Betapure[™] NT-P <u>Series</u>

The Next Generation in Pharmaceutical 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.

Features & Benefits

Superior Service Life.

As much as 4 times greater contaminant 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.



Applications

Pharmaceutical	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
Biologicals & Bioprocessing	Plasma Fractionation Bacterial Fermentation Vaccines Downstream Protein Purification Animal Sera & Media Feeds Pre-column clarification (protection) Mammalian Cell Culture TFF Protection
Facilities & Plant Services	Deionized Water Water-for-Injection Systems (WFI) Air/Gas Pre-filtration Solvent Streams





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

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



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 Inc. 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 Series pharmaceutical grade filter's exceptionally long service life, low pressure drops, and increased cost effectiveness.

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 110 GPM System

	Betapure NT-P Series Filters	Pall Profile II (AB Style)	
Flow (gpm) / 10" cartridge @ 1 psid	3.1	1.33	
Number of filters for a 110 gpm flow rate	12 / 30" cartridges	28 / 30" cartridges	
* Based on the manufacturer's published rating.			

For the same initial cartridge differential pressure, a 110 gpm 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 Inc. 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 (B_x) = 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 labor 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.

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

I-P Series harmaceutical Grade Filters

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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

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

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



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	180°F (82°C)
Maximum Differential Pressure	50 psid at 86°F (3.4 bar at 30°C) 30 psid at 131°F (2.0 bar at 55°C) 15 psid at 180°F (1.0 bar at 82°C)
Recommended Change-Out Differential Pressure	35 psid at 86°F (2.4 bar at 30°C)
In-situ steam sterilization**	Maximum ten (10) 1 hour cycles at 259°F (126°C)
Operating Conditions, Capsules	
Maximum Operating Pressure	75 psig (5.2 bar) at 104°F (40°C)
Maximum Forward Differential Pressure	35 psid at 104°F (2.4 bar at 40°C)
Recommended Change-out Differential Pressure	35 psid at 86°F (2.4 bar at 40°C)
Sterilization	DO NOT <i>in-situ</i> STEAM
Autoclave	5 cycles maximum for 30 minutes at 129°F (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 Langth***	With End Connections*** (inches)				
	Norminal Lengur	А	В	С	D	E
Longth (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
Diamotor (D)	01	3				
	02					
Width to Vant (M)	01	2 3/4				
	02					
*** see Ordering Gu	uide					



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VT-P Series Pharmaceutical Grade Filters

* 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.

Grade	Absolute Rating (µm)	Specific Pressure Drop per 10" Cartridge			
		psid/gpm/cps	mbar/lpm/cps		
P005	0.5	4.5	81.9		
P010	1	2.5	45.5		
P020	2	0.87	15.9		
P030	3	0.44	8.0		
P050	5	0.32	5.9		
P100	10	0.14	2.5		
P200	20	0.065	1.2		
P300	30	0.05	0.91		
P400	40	0.042	0.76		
P500	50	0.029	0.52		
P700	70	0.025	0.45		

Table 4: Betapure NT-P Series Cartridge Flow Rates

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

End Fitting	Maximum Recommended Flow Rate (gpm)	Housing Pressure Loss (psid)
1 1/2" Sanitary Flange	6.00	1.00
³ / ₈ " FNPT	6.00	1.00
¹ / ₂ " Hose Barb	3.00	1.50
¹ / ₄ " MNPT	1.50	2.40
Tapered Hose Barb	0.50	2.20

Clean	(Total System gpm [lpm]) (Viscosity in Cp) (Value From Table)
Δp =	
psi (mbar)	(Number of Equivalent Single Length Cartridges in Housing)

Capsule Flow Rates

The following are typical water flow rates for Betapure NT-P Series capsules with $1 \frac{1}{2}$ " 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 Inc. Filter Housings

3M Purification Inc. 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	Literature Reference
ZWB	T-type with bolt closure	SOE - 226 O-rings	3, 5, 7, 12	10" to 40"	360 gpm (1,360 lpm)	150 psi @ 200°F	LITZRH106
ZMS	T-type with clamp closure	SOE - 226 O-rings	1	10" to 40"	26 gpm (98 lpm)	150 psi @ 200°F	LITZRH104
ZMS Mini- Housing	T-type with clamp closure	SOE - 226 O-rings	1	2.5" or 5"	26 gpm (98 lpm)	150 psi @ 200°F	LITZRHZMS2
ZVS	In-line with clamp closure	SOE - 226 O-rings	1	10" to 40"	26 gpm (98 lpm)	150 psi @ 200°F	LITZRH104
* 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							

Graph 3: Flow Rates for 2 $^{1}\!/_{2}$ " capsules with 1 $^{1}\!/_{2}$ " Sanitary Flanges @ 20°C

H-P Series Pharmaceutical Grade Filters

Betapure



Graph 4: Flow Rates for 5" capsules with $1 \frac{1}{2}$ " Sanitary Flanges @ 20°C



Betapure[™] NT-P Series Cartridge Ordering Guide



 \ast 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



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 INC. BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.

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