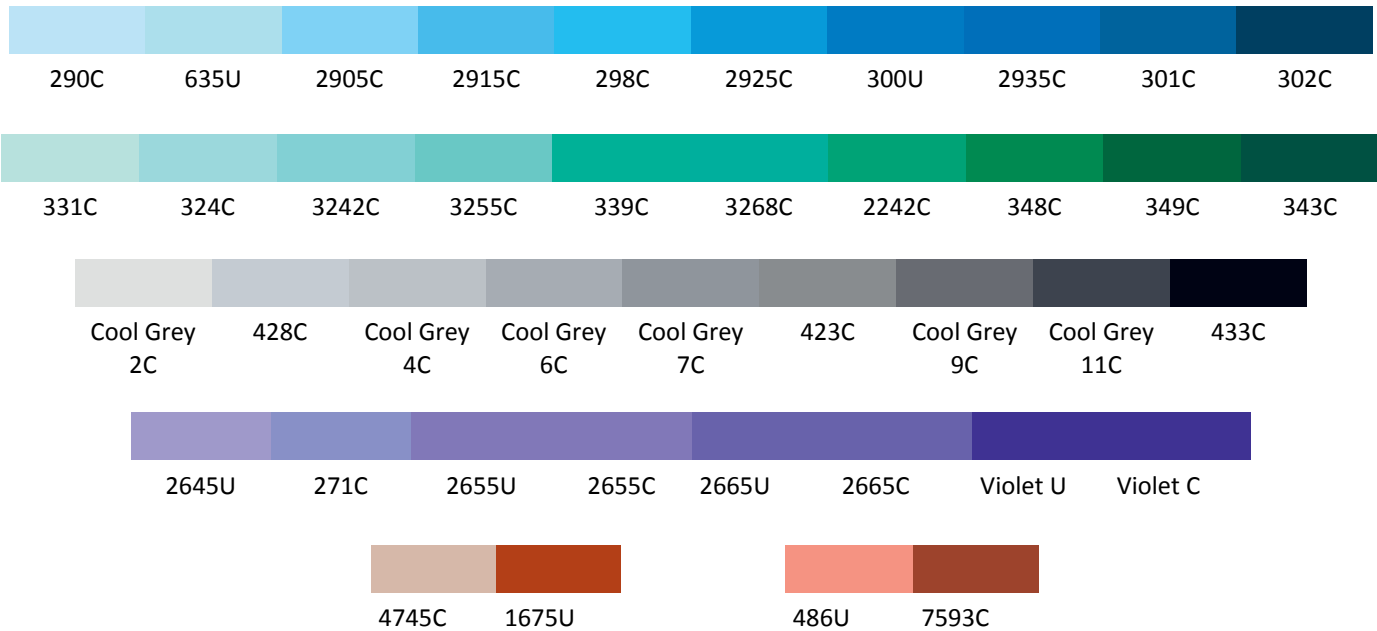


Custom Compounds Utilizing FDA 21 CFR 73 Subpart D Pigments for Medical Devices

At Compounding Solutions, we strive to help accelerate and simplify the product development and FDA approval process. We offer custom compounding to achieve a wide range of colors utilizing pigments listed under the FDA 21 CFR 73 Subpart D colorants exempt from certification in medical devices.

The colors shown below are representations of colors that can be achieved using only pigments listed under FDA 21 CFR 73 Subpart D. These colors may appear different based on monitor and printer settings and limitations and do not represent all possible color options. A larger range can be found on our website in our EZ Med Color Selector. Color options may also vary based on base resin and other additives required.



About FDA 21 CFR 73 Subpart D

The United States Food & Drug Administration (FDA) restricts the colorants that can be used in medical devices that may contact the human body directly. Colorants approved for use in medical devices are listed under Title 21 of the Code of Federal Regulations Parts 73 & 74, subpart D. Colorants listed under part 73 are exempt from batch certification, while those listed under part 74 do require certification. While the colorants used in the device may meet FDA requirements, FDA submission and associated testing of the final device must be completed by the device manufacturer.

The complete list of FDA color additive regulations can be found at www.fda.gov

Compounding Solutions

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Compounding Solutions believes that the information contained in this document is an accurate description of the typical characteristics and/or uses of the product or products, but it is the customer's responsibility to thoroughly test the product in each specific application to determine its performance, efficacy and safety for each end-use product, device or other application. Suggestions of uses should not be taken as inducements to infringe any particular patent. The information and data contained herein are based on information we believe reliable.

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