In this procedure, the count loss would lead to a high estimate for the quantity of undersize particles.

Dissolution studies have been carried out with the Coulter counter. In these studies, frequency counts are usually obtained as a function of time at $t'/I$ settings corresponding to the finer sizes. A large initial count is desired so that subsequent counts are possible as the dissolution proceeds. Larger particles are apt to be present in these systems unless specifically removed. The emulsion data in Table VIII can be used to demonstrate the frequency error, although initial data are seldom obtained in such experiments. The 15-ml. dilution would normally be used since the counts are near the maximum permitted by coincidence correction. At the higher $t'/I$ settings, the counts are seen to be as much as 50% low when compared to the 2-ml. dilution. A concern with count loss due to the larger particles would appear to be quite important in this type of study. Removal of the large particles or monitoring at the larger sizes or at lower dilutions would seem to be desirable.

## CONCLUSIONS

Count loss has been demonstrated for samples meeting the generally stated size restrictions for the Coulter counter. This count loss was shown to be a function of the larger particles present in the samples. The counting range for accurate frequency data is thus more restrictive than previously thought.

The two Coulter counters checked were found to differ in their performance. This difference suggests possible changes occurring for a single counter with age, time, use, etc. The appearance of the oscilloscope pattern was also noted in these studies. In many cases, count loss preceded a poor oscilloscope pattern.

The count loss appears to be of greatest importance where the frequency data are used directly, such as in a dissolution study. The error is least important in a size analysis where the data are converted to weight per cent.

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(1) "Instruction Manual," Coulter Counter Industrial Model A, Section 21.

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(3) Coulter Electronics, private communication.

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# Characterization of Tablet Colors Obtainable from Some Certified Dyes

By FRANK W. GOODHART, MARGERY A. KELLY, and HERBERT A. LIEBERMAN

**The ISCC-NBS method of designating color was employed to classify and describe the colors formed by varying the concentrations of several dyes and carbon black in compressed tablets. The use of centroid color charts gives the investigator a ready reference for colors already produced and classified. Eventually, after sufficient classification, a library of colors can be developed which aids in compounding of new colors and the understanding of color in the tridimensional sense.**

A LACK of a suitable color description method exists throughout the pharmaceutical industry. Investigators will often construct a library of colors by saving samples of colored products that have been made in the laboratory. These samples are then used as references when a new color is to be developed. Anyone who has tried this method knows that it is not possible to build any permanence into such a group of samples, since the effects of aging cause eventual changes that render them useless. Furthermore, since the collection is merely a random group without order, it is not possible to communicate effectively in terms of color nomenclature. A similar problem exists for suitable manufacturing standards of colored products. An initial production sample may be placed aside as a reference for future product comparison. This is a poor procedure since the product itself often has insufficient stability to serve as a reference standard. This initial standard then is often replaced by some future batch causing difficulty in judging color acceptability of a batch because color drift occurred. Second, the use of one batch as a color standard is not satisfactory, since the range of colors that can be produced as inherent color variation of the process is unknown.

Many attempts have been made to character-

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ize colors by use of empirical charts, such as those available for paint samples. However, the use of such random arrangements does not allow one to deduce the colors of intermediate samples from those that are displayed. In fact, a random collection furnishes no basis whatsoever on which to build a logical system of color designation.

Among the systems based on physical samples having orderly arrangements are the Maerz and Paul dictionary of color (1), the Ridgeway color standards (2), and the Lovibond glasses (3). The first two of these arrangements are produced by mixing a few highly colored samples with black, gray, or white. A large number of colors are produced that serve not only as a reference library but also as sales samples as, for example, in the paint industry. The Lovibond glasses are widely used for measurement of materials that transmit light. These colors are produced by mixing various red, yellow, and blue glasses in a visual color comparator, the Lovibond tintometer. The "Color Harmony Manual" (4) is a collection of 900 samples based on the Ostwald system, arranged in groups by Ostwald hue. The manual is used principally for the selection of harmonious color and to a lesser extent for color specification. Since the manual is based on the Ostwald system, the "Color Harmony Manual" cannot be adapted to visualization of color or interpolation of colors falling between given samples.

