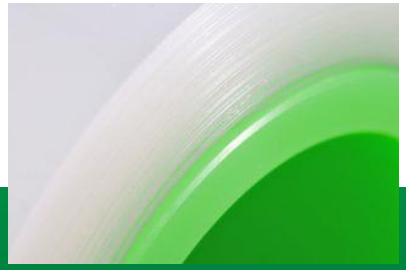
Production Process and Qualification of a Pharmaceutical Film



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PHARMACEUTICAL PACKAGING SOLUTIONS

Agenda

- Production process
- Customer requirements
- Raw material requirements
- Film requirements
- Conclusion

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Production Process

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Production Process

Multi-Layer blown film & tube extrusion

Extrusion

Lay-Flat and cutting unit

Controls

Winding

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Customer Product Requirements

Application

Drug compatibility

Sterilisation method

Barrier properties

Technical requirements

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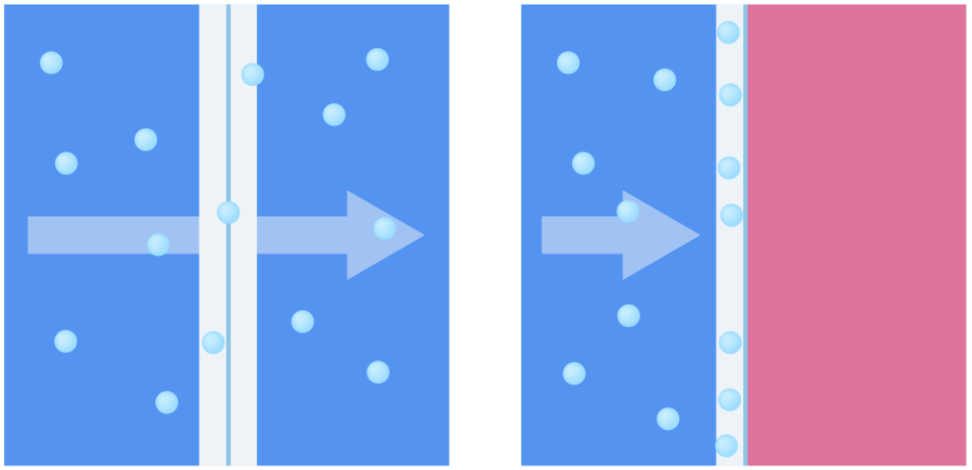
Customer Product Requirements

Drug compatibility

Extractables & Leachables

Film Additivation

Low Particle Level



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Customer Product Requirements

