

Medical Color Concentrates

Compounding Solutions' PurTone Rx color concentrates use ISO 10993 and/or FDA 21 CFR part 73 subpart D complement components, which are exempt from batch certification for use in medical devices. Our color concentrates suggested let down ratio is 4% for all of your injection molding and tubing extrusion applications. Our color concentrates can help you with:

- Quick prototyping – Use in conjunction with our wide range of natural or compounded materials, or take advantage of our dry blending services

- Product Identification – Enhance product or company brand with the correct color scheme.

- Safe Identification – Colors can be used to identify sizes of device, and make visual confirmation easier in the operation room.

Offered for use in:

- | | | | |
|---|---|--------------------------------------|--|
| -Polyamidas
• PA6
• PA11
• PA12
• PEBA | - Polyolefins
• PP
• LDPE
• LLDPE
• HDPE | - Styrenics
• SAN
• ANS | - Polycarbonates

- Thermoplastic Polyurethane |
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Colors available

Blues		Greens		Purples		Greys	
Pantone	Shade	Pantone	Shade	Pantone	Shade	Pantone	Shade
290C		3248C		2655C*		Cool Grey 4C	
2925C		3268C		Violet C*		Cool Grey 7C	
301C		3298C					
295C*				White*		Black**	

Ready for order?
Call you sales manager representatives and ask for your **Purtone rx + material selection + Pantone number.**

At Compounding Solutions, we make the ordering process the easiest way for you.

Low minimum quantities of 1lb, 5lb, & 10lbs of any given concentrate can be ordered!
This provides a fantastic low cost gateway for any new R&D project.

** The black formulations utilize an FDA Food Contact compliant Furnace Carbon Black, this is the preferred carbon black of the FDA. Compounding Solutions has submitted these concentrates for further testing under ISO10993-05 guidelines. Reports will soon be available for the black..

****NEW**** Expanded Color Palette
with ISO-10993-5 Tested Pigments

As regulations continue to become stricter, the achievable color spaces for medical device compounds has become abbreviated. Compounding Solutions has submitted a range of bright FDA 21 CFR 178.3297 (indirect food contact) approved pigments for ISO 10993-5 cytotoxicity testing with successful results. The addition of these pigments expands our color palette beyond the EZ MED Color Selector which utilize the 21 CFR 73 Subpart D approved colorants. Allowing Compounding Solutions to offer bright yellow shades of green, bright shades of red and magenta, bright yellows and oranges, and bright violets and purples Pantones, while offering our customers assurance that devices made from compounds utilizing these pigments will pass biocompatibility testing.

Now have freedom to choose your medical color with CS's new ISO10993-05 pigments



C.I. Pigment Yellow 183

C.I. Pigment Yellow 138

C.I. Pigment Orange 79

C.I. Pigment Red 254

C.I. Pigment Red 202

C.I. Pigment Red 122

C.I. Pigment Blue 29

C.I. Pigment Blue 15:1

C.I. Pigment Blue 15:3

C.I. Pigment Violet 15

C.I. Pigment White 6

C.I. Pigment Black 7

*Resins which may limit color selection include PEEK, PPSU, PESU, PSU, PEI, PA 6/6 and in some cases PC.

** Fillers which can limit color selection are Bismuth fillers and Tungsten.

EZ Med Color Selector

At Compounding Solutions, we strive to help accelerate and simplify the product design process and FDA approval process. In the last few years, the selection of colorants used in medical devices has come under scrutiny from the FDA. This increased scrutiny can make the approval process long and tedious, however, working with Compounding Solutions gives you an advantage by working with a team staying on top of the newest FDA, EU MDR, cFDA regulations.

We have developed our EZ Med Color Selector to assist in choosing in choosing color that will ease the painful FDA submission process as well as decrease R&D time in the design process.

These colors can be achieved utilizing FDA 21 CFR 73 Sub part D pigments, which are approved for use in medical devices without batch certification.

These pantones are achievable with various resins including but not limited to Polyamides (nylon), Polyolefins (PE, PP) Polycarbonates, Polyesters, PEBAs, TPUs, and ABS. Heat stability of the FDA CFR 73 subpart D and white pigment is challenged in resins with processing temperature >440 F. Darker pantones are difficult to achieve formulations containing Bismuth fillers or high loadings of Barium Sulfate.

21 CFR 73 Subpart D Pantone Shades

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