While all the previously described color collections have some usefulness, especially for certain fields of work, the deficiencies of these systems are sufficiently great to call for a better method of evaluating colors in the pharmaceutical industry.

## DISCUSSION

**Munsell Color System (5.)**—The preferred color arrangement based on principles is the Munsell system. This system is not only a collection of colored samples painted to represent equal visual perceptions between adjacent samples, but it is also a system that adequately describes color in three dimensions: Munsell hue, Munsell value, and Munsell chroma. These three variables, which form the coordinates commonly used to describe color, are defined as follows. (*a*) Hue is that quality of color that the observer describes as red, green, blue, etc. (*b*) Value is that attribute of color that describes the degree of lightness or darkness in some group of samples ranging from white to black. (*c*) Chroma is that quality of color that describes the various degrees of intensity compared to a gray color of the same lightness or value.

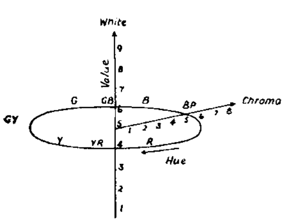


Fig. 1.—The coordinates of the Munsell color system illustrating the three dimensions of color (6).

Since color is three-dimensional, it is best illustrated by a color solid as shown in Fig. 1 (6). This figure can be explained by noting the similarity to a spherical shape such as the earth. The center line showing the range of lightness from black to white may be likened to the earth's axis. The Munsell values shown on this scale range from 0 for perfect black to 10 for perfect white. Now the circular line, similar to the equator and other latitudinal lines, gives the full range of hues going through various stages of red, yellow, green, and blue. The line perpendicular to the axis and in the same plane as the equator gives varying degrees of chroma. Thus, in this over-all color solid, we would find dark colors toward the bottom and light colors at the top. The more intense colors are further from the axis,

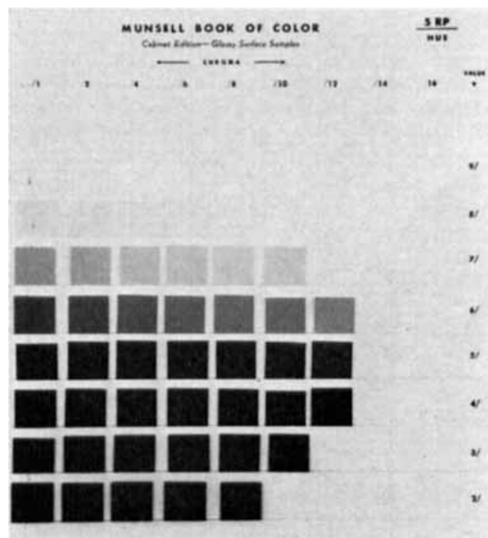


Fig. 2.—A typical page from the "Munsell Book of Color" showing range of chips at hue, 5RP (5).

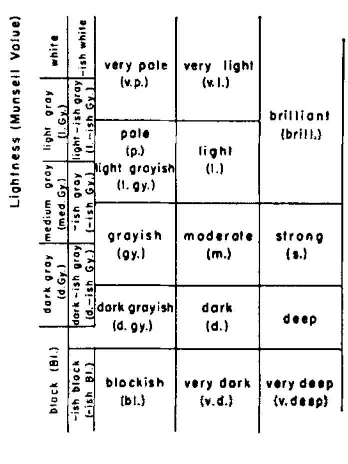


Fig. 3.—General locus of modifiers used in the ISCC–NBS system of color nomenclature.

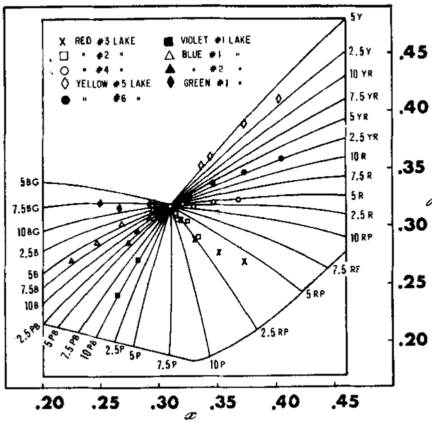


Fig. 4.—A portion of the chromaticity diagram illustrating the locus of colors having Munsell values between 7 and 9.