Application

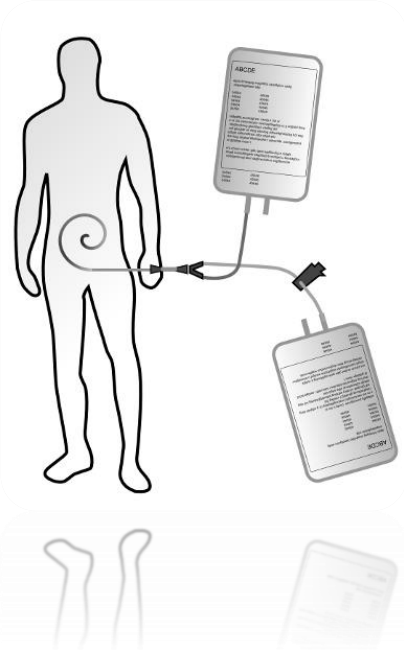
IV Therapies

Dialysis bags

Multi-Chamber bags

Drug delivery systems

Nutrition / TPN



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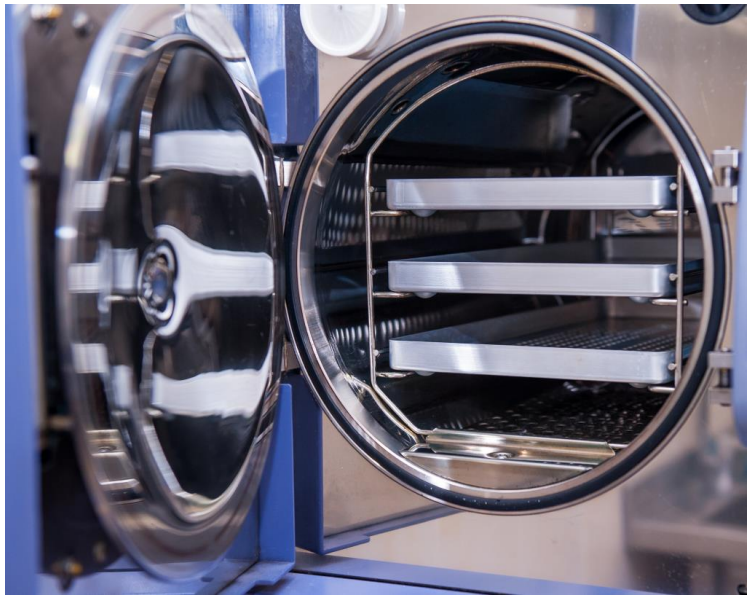
Customer Product Requirements

Sterilisation methods

Steam Sterilisation +121°C

Irradiation

ETO-Gas



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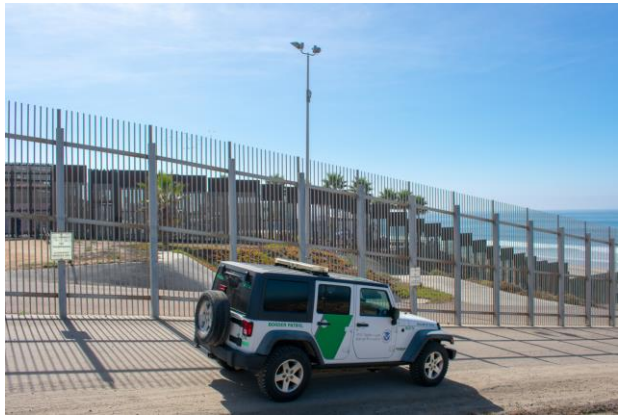
Customer Product Requirements

Barrier properties

Oxygen permeability

Nitrogen permeability



Water vapour transmission

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Customer Product Requirements

Technical requirements

Line processing

Resistance (Impact & Drop)

Softness

Drainability / Collapsibility

Reduction of packaging waste

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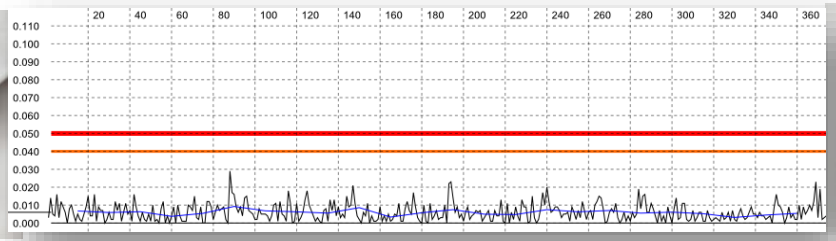
Raw Material Requirements

- Technical & Processing
- Toxicological and Chemical
- Regulatory



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Film Requirements

United States Pharmacopoeia

Examples:

- USP <661> Plastic Packaging Systems and Their Materials of Construction
- USP <661.1> Plastic Materials of Construction

European Pharmacopoeia

Examples:

- 3.1.3. Polyolefins
- 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations

Example:

- CFDA Standard for “Imported Pharmaceutical Packaging”

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Film Requirements

- Chemical tests in comparison

USP <661>	USP <661.1>	EP 3.1.6
Identification	Identification	Identification
Heavy metals	Absorbance	Appearance of Solution
Non-volatile residue	Acidity /Alkalinity	Absorbance
Buffering capacity	TOC	Acidity /Alkalinity
	Extractable metals	Reducing Substances
	Antioxidants	Extractable Metals
	Amides and Stearates	Extractable Heavy Metals
		Sulphated Ash
		Antioxidants
		Amides and Stearates

