

# 3M Purification

## Betapure™ NT-P Series

### Pharmaceutical Grade Filters



#### The Next Generation in Depth Filter Technology

Enhanced flow. Lower pressure drop. Extended service life and lower total filtration costs... these are the benefits of Betapure™ NT-P Series filter cartridges & capsules, the latest advance in depth filtration technology. The all polypropylene filter is constructed using a process that utilizes flow enhancing filter media and an innovative flow pattern. The result is an absolute-rated filter with vastly superior life that provides more cost effective filtration than conventional polypropylene depth filters. Betapure™ NT-P Series filter cartridges - the new leader in filtration performance.

#### Betapure™ NT-P Series Filter Construction

Betapure™ NT-P Series cartridges and capsules are designed to provide significantly superior service life while maintaining a consistent filtration efficiency. They achieve this through an innovative design that allows uniform distribution of fluid flow and contaminant throughout the entire depth of the filter. Betapure™ NT-P Series filter construction combines a unique polypropylene media with fluid distribution netting to form multiple layers. Critically positioned media flow channels allow greater movement of fluid from layer to layer. Three distinct media sections, made from multiple media/netting layers, are combined to form the filter cartridge (see Figure 1).

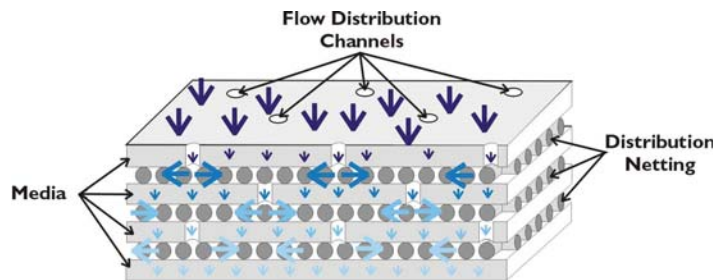


Figure 1: Betapure NT-P Series Media Sections. Note that the actual filter sections contain multiple layers of media.

### Applications

|  |   |
|--|---|
| <b>Pharmaceutical</b>                  | Large and Small Volume, Parenterals (LVP/SVP), Diagnostic Reagents & Buffers, Fine Chemical/Bulk Pharmaceutical, Chemical (BPC), Orals & Topicals, Antibiotics, Vial & Stopper Washers, Ophthalmic, Solvent streams |
| <b>Biologicals &amp; Bioprocessing</b> | Plasma Fractionation, Bacterial Fermentation, Vaccines Downstream Protein Purification, Animal Sera & Media Feeds, Pre-column clarification (protection), Mammalian Cell Culture, TFF Protection                    |
| <b>Facilities &amp; Plant Services</b> | Deionized Water, Plant Services Water-for-Injection Systems (WFI), Air/Gas Pre-filtration, Solvent Streams  |

### Features & Benefits

#### Superior Service Life.

- As much as 4 times greater dirt holding capacity than competitive filters.

#### All polypropylene depth filter cartridges

- Allow for broad chemical and temperature compatibility

#### Ratings from 0.5 to 70 micron

- Suit a wide range of applications

#### Absolute-Rated Performance

- Allows for consistent filtration quality

Provided with Certificate of Quality documenting pharmaceutical testing & lot release criteria.





Cut-away of the Betapure™ NT-P Series filter cartridge showing the three sections of media layers

The outer and middle sections contain multiple layers of interleaved filter media and fluid distribution netting. Within each media layer a portion of the fluid travels through the media while the balance of the fluid is delivered directly to the next distribution layer through the flow channels. The fluid distribution netting provides longitudinal and latitudinal flow paths to evenly distribute fluid flow across the surface of each successive media layer.

### The Difference is Performance

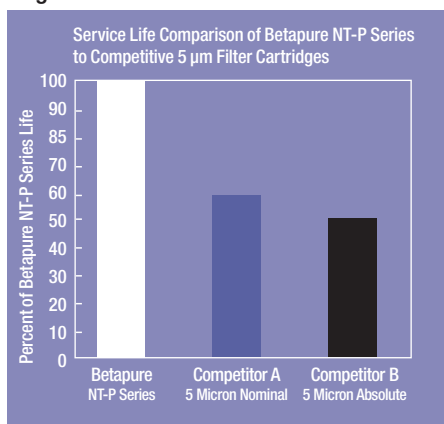
Flow channels appear in the outer and middle sections of the filter matrix, as seen in the cartridge cut-away. The size, number, and location of the flow channels combined with the fluid distribution netting ensure that a uniform amount of contaminant is distributed to each layer within these two sections, while maintaining a consistent flow.