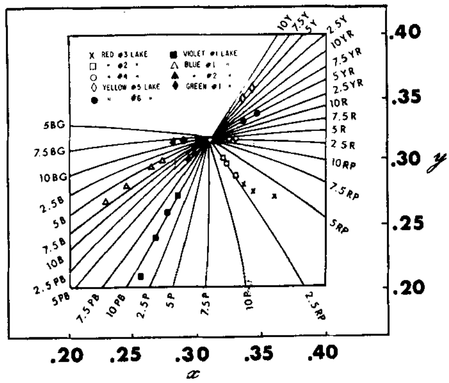


Fig. 5.—A portion of the chromaticity diagram illustrating the locus of various colors having Munsell values between 5 and 7. All points represent certified colorants in combination with black except the outermost points for FD&C Violet No. 1, and FD&C Blue No. 1 which represent pure colorant.

and the locus of hues is at various angles around the axis.

A page from the "Munsell Book of Color" is illustrated in Fig. 2. The book contains 20 charts representing 10 major hues and 1225 color chips. Each succeeding page advances 2.5 hue steps, while value steps increase in single units and chroma steps in single or double units. A complete Munsell designation lists hue, value, and chroma in that order, the value and chroma being separated by a diagonal line (/). The designation for a color having a red hue of 2.5, a value of 5, and a chroma of 6 is 2.5R5/6.

The Munsell color system has wide acceptance in many industries and is particularly useful for several reasons. First, it conforms to equal visual perception; *i.e.*, each step in any of the Munsell coordinates gives little deviation from true visual steps. Another advantage of the Munsell system is that any colors not made can conveniently be given a notation. Most collections of physical samples are based on highly colored specimens and could not accommodate a still more highly colored sample if one was found.

**The Intersociety Color Council, National Bureau of Standards (ISCC–NBS) Method of Designating Colors (7).**—The history of this method is particularly interesting, since it apparently grew out of a need for a systematic way of naming the colors of drugs and chemicals. The first chairman of the ISCC proposed in 1932 that the council's development of "a means of designating colors in the United States Pharmacopeia, in the National Formulary, and in general pharmaceutical literature is desired; such designation to be sufficiently standardized as to be acceptable and usable by science, art, and industry...". Through the assistance of the AMERICAN PHARMACEUTICAL ASSOCIATION, a method was developed in cooperation with the ISCC, later approved by the ISCC, and recommended to the N.F. revision committee and U.S.P. convention (8, 9). A number of suggestions for improvement were later received, and the current method is a result of revision and adoption in 1949 by the ISCC. Known as the ISCC–NBS method, it divides color space into 267 blocks, each having a name, a number, and limits given in Munsell terms.

Figure 3 shows the basic plan used in the ISCC–NBS system that corresponds to a page from the Munsell book. Various hue modifiers are indicated as well as the approved abbreviations. The terms "light" and "dark" give the range in value from moderate to light and dark. Deviations in chroma are described by the terms "grayish," "strong," and "vivid." The terms "light grayish" or "pale," "dark grayish," "blackish," "brilliant," and "deep" describe deviations in both value and chroma. The entire color designation, hue name and modifiers, therefore, defines a tridimensional section of color space. Vertical planes are hue boundaries, horizontal planes are value boundaries, and concentric circular surfaces give the chroma boundaries.

Recently, ISCC–NBS color-name charts, illustrated with centroid colors, have been made available (10) and are described by Kelly (11, 12). These color chips represent the typical color for each particular color name. Listed in the NBS supplement to circular 553 (10) are the color number, color name, and the Munsell renotation. In subsequent pages of the supplement, the color chips are illustrated in the form of 1-in. glossy painted squares arranged on paper of variable lightness background, which affords a viewing surface of about the same lightness as each chip. Beneath each chip the color block number and ISCC–NBS color name are given.

