REMAFIN™ EP is a range of PE and PP based masterbatches designed for protecting oral, topical, parenteral, ophthalmic and nasal pharmaceuticals by opacifying primary and secondary pharmaceutical packaging. High loading and optimized dispersion of pigments provide a cost-effective way to safeguard light transmission requirements while supporting regulatory requirements for pharmaceutical packaging materials.

KEY CHARACTERISTICS
- Manufactured under change control principles beyond CAS number (similar level as MEVOPUR concentrates), reducing risk of change
- Free from animal-derived substances and phthalates
- Suitable for blown film, injection molding, blow molding and extrusion

REGULATORY SUPPORT
- Raw materials tested to:
  - ISO 10993-1
  - USP chapters <87>, <88> including Class VI, a requirement for ophthalmic and nasal drugs
  - European Pharmacopeia 3.1.3/3.1.5 (polyolefin)
  - USP <661.1> (polyethylene)
  - ICH Q3D elemental impurities
  - USP <671> and USP <661.2> light transmission
- Registered Drug Master File (Type III)
- Food contact compliance established with FDA/EU*

* FDA/EU compliance information available upon request
# REMAFIN™ EP WHITE PORTFOLIO

<table>
<thead>
<tr>
<th>CARRIER MATERIAL</th>
<th>PIGMENT CONTENT/TYPE</th>
<th>LIGHT FASTNESS</th>
<th>THERMAL STABILITY</th>
<th>PRODUCT CODE</th>
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<tbody>
<tr>
<td>HDPE</td>
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(a) medical devices categorized by either the United States Food and Drug Administration (FDA) or the International Standards Organization (ISO) as an “implant” device; or “Permanent” as defined under US Pharmacopoeia (USP) or ISO standards; or
(b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
(c) medical devices for “Long Term” use as defined in EU Directive 90/385/EEC as amended.

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(2) “plastic” (cosmetic or reconstructive) surgery use;
(3) reproductive implants or any birth control device; or
(4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.

It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, and with all applicable laws and regulations.