

THE MINISTER OF PUBLIC HEALTH

**ORDER**

**on approval of Norms relating to the colouring matters which may be added to medicinal products for human use**

Taking into account provisions of Law No. 95/2006 on healthcare reform, Title XVII, The medicinal product, and of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002, with further changes and completions,

on seeing Approval Report of the General Pharmaceutical and Medical Devices Directorate No. E.N. 2.144 din 17 July 2006,

based on Government Decision No. 862/2006 on organisation and functioning of the Ministry of Public Health,

**the minister of public health** hereby issues the following order:

Article 1. - Approval of Norms relating to the colouring matters which may be added to medicinal products for human use, provided in the Annex which is integral part of this order.

Article 2. - Provisions of this order come into force on 28 July 2006, at which date all contrary provisions shall be repealed.

Article 3. - The present order is to be published in the Official Gazette of Romania, Part I.

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The present order is a transposition of Council Directive 78/25/EEC din 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products, published in the Official Journal of European Communities no. L 11 of 14 January 1978, with further changes and completions.

The minister of public health,  
**Gheorghe Eugen Nicolăescu**

Bucharest, 17 July 2006.  
No. 875.

## **NORMS**

### **relating to the colouring matters which may be added to medicinal products for human use**

Article 1. - (1) The only colouring matters authorised in Romania for the colouring of medicinal products for human use as defined in Law No. 95/2006 on healthcare reform, Title XVII, The medicinal product, are as covered by the Annex which is integral part of these norms.

(2) No distinction shall be made between colouring matter for both mass and surface colouring and colouring matter for surface colouring only.

Article 2. - Colouring matters covered by the Annex must satisfy all specific criteria of purity laid down in Annex XV of Norms concerning the colouring matters authorised for use in foodstuffs intended for human use, approved through Order of the minister of public health and the family and the minister of agriculture, food and forestry No. 438/295/2002, with further changes and completions.

Article 3. - The methods of analysis needed to verify that the specific criteria of purity pursuant to the Norms approved through Order of the minister of public health and the family and the minister of agriculture, food and forestry No. 438/295/2002, with further changes and completions, also applies to use of respective colouring matters for colouring medicinal products for human use.

**LIST  
of colouring materials authorised for colouring medicinal products for human  
use**

<b>No. EC</b>	<b>Common Name</b>	<b>No. in the Colour Index*1) or description</b>
E 100	Curcumin	75300
E 101	(i) Riboflavin (ii) Riboflavin - 5'-phosphate	
E 102	Tartrazine	19140
E 104	Quinoline yellow	47005
E 110	Orange yellow S Sunset yellow FCF	15985
E 120	Cochineal, Carminic acid, Carmines	75470
E 122	Azorubine, Carmoisine	14720
E 123	Amaranth	16185
E 124	Cochineal Red A, Ponceau 4R	16255
E 127	Erythrosine	45430
E 128	Red 2G	18050
E 129	Allura Red AC	16035
E 131	Patent bleu V	42051
E 132	Indigo carmine	73015
E 133	Brilliant blue FCF	42090
E 140	Chlorophylls and Chlorophyllins: (I) Chlorophylls (ii) Chlorophyllins	75810 75815
E 141	Copper complexes of chlorophylls and chlorophyllins: (i) Copper complexes - chlorophylls (ii) Copper complexes - chlorophyllins	75815
E 142	Green S	44090
E 150a	Plain caramel *2	
E 150b	Caustic sulphite caramel	
E 150c	Ammonia caramel	
E 150d	Sulphite ammonia caramel	
E 151	Brilliant black BN, Black PN	28440
E 153	Vegetable carbon	
E 154	Brown FK	
E 155	Brown HT	20285

E 160a	Carotens: (i) Mixed carotens (ii) beta-carotene	75130 40800
E 160b	Annato, bixin, norbixin	75120
E 160c	Paprika extract, capsanthin, capsorubin	
E 160d	Lycopene	
E 160e	Beta-apo-8'-carotenal (C30)	40820
E 160f	Ethyl ester of beta-apo-8'- carotenic acid (C30)	40825
E 161b	Lutein	
E 161g	Canthaxanthin	
E 162	Beetroot Red, betanin	
E 163	Anthocyanins	Prepared by physical means from fruits and vegetables
E 170	Calcium carbonate	77220
E 171	Titanium dioxide	77891
E 172	Iron oxides and hydroxides	77491 77492 77499
E 173	Aluminium	
E 174	Silver	
E 175	Gold	
E 180	Litholrubine BK	

\*1) Colour index numbers are taken from the third edition (1982) of the Colour Index, volumes 1 to 7, 1315; also amendments 37 to 40 (127), 41 to 44 (127 - 50), 45 to 48 (130), 49 to 50 (132 - 50), 53 to 56 (135).

\*2) The term caramel relates to products of a more or less intense brown colour which are intended for colouring. It does not correspond to the sugary aromatic product obtained from heating sugars and which is used for flavouring food (e.g., confectionery, pastry, alcoholic drinks).