The ISCC–NBS method has limitations; first, because a trained human observer can distinguish several million colors. Since each block represents thousands of shades, other methods, such as color matching (13), should be employed if a very exacting specification is needed (such as dye replacement). Second, the color solid is continuous, not discrete. Yet, the ISCC–NBS method has defined color as the locus and centroid point of certain color blocks. Kelly (12) in a recent article describes, in detail, the ISCC–NBS method of color designation and lists six levels of color description that differ in accuracy or fineness.

## EXPERIMENTAL

**Materials and Preparation of Tablets.**—The lakes of the following FD&C dyes[1] were employed and

[1] Product of H. Kohnstamm and Co., Inc., New York, N. Y.

TABLE I.—COLORIMETRIC DATA FOR FD&C, LAKES ALONE, AND IN COMBINATION WITH BLACK, INCLUDING ISCC–NBS NAME, MUNSELL NOTATION, CHROMATICITY COORDINATES, AND BRIGHTNESS

| Colorant | Concn. of Pure Colorant, % | ISCC–NBS Name | ISCC–NBS Serial No. | Munsell Designation[a] | | Chromaticity Coordinates x | Chromaticity Coordinates y | Lightness Y |
|---|---|---|---|---|---|---|---|---|
| Red No. 2 | 0.00448 | Pale purplish pink | 252 | 3.5RP | 9.1/2.2 | 0.3149 | 0.3099 | 0.8025 |
| | 0.028 | Pale purplish pink | 252 | 1.5RP | 8.9/3.8 | 0.3205 | 0.3038 | 0.6619 |
| | 0.084 | Moderate purplish pink | 250 | 1.5RP | 7.4/5.2 | 0.3273 | 0.2930 | 0.4848 |
| | 0.28 | Moderate purplish pink | 250 | 1.5RP | 7.5/5.4 | 0.3359 | 0.2888 | 0.3651 |
| | 0.28 0.01 Bl. | Light reddish purple | 240 | 1.0RP | 6.3/5.4 | 0.3300 | 0.2893 | 0.3331 |
| | 0.28 0.05 Bl. | Pale reddish purple | 244 | 0.5 RP | 6.0/3.6 | 0.3225 | 0.2973 | 0.3012 |
| | 0.28 0.1 Bl. | Pale purple | 227 | 10.0P | 5.6/2.6 | 0.3199 | 0.3015 | 0.2510 |
| Red No. 3 | 0.00234 | Pale purplish pink | 252 | 6.5RP | 9.1/3.4 | 0.3210 | 0.3030 | 0.8102 |
| | 0.018 | Light purplish pink | 249 | 3.0RP | 8.6/6.0 | 0.3347 | 0.2923 | 0.7006 |
| | 0.054 | Brilliant purplish pink | 246 | 4.0RP | 7.7/9.4 | 0.3552 | 0.2760 | 0.5367 |
| | 0.18 | Strong purplish pink | 247 | 5.0RP | 7.0/11.0 | 0.3760 | 0.2682 | 0.4338 |
| | 0.19 0.01 Bl | Dark purplish pink | 251 | 4.0RP | 6.3/8.2 | 0.3601 | 0.2718 | 0.3345 |
| | 0.19 0.05 Bl. | Dark purplish pink | 251 | 3.0RP | 5.8/6.4 | 0.3431 | 0.2764 | 0.2819 |
| | 0.19 0.1 Bl. | Moderate reddish purple | 241 | 2.5RP | 5.3/5.8 | 0.3361 | 0.2808 | 0.2245 |
| Formerly certified Red No. 4 | 0.0105 | Pale pink | 7 | 1.0R | 9.2/2.0 | 0.3232 | 0.3177 | 0.8337 |
| | 0.035 | Pale pink | 7 | 2.0R | 8.6/2.8 | 0.3331 | 0.3186 | 0.7607 |
| | 0.105 | Light pink | 4 | 2.0R | 8.2/4.2 | 0.3497 | 0.3187 | 0.6272 |
| | 0.35 | Moderate pink | 5 | 2.0R | 7.5/5.6 | 0.3710 | 0.3216 | 0.4999 |
| | 0.35 0.01 Bl. | Moderate pink | 5 | 2.5R | 7.2/3.2 | 0.3489 | 0.3195 | 0.4608 |
| | 0.35 0.05 Bl. | Light grayish red | 18 | 2.5R | 6.5/4.2 | 0.3300 | 0.3178 | 0.3619 |
| | 0.35 0.1 Bl. | Purplish gray | 233 | 2.0R | 5.8/1.4 | 0.3252 | 0.3177 | 0.2816 |
| Yellow No. 5 | 0.0135 | Pale yellow | 89 | 4.0Y | 9.5/1.8 | 0.3394 | 0.3511 | 0.8897 |
| | 0.027 | Pale yellow | 89 | 3.0Y | 9.4/2.4 | 0.3481 | 0.3604 | 0.8844 |
| | 0.081 | Pale yellow | 89 | 3.0Y | 9.2/4.8 | 0.3760 | 0.3876 | 0.8254 |
| | 0.27 | Light yellow | 86 | 2.0Y | 8.8/7.0 | 0.4047 | 0.4091 | 0.7421 |
| | 0.26 0.01 Bl. | Pale yellow | 89 | 4.0Y | 8.0/3.8 | 0.3654 | 0.3823 | 0.5978 |
| | 0.26 0.05 Bl. | Grayish yellow<br>Yellowish gray | 90<br>93 | 6.5Y | 6.9/2.0 | 0.3429 | 0.3589 | 0.4102 |
| | 0.26 0.1 Bl. | Light olive gray | 112 | 6.5Y | 6.2/1.8 | 0.3347 | 0.3499 | 0.3218 |
| Yellow No. 6 | 0.002 | Pinkish white | 9 | 4.0YR | 9.5/1.0 | 0.3226 | 0.3236 | 0.8918 |
| | 0.02 | Pale yellowish pink | 31 | 3.0YR | 8.7/2.6 | 0.3490 | 0.3361 | 0.7234 |
| | 0.06 | Light yellowish pink | 28 | 0.5YR | 8.6/4.6 | 0.3761 | 0.3461 | 0.6945 |
| | 0.20 | Light yellowish pink | 28 | 1.5YR | 7.8/6.4 | 0.4080 | 0.3565 | 0.5505 |
| | 0.20 0.01 Bl. | Moderate yellowish pink | 29 | 3.5YR | 7.6/4.0 | 0.3684 | 0.3472 | 0.5170 |
| | 0.20 0.05 Bl. | Grayish yellowish pink | 32 | 3.5YR | 6.6/2.0 | 0.3458 | 0.3375 | 0.3693 |