The number of media flow channels decrease from the outer to middle sections to ensure even contaminant loading throughout the entire filter matrix. Extensive laboratory testing has demonstrated that 3M Purification has developed the optimal filter cartridge design.

The inner section, supported by a rigid polypropylene core and equal to approximately one third of the filter's depth, contains no flow channels and is the final qualifying section ensuring absolute rated performance.

The even distribution of contaminated fluid throughout the depth of the cartridge is the key to the Betapure™ NT-P pharmaceutical grade filter's exceptionally long service life, low pressure drops, and increased cost effectiveness.

**Graph 1: Betapure NT-P Series filters deliver longer service life**



### The Result

#### Superior Filter Service Life

Extensive testing has demonstrated that competitive filters of equivalent removal ratings subjected to the same contaminant load plug more quickly than Betapure™ NT-P Series filters. The result is significantly shorter service life, and unpredictable filtration efficiencies. In this case, Betapure™ NT-P Series 5 micron filters provide a service life improvement of up to 2 times greater than competitive products. (Graph 1)

#### Lower Pressure Drop

The unique design and construction of the Betapure™ NT-P Series cartridge allows for significantly lower pressure drops compared to equivalently rated polypropylene depth filters. Based on published data, a 5 micron Betapure™ NT-P Series filter system with a given flow would use up to 50% fewer cartridges than a 5 micron Pall® Profile. To underscore the Betapure™ NT-P Series filter cost benefit, use the example in Table 1 as a guideline.

**Table 1: Comparison of 5 Micron\* Filters in a 415 lpm System**

|   | Betapure NT-P Series Filters | Pall Profile II (AB Style) |
|---|------------------------------|----------------------------|
| Flow (lpm) / 10" cartridge @ 1 psid             | 11.7                         | 5.0                        |
| Number of filters for a 415 lpm flow rate       | 12 / 30" cartridges          | 28 / 30" cartridges        |
| * Based on the manufacturer's published rating. |                              |                            |

For the same initial cartridge differential pressure, a 415 lpm system using Betapure™ NT-P Series 5 micron filters require significantly fewer, less than half, cartridges. This results in lower capital investment for the filter housing and fewer cartridges to purchase.

### The Confidence of Consistency

Betapure™ NT-P Series filters utilize advanced design and construction to achieve a level of filtration consistency unattainable by competitive filters. Combined with an exceptionally long service life, the Betapure™ NT-P Series filter's consistent performance, as illustrated by comparative Beta-Ratio vs. Differential Pressure (Graph 2), provides predictable results throughout the filter's usable life. Filters A, B, and C show a degradation in the Beta-Ratio as the differential pressure increases. These filters exhibit a pattern of either unloading previously held particles or a loss of filtration efficiency. The result of this inconsistent performance is a reduction in finished product quality, product yield, and an increase in total filtration cost.

## Absolute Betapure™ NT-P Series

Consistent filtration performance, time after time, from start to finish - the goal of every filter user, the solution provided by Betapure™ NT-P Series filters. Absolute removal ratings for Betapure™ NT-P Series filters are determined using a filter performance test developed by 3M Purification to comply with the general procedures outlined in ASTM STP 975. 3M Purification Inc. defines absolute rating as the particle size (x) providing an initial Beta Ratio (Bx) = 1000. At this Beta Ratio, the removal efficiency is equal to 99.9%. Betapure™ NT-P Series filter ratings are specified in Table 2.

## Your Benefit - Total Filtration Cost Reduction

The Betapure™ NT-P Series filter's performance and superior life advantage allows direct cost savings by reducing the number of filters used. In addition, the resulting reduction in filter change-out frequency decreases direct labour and filter disposal costs. Betapure™ NT-P Series filter cartridges - providing performance and value.