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Film Requirements

- Examples for Biological tests

Biological Reactivity	USP	ISO 10993 Biological evaluation of Medical devices
In vitro	<85> Endotoxins <87> Cytotoxicity	ISO 10993-4 (Hemocompatibility) ISO 10993-5 (Cytotoxicity) ISO 10993-11 (Systemic toxicity)
In vivo	<88> „Class VI“ Systemic Toxicity Intracutaneous Test Implantation Test	ISO10993-6 (Implantation) ISO 10993-10 (Sensitization and Irritation) ISO 10993-11 (Systemic toxicity)

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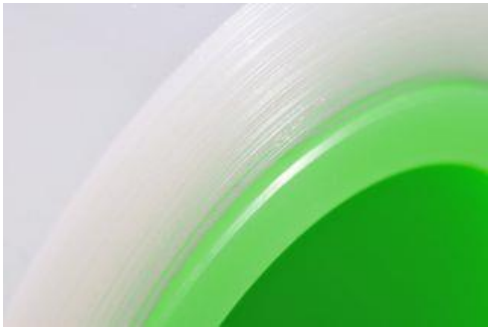
Film Requirements

ISO 15747

- Plastic containers for intravenous injections
- Chemical tests
- Physical tests
- Biological tests



ICH Q3D

- Elemental impurities

Drug Master Files

- US: FDA DMF Type III Packaging Material
- Letters of authorization

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Conclusion

- Consideration of all aspects and requirements not only limited to primary bag (incl. tube, ports, printing, overwrap etc.)
- Today a bag must offer more than being more robust than a glass bottle
- Smart flexible bags can differentiate from competitor product

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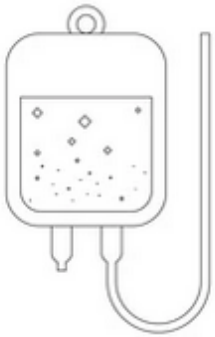
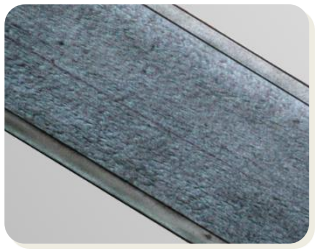
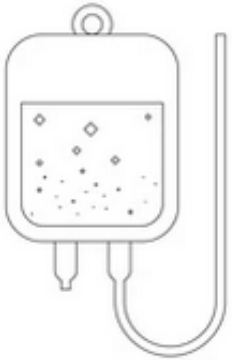
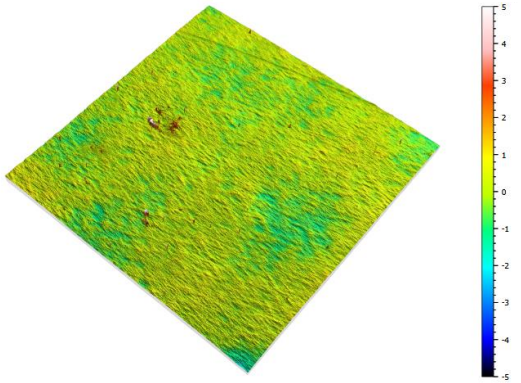
Conclusion

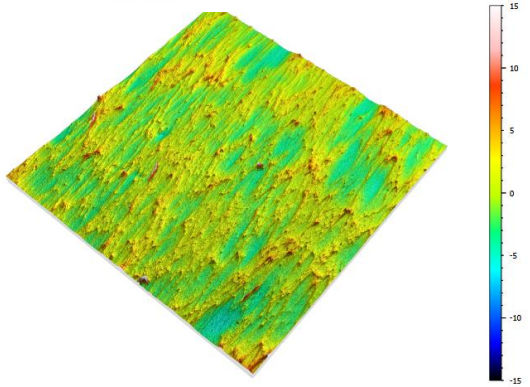
- Analytical comparison & methods can show the difference beyond visual appearance











PolyCine Overview…

- ✓ Tailor-made and standard products for every kind of pharmaceutical solution
- ✓ Continuous growth and investment for development and increase of capacity
- ✓ PolyCine® fulfils all necessary regulations and standards
- ✓ Pharmaceutical primary packaging expertise

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