the labeled content is noted in parentheses: Red No. 2 (28%), Red No. 3 (18%), Red No. 4 (35%) (formerly certified), Yellow No. 5 (27%), Yellow No. 6 (20%), Green No. 1 (12%) (formerly certified), Blue No. 1 (11%), Blue No. 2 (12%), and Violet No. 1 (14%). Ebonine confectioner's black[1] was sometimes used in combination with the above colorants.

The following general formula was used throughout the study:

| | |
|---|---|
| Colorants | *q.s.* |
| Magnesium stearate U.S.P. | 1.0% |
| Lactose U.S.P. | *q.s. ad.* 100.0% |

Most formulations were prepared by prescreening all three ingredients together, premixing in a twin-shell blender, and micropulverizing through a 0.020-in. herring-bone screen. The blending step was then repeated to insure a uniform mix. In some cases, the ingredients were micropulverized separately, screened together, and blended.

Tablets were prepared by hand compression on the Stokes RB-2 press using a 5/8-in. FFBE punch and die. Care was taken to use uniform pressures throughout, since some change in lightness was noted if the tablet hardness was altered. Therefore, tablet weights and gauges were closely controlled so that variations in lightness were minimized. Tablets of each color were mounted in a hole drilled in a No. 9 black rubber stopper so that they were flush with the top of the stopper.

**Reflectance Measurements.**—Duplicate samples of each color were measured with the G.E. recording spectrophotometer, using source *C* as the illuminant and barium sulfate as the white standard. Tristimulus values were calculated directly by means of the tristimulus integrator, and CIE lightness ($Y$) was transformed into Munsell value ($V_y$) by means of Table B found in Judd (14).