## Pharmaceutical Testing and Optimization

Betapure™ NT-P Series filters undergo extensive quality testing prior to release, assuring safe and consistent performance in critical applications. Betapure™ NT-P Series filter cartridges and capsules are manufactured and tested in accordance with an ISO 9001:2008 Quality Management Systems Standard. Betapure™ NT-P Series filter cartridges and capsules are supplied with a Certificate of Quality for traceability and documentation control. Filter cartridges and capsules are marked with a unique lot number to provide full traceability through manufacturing records of raw material components. A Regulatory Support File (70-0201-8826-7) is available for ease of compliance to regulatory requirements. Specific biosafety and effluent quality tests include the following:

- Meets USP Biological Reactivity, In Vivo, for Class VI 121°C Plastics.
- Non-pyrogenic per USP Bacterial Endotoxins Test (<0.25 EU/ml).
- Meets oxidizable substances and pH test per USP Purified Water.
- Cleanliness - Meets USP Particulates in Injectables limits, microscopic examination of effluent particle counts serve to conform with requirements for non-fiber releasing filter per CFR 21.
- Conductivity & Total Organic Carbon (TOC) - Meets requirements of USP Purified Water after flushing.

## Betapure™ NT-P Series Filter Applications

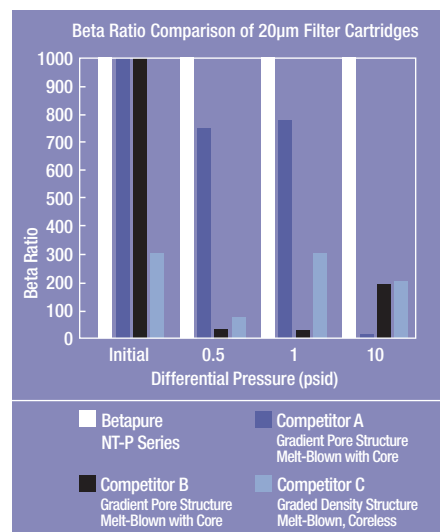
Increasing emphasis on pharmaceutical process economies and end product purity are driving today's pharmaceutical and biotechnology industries to high technology filtration products that offer tangible performance benefits. Betapure™ NT-P Series filters provide high throughput, enabling reduced filter change-outs, longer on-stream service life, and significant improvements in overall process economies.

## Pharmaceutical

Betapure™ NT-P Series filters are ideally suited for general clarifying and prefiltration applications such as solvent streams, prefiltration of fermentation additives, and parenteral prefiltration. Specific pharmaceutical process applications for Betapure™ NT-P Series filters include:

- Large and Small Volume Parenterals (LVP/SVP)
- Fine Chemical/Bulk Pharmaceutical Chemical (BPC)
- Antibiotics
- Ophthalmic
- Diagnostic Reagents & Buffers
- Orals & Topicals
- Vial & Stopper Washers
- Solvent Streams

**Graph 2: Beta Ratios demonstrate the Betapure NT-P Series filter's ability to perform consistently throughout its life**



**Table 2: Betapure NT-P Series Filter Ratings**

| Grade Designation | Absolute Rating (Micron) |
|-------------------|--------------------------|
| P005              | 0.5*                     |
| P010              | 1                        |
| P020              | 2                        |
| P030              | 3                        |
| P050              | 5                        |
| P100              | 10                       |
| P200              | 20                       |
| P300              | 30                       |
| P400              | 40                       |
| P500              | 50                       |
| P700              | 70                       |

\* extrapolated



# Betapure™ NT-P Series Filter Applications

## Biologicals & Bioprocessing

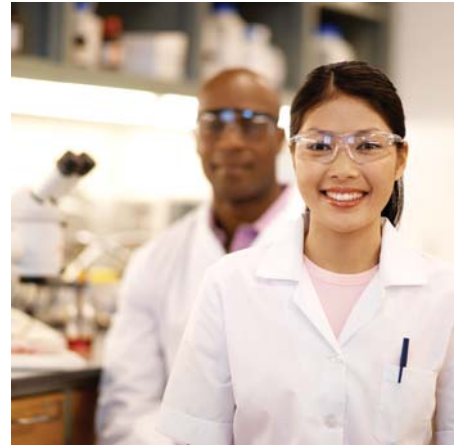
In biological and bioprocess production, Betapure™ NT-P Series filters provide high capacity clarification of turbid biological solutions, including animal sera, vaccine broths, and plasma fractions. Effective prefiltration with Betapure™ NT-P Series cartridges can avoid costly oversized final filter systems. Specific biological and bioprocess applications for Betapure™ NT-P Series filters include:

- Plasma Fractionation
- Vaccines
- Animal Sera & Media Feeds
- Mammalian Cell Culture
- Bacterial Fermentation
- Downstream Protein Purification
- Pre-Column Clarification (Protection)
- TFF Protection

## Facilities & Plant Services

The Betapure™ NT-P Series filter's unique construction provides longer service life in general water filtration service, and in other continuous use applications. Polypropylene depth media offers high contaminant capacity and low extractables in demanding solvent filtration applications:

- Deionized Water
- Water-for-Injection Systems (WFI)
- Air/Gas Prefiltration
- Solvent Streams

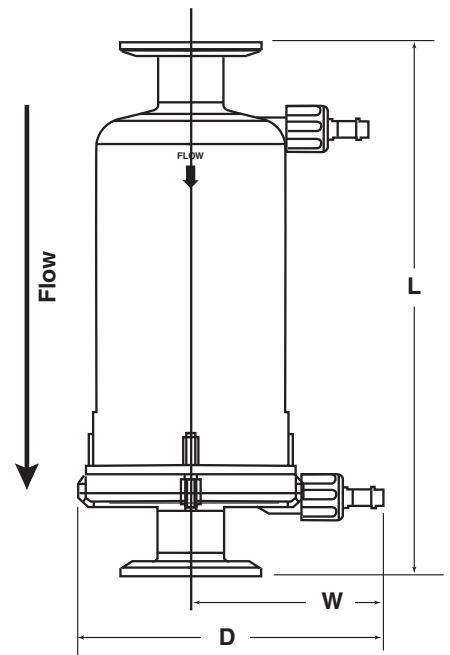


**Table 3: Betapure NT-P Series Filter Specifications**

| Materials of Construction, Cartridge & Capsules*          |   |
|---|---|
| Filter Media, Netting, Core, End Connector & Capsule Body | Polypropylene   |
| Optional Support Ring                                     | Stainless Steel or Polysulfone                        |
| Gaskets & O-ring Options                                  | See ordering guide                                    |
| Operating Conditions, Cartridges                          |   |
| Maximum Operating Temperature                             | 82°C  |
| Maximum Differential Pressure                             | 3.4 bar at 30°C<br>2.0 bar at 55°C<br>1.0 bar at 82°C |
| Recommended Change-Out Differential Pressure              | 2.4 bar at 30°C                                       |
| <i>In-situ</i> steam sterilization**                      | Maximum ten (10) 1 hour cycles at 126°C               |
| Operating Conditions, Capsules                            |   |
| Maximum Operating Pressure                                | 5.2 bar at 40°C                                       |
| Maximum Forward Differential Pressure                     | 35 psid at 2.4 bar at 40°C                            |
| Recommended Change-out Differential Pressure              | 35 psid at 2.4 bar at 40°C                            |
| Sterilization   | DO NOT <i>in-situ</i> STEAM                           |
| Autoclave   | 5 cycles maximum for 30 minutes at 126°C              |
| Cartridge Dimensions                                      |   |
| Inside Diameter   | 1 3/32" nominal                                       |
| Outside Diameter  | 2 1/2" nominal  |
| Available Lengths   | 2.5, 5, 10, 20, 30, and 40 inches                     |

| Nominal Capsule Dimensions |                   |                                  |       |       |       |       |
|----------------------------|-------------------|----------------------------------|-------|-------|-------|-------|
|                            | Nominal Length*** | With End Connections*** (inches) |       |       |       |       |
|                            |                   | A                                | B     | C     | D     | E     |
| Length (L)                 | 01                | 5                                | 5 1/2 | 5     | 5     | 5 1/4 |
|                            | 02                | 7 1/2                            | 8     | 7 1/2 | 7 1/2 | 7 3/4 |
| Diameter (D)               | 01                | 3                                |       |       |       |       |
|                            | 02                |                                  |       |       |       |       |
| Width to Vent (W)          | 01                | 2 3/4                            |       |       |       |       |
|                            | 02                |                                  |       |       |       |       |

\*\*\* see Ordering Guide



\* All materials are FDA compliant per CFR 21

\*\* For cartridges with support ring options (1 or 2) only. Capsules cannot be steam sterilized.



