Newform™

MEDICAL GRADE LDPE BAGS

In the biopharmaceutical and medical industries, visible and subvisible contaminants from packaging materials not only reduce process efficiency by generating unacceptable waste percentages, but they can also constitute real chemical and biological hazards when delivering parenteral drugs to patients. Low particle levels should be guaranteed by the product supplier, and product integrity must be 100% guaranteed by the packaging itself.

Newform™ bags are medical-grade, low-density-polyethylene (LDPE) bags, ideal for packaging and gamma irradiation of powders, products and components.

Fig 1. Newform medical grade LDPE bags.

Features

- In-house extrusion of LDPE film using certified and virgin resin without any additives
- Winding, conversion, and packaging in certified ISO Class 5 cleanrooms (at rest)
- Flexibility in customizing sizes, thicknesses, and shapes (bags, tubing, sheets, film)
- Dye-penetration test (methylene blue) to show packaging integrity
- cGMP focused manufacturing
- Material drug master file on resin is registered with FDA

Benefits

- Low visible and subvisible contaminant level
- Low bioburden and endotoxin level
- Low leachables and extractables level
- Certified cleanliness level
- Improved process efficiency
- Gamma-sterilizable up to 50 kGy
- Pre-sterilized bags available upon request (gamma-irradiated between 25 to 50 kGy, certified)

Applications

Packaging and when needed gamma sterilization of:

- Stoppers, caps, and closures
- Vials and containers
- API, medical powders, buffers, media
- Filters
- Medical devices
- Cleanroom garments
- Syringe components

Quality

- Cleanliness level 100 according to IEST-STD-CC1246D standard
- LDPE film is Animal-Derived-Component-Free (ADCF)

Compliant to:

- FDA Title 21 CFR 177.1520 'olefin polymers'
- EU Commission Directive 10/2011 (food contact approval) USP <87> biological reactivity test *in vitro*
- USP <88> biological reactivity test *in vivo*, class VI
- USP <661> physicochemical test – plastics
- EP monograph 3.1.3 'polyolefins'
- EP monograph 3.1.4 'polyethylene without additives for containers for parenteral and ophthalmic preparation'
- EP monograph 3.2.2 plastic containers and closures for pharmaceutical use'

Ordering information

Inner bag size	Product code
150 mm W × 200 mm L (7.9 in. L × 5.9 in. W)	UP1F10-0000-0001
200 mm W × 300 mm L (11.8 in. L × 7.9 in. W)	UP1F10-0000-0002
300 mm W × 450 mm L (17.7 in. L × 11.8 in. W)	UP1F10-0000-0003
450 mm W × 600 mm L (23.6 in. L × 17.7 in. W)	UP1F10-0000-0004
600 mm W × 800 mm L (31.5 in. L × 23.6 in. W)	UP1F10-0000-0005

Width (W) equals opening of the bag

Thickness: 100 µm

All bags with the exception of UP1F10-0000-0005 are double packed per 100 pieces. UP1F10-0000-0005 are double packed per 50 pieces.

A COC (certificate of conformity) is included with each delivery

Customization is available on request and can include:

- Other sizes
- Other thicknesses (from 75 up to 200 µm)
- Gamma irradiation (25 to 50 kGy)
- Other shapes (sheets, sleeves, tubing, film...)

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For local office contact information, visit cytiva.com/contact
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