**Determination of Munsell Designation and ISCC–NBS Color Name.**—The usual method of achieving these designations is to first visually estimate the value, then chroma and hue. Since $V_y$ was already determined instrumentally, only chroma and hue are reported as visual estimations. Initially, in order to become accustomed to the method, all three parameters were estimated visually. This operation was helpful since those workers not familiar with the three dimensions of color were forced to learn the classification.

The lighting and viewing conditions were those recommended in the ISCC–NBS method of designating colors (7). A table having a black cloth covering was placed adjacent to windows giving good northern daylight illumination (no sunlight) White or gray masks supplied with the "Munsell

TABLE I.—(*Continued*)

| Colorant | Concn. of Pure Colorant, % | ISCC–NBS Name | ISCC–NBS Serial No. | Munsell Designation[a] | Chromaticity Coordinates *x* | Chromaticity Coordinates *y* | Lightness *Y* |
|---|---|---|---|---|---|---|---|
| | 0.20 0.1 Bl. | Lt. grayish reddish brown | 45 | 4.0YR 6.0/1.8 | 0.3355 | 0.3320 | 0.2991 |
| Formerly certified Green No. 1 | 0.00204 | Very pale blue | 184 | 7.0B 9.2/1.6 | 0.2987 | 0.3171 | 0.8406 |
| | 0.012 | Very pale blue | 184 | 2.5B 8.6/2.0 | 0.2855 | 0.3174 | 0.7003 |
| | 0.036 | Very light greenish blue | 171 | 10.0B 8.1/3.6 | 0.2686 | 0.3150 | 0.6083 |
| | | Very light bluish green | 162 | | | | |
| | 0.12 | Light bluish green | 163 | 9.5BG 7.1/5.6 | 0.2515 | 0.3179 | 0.4451 |
| | 0.12 0.01 Bl. | Light bluish green | 163 | 10.0BG 7.1./4.6 | 0.2636 | 0.3141 | 0.4406 |
| | | Light greenish blue | 172 | | | | |
| | 0.12 0.05 Bl. | Pale blue | 185 | 0.5B 6.4/2.4 | 0.2807 | 0.3146 | 0.3531 |
| | 0.12 0.1 Bl. | Pale blue | 185 | 0.5B 5.9/1.8 | 0.2885 | 0.3156 | 0.2919 |
| Blue No. 1 | 0.0011 | Very pale blue | 184 | 8.5B 9.3/1.8 | 0.2979 | 0.3162 | 0.8513 |
| | 0.011 | Very light greenish blue | 171 | 7.5B 8.3/4.0 | 0.2710 | 0.2998 | 0.6522 |
| | 0.033 | Very light greenish blue | 171 | 7.0B 7.9/4.8 | 0.2504 | 0.2841 | 0.5667 |
| | 0.11 | Brilliant greenish blue | 168 | 7.5B 6.8/6.6 | 0.2284 | 0.2681 | 0.4057 |
| | 0.11 0.01 Bl. | Light greenish blue | 172 | 7.5B 6.8/6.0 | 0.2445 | 0.2800 | 0.3978 |
| | 0.11 0.05 Bl. | Light greenish blue | 172 | 8.0B 6.2/4.2 | 0.2640 | 0.2957 | 0.3225 |
| | 0.11 0.1 Bl. | Light greenish blue | 172 | 7.5B 5.6/3.8 | 0.2728 | 0.3013 | 0.2589 |
| Blue No. 2 | 0.0018 | Bluish white | 189 | 5.5PB 9.3/1.2 | 0.3044 | 0.3124 | 0.8593 |
| | 0.0012 | Very pale blue | 184 | 4.5PB 8.5/2.6 | 0.2956 | 0.3045 | 0.6880 |
| | 0.036 | Very pale blue | 184 | 4.5PB 8.1/2.8 | 0.2839 | 0.2925 | 0.6083 |
| | 0.12 0.01 Bl. | Light blue | 181 | 5.0PB 7.1/5.0 | 0.2750 | 0.2824 | 0.4405 |
| | 0.12 0.05 Bl. | Pale purplish blue | 203 | 5.0PB 7.1/4.2 | 0.2822 | 0.2912 | 0.4412 |
| | 0.12 0.1 Bl. | Pale blue | 185 | 4.5PB 6.4/2.4 | 0.2935 | 0.3027 | 0.3492 |
| | | | | 4.0PB 5.8/1.6 | 0.2980 | 0.3068 | 0.2735 |
| Violet No. 1 | 0.000924 | Very pale purple | 226 | 2.5P 9.2/2.2 | 0.3041 | 0.3051 | 0.8179 |
| | 0.014 | Very light violet | 209 | 2.5P 7.7/5.0 | 0.2854 | 0.2701 | 0.5407 |
| | 0.042 | Light violet | 210 | 0.5P 6.8/7.4 | 0.2679 | 0.2392 | 0.4060 |
| | 0.14 | Light violet | 210 | 1.5P 5.6/8.6 | 0.2562 | 0.2092 | 0.2538 |
| | 0.14 0.01 Bl. | Brilliant violet | 206 | 10.0PB 6.0/8.8 | 0.2651 | 0.2353 | 0.2965 |
| | 0.14 0.05 Bl. | Pale violet | 214 | 10.0PB 5.5/4.8 | 0.2772 | 0.2591 | 0.2465 |
| | 0.14 0.1 Bl. | Pale violet | 214 | 10.0PB 5.2/3.8 | 0.2855 | 0.2737 | 0.2194 |