### Cartridge Flow Rates

Flow vs. differential pressure in water is calculated for each Betapure™ NT-P Series filter grade using the formula below. Detailed information for calculating flows for fluids with other viscosities is located in the following table. Use the formula in conjunction with the values from columns 3 or 4 in the table. The specific pressure drop values may be effectively used when three of the four variables (viscosity, flow, differential pressure, and cartridge grade) are set.

The specific aqueous pressure drop at ambient temperature is for a single length equivalent (10") cartridge. For cartridge lengths OTHER than 10", divide the total flow by the number of equivalent lengths. For liquids other than water, multiply the specific pressure drop value provided in the table by the viscosity in centipoise.

$$\Delta p \text{ mbar} = \frac{\text{Clean (Total System gpm [lpm]) (Viscosity in Cp) (Value From Table)}}{\text{(Number of Equivalent Single Length Cartridges in Housing)}}$$

Table 4: Betapure NT-P Series Cartridge Flow Rates

| Grade | Absolute Rating (µm) | Specific Pressure Drop per 10" Cartridge |
|-------|----------------------|--|
|       |                      | mbar/lpm/cps                             |
| P005  | 0.5                  | 81.9                                     |
| P010  | 1                    | 45.5                                     |
| P020  | 2                    | 15.9                                     |
| P030  | 3                    | 8.0                                      |
| P050  | 5                    | 5.9                                      |
| P100  | 10                   | 2.5                                      |
| P200  | 20                   | 1.2                                      |
| P300  | 30                   | 0.91                                     |
| P400  | 40                   | 0.76                                     |
| P500  | 50                   | 0.52                                     |
| P700  | 70                   | 0.45                                     |

### Capsule Flow Rates

The following are typical water flow rates for Betapure™ NT-P Series capsules with 1 1/2" sanitary flange connections. Other end connections will affect maximum flow rates, see the following table. Consult factory representative for flow rates for other end connections.

### 3M Purification Filter Housings

3M Purification provides a wide array of filter housings designed to meet the sanitary requirements of the pharmaceutical and biological manufacturing industries. Surface finishes of all sanitary housings are mirror polished 316L stainless steel, providing a high quality, low adhesion surface for full cleanability.

Table 6: Betapure NT-P Series Housing Specifications

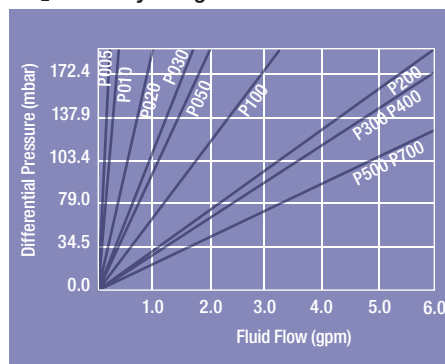
| Model            | Description                | Cartridge Style   | Number of Cartridges | Length of Cartridge | Maximum Flow Rate* | Maximum Pressure @ Temperature |
|------------------|----------------------------|-------------------|----------------------|---------------------|--------------------|--------------------------------|
| ZWB              | T-type with bolt closure   | SOE - 226 O-rings | 3, 5, 7, 12          | 10" to 40"          | 1,360 lpm          | 150 psi @ 200°F                |
| ZMS              | T-type with clamp closure  | SOE - 226 O-rings | 1                    | 10" to 40"          | 98 lpm             | 150 psi @ 200°F                |
| ZMS Mini-Housing | T-type with clamp closure  | SOE - 226 O-rings | 1                    | 2.5" or 5"          | 98 lpm             | 150 psi @ 200°F                |
| ZVS              | In-line with clamp closure | SOE - 226 O-rings | 1                    | 10" to 40"          | 98 lpm             | 150 psi @ 200°F                |

\* Flow rates are for housings only. Do not use to size an application. Actual process flow rates are determined by the recommended flow rates of the installed cartridge and other process conditions.