[a] Hue and chroma are visual determinations and value is obtained from CIE lightness ($Y$).

Book of Color" were used to provide equal viewing areas. Generally, two good experienced observers independently viewed samples, and averages were compiled for chroma and hues.

Once a color had been given a Munsell designation, the appropriate color reference chart (7) was chosen, and the color name and serial number were recorded.

Occasionally errors in judgment of chroma and hue were made, particularly for the very light shades. By starting out with a known value, errors were greatly reduced. They were uncovered by noting the disagreement in notations by two workers. The discrepancy was checked by referring to Munsell–CIE diagrams.[2] However, once the two observers were experienced, their judgment agreed within narrow differences in all three color attributes.

## RESULTS AND DISCUSSION

**Colorimetric Data.**—Figures 4 and 5 illustrate a portion of the chromaticity diagrams, giving the locus of various colors obtained by increasing their concentrations or mixing with black. Figure 4 illustrates those colors falling between the values of about 7 to somewhat above 9, while Fig. 5 shows those colors having values between 5 and 7. Included in the diagrams are the loci of Munsell hues. While these hue lines are not vertical in the CIE diagram at all values, they can be included in these figures as being good approximations, since only a small portion of the color solid is being illustrated. Chroma lines are not shown in these figures, since they change significantly with changes in value. These diagrams are available only for whole number values of 1 through 9 and are, therefore, not useful for accurate transformation from CIE coordinates to the Munsell system. In this work, Figs. 4 and 5 were found to be useful in obtaining an estimation of hue. It can be noted in the diagram that no single hue can be assigned to any one colorant, since the hue changes somewhat with increasing concentrations of colorant. All colorants show this trend to varying degrees.

Listed in Table I, columns 6, 7, and 8, are the colorimetric data for all colors. Chromaticity coordinates, $x$ and $y$, had very low variation between samples. This indicates that hues and chromas vary only slightly. However, fluctuations in the lightness, $Y$, were noticeable if constant machine compression pressure was not maintained.

**Munsell Notations and Color Names.**—Listed in Table I are the color names, serial numbers, and Munsell notations. In a few cases, where the Munsell notation fell on a boundary, it was necessary to give two names and numbers.

Shown in Fig. 6 is a typical color name chart used for determining color names and serial numbers.

[2] Obtainable from the Munsell Color Co., Baltimore, Md.

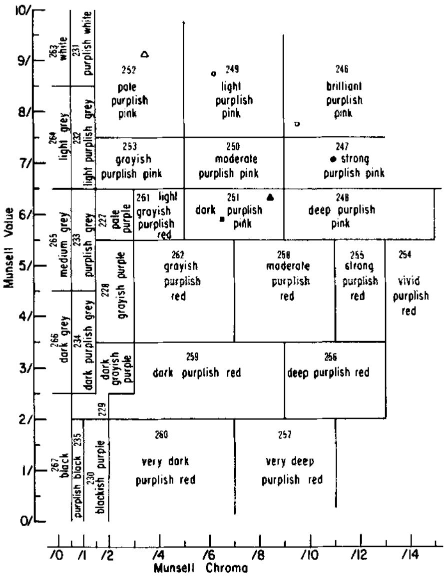


Fig. 6.—A color name chart giving the name and location of color produced from various concentrations of FD&C Red No. 3 Lake alone and in combination with black colorant. Key: △, 0.00234% dye; ○, 0.018% dye; □, 0.054% dye; ●, 0.18% dye; ▲, 0.19% dye and 0.01% black; ■, 0.19% dye and 0.05% black.

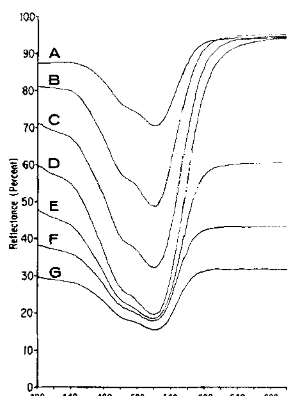


Fig. 7.—Reflectance curves obtained for colored tablets containing various concentrations of FD&C Red No. 3 alone and in combination with black. Key: A, 0.00234% dye; B, 0.018% dye; C, 0.054% dye; D, 0.18% dye; E, 0.19% dye and 0.01% black; F, 0.19% dye and 0.05% black; G, 0.19% dye and 0.1% black.

The chart illustrated covers the hue range of 3RP to 9RP. Plotted on the diagram are the loci of four concentrations of FD&C Red No. 3 Lake and two points representing a combination of the lake with black. The trend shown for increasing concentrations of colorant alone in this figure is generally true for all colorants but to varying degrees. An increase in colorant concentration increases saturation (chroma) and also decreases lightness (value). Had higher concentrations of FD&C Red No. 3 Lake been made, the same pattern would follow; and reduction in value and chroma would not be linearly related to concentration. Addition of black to the maximum concentration of Red No. 3 Lake reduces both value and chroma as seen in Fig. 6. A third mixture of Red No. 3 Lake with black is not shown in this figure, since the reduction in hue (2.5RP) occurred going below the 3RP minimum range on the diagram. Columns 2 and 3 of Table I list the ISCC–NBS color name and serial number of the colorants. From these data, similar charts like Fig. 6 may be prepared for any colorant or blends of colorants. These serve to identify a color permanently and allow it to be compared effectively to standard centroid color chips.

The reflectance curves for the colors obtained using FD&C Red No. 3 Lake are shown in Fig. 7. The shape of the curves using only the red dye remains the same, differing only in depth. This corresponds to the rapid increase in chroma for this dye, while value is decreasing and hue is unchanged. The colors containing black as well as Red No. 3 Lake are marked by a decreasing peak depth and a flattening of the reflectance curve. Reduction in both chroma and value corresponds to this change in curve shape.

## CONCLUSIONS

The application of the ISCC–NBS method of color designation has been demonstrated for compressed tablets. The first step involves determination of the Munsell designation either visually, instrumentally, or by a combination of the two. Having these data, the appropriate color name and number can be assigned to the particular formulation by reference to NBS circular 553 (7). The color name charts illustrated with centroid colors (10) may then be used as a reference for the colored products already prepared. The collection of color designations and names is useful in preparing colors for new products since a starting point has already been determined by previous work. As the collection of color names grows, especially those obtained by mixing two or three colorants, the development of new colors is simplified. Along with the color designations, the type and concentration of substrate should be noted. In some cases, changes in the kind of tablet diluent or alteration in the kind and amount of drug used could conceivably alter the characteristic color of the dye. The method of processing and the physical form of the colorant are also factors that should be recorded in the application of this method to color description.

The method can also be used for color classification of other opaque products such as sugar-coated tablets, suspensions, and semisolids. The same precautions stated above should be followed in the color classification of these products.

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