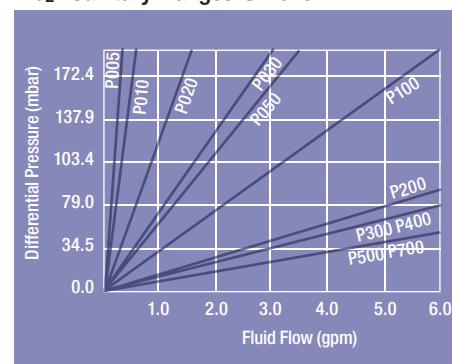
Table 5: Betapure NT-P Series Capsules - Maximum Recommended Flow by End Fitting

| End Fitting            | Housing Pressure Loss (psid) |
|------------------------|------------------------------|
| 1 1/2" Sanitary Flange | 1.00                         |
| 3/8" FNPT              | 1.00                         |
| 1/2" Hose Barb         | 1.50                         |
| 1/4" MNPT              | 2.40                         |
| Tapered Hose Barb      | 2.20                         |

Graph 3: Flow Rates for 2 1/2" capsules with 1 1/2" Sanitary Flanges @ 20°C



Graph 4: Flow Rates for 5" capsules with 1 1/2" Sanitary Flanges @ 20°C



100 mbar = 10 kPa  
1 gpm = 3.78 lpm

# Betapure™ NT-P Series Ordering Guide

| Cartridge Type            | Length   | Grade Code Rating (µm)   | Packaging Option | Support Ring Option                                   | End Modification  | Gasket/O-ring Material   |
|---------------------------|--|--|------------------|---|---|--|
| NT - Betapure NT-P Series | 03 - 2.5" *<br>06 - 5" *<br>10 - 10"<br>20 - 20"<br>30 - 30"<br>40 - 40" | P005 0.5<br>P010 1<br>P020 2<br>P030 3<br>P050 5<br>P100 10<br>P200 20<br>P300 30<br>P400 40<br>P500 50<br>P700 70 | Z - Standard     | 0 - None<br>1 - Polysulfone **<br>2 - Stainless Steel | B - 226 O-Ring with Spear<br>C - 222 O-Ring with Spear<br>F - 222 O-Ring with Flat Cap<br>J - 226 O-Ring with Flat Cap*** | A - Silicone<br>B - Fluorocarbon<br>C - EPR<br>D - Nitrile<br>K - PTFE Encapsulated Fluorocarbon |

\* 2.5" and 5" length cartridges available with "J" end modification only.

\*\* Optional polysulfone support ring is available for applications requiring complete cartridge disposal or incineration.

\*\*\* Available for 2.5" and 5" cartridge lengths only.

# Betapure™ NT-P Series Capsule Ordering Guide

| Cartridge Type            | Grade Code Rating (µm)   | Configuration | Nominal Length         | End Connection   | Vent O-Ring Option                          | Packaging Option                                |
|---------------------------|--|---------------|------------------------|--|---|---|
| NT - Betapure NT-P Series | P005 0.5<br>P010 1<br>P020 2<br>P030 3<br>P050 5<br>P100 10<br>P200 20<br>P300 30<br>P400 40<br>P500 50<br>P700 70 | C - Capsule   | 01 - 2 1/2"<br>02 - 5" | A - 1 1/2" Sanitary Flange<br>B - 1/2" (14 mm) Hose Barb<br>C - 1/4" MNPT<br>D - 3/8" FNPT<br>E - 1/4" - 5/16" - 3/8" Tempered Hose Barb | A - Silicone<br>B - Fluorocarbon<br>C - EPR | 01 - Single Pack<br>03 - 3 Pack<br>20 - 20 Pack |

### Important Notice

The information described in this literature is accurate to the best of our knowledge. A variety of factors, however, can affect the performance of the Product(s) in a particular application, some of which are uniquely within your knowledge and control. INFORMATION IS SUPPLIED UPON THE CONDITION THAT THE PERSONS RECEIVING THE SAME WILL MAKE THEIR OWN DETERMINATION AS TO ITS SUITABILITY FOR THEIR USE. IN NO EVENT WILL 3M PURIFICATION BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.

It is your responsibility to determine if additional testing or information is required and if this product is fit for a particular purpose and suitable in your specific application.

### Limitation of Liability

3M Purification Pty Limited will not be liable, to the extent permitted by law, for any loss or damage from the use of the Product(s), whether direct, indirect, special, or consequential, regardless of the legal theory asserted, included warranty, contract, negligence or strict liability.



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