

Instructions

Column 3: Substance name, i.e. the actual active substance (not a possible declared active substance). Example: Tetracycline hydrochloride and *not* Tetracycline (as chloride). The active substance names to be used are those listed in the Danish Drug Standards (Danske Lægemiddelstandarder). If no name is listed here, please use the INN, NFN, BAN or USAN name. If none of these names are determined, use the trade name or the chemical name. As regards dyes, please also specify the Colour Index numbers as used in the publication Colour Index, 3rd edition, 1971.

Column 4: The quantitative composition of the product in mg or g, excl. any excess of active substances. If an excess of active substance is added, please write this in percentage in a parenthesis after the quantity stated. The quantities are specified per unit (ml, g, tablet, etc.) with as few digits as possible, and the unit concerned is listed at the top of the column. If it is impossible to specify an exact quantity, add "approx." in front of the quantity indication.

Column 5: Specification of identity and purity of all active substances. If it is not possible to refer to a pharmacopoeia or the like (e.g. Ph.Eur, Ph.Nord, BP, UPS or DLS), please refer to an enclosed document or appendix to the material submitted.

Column 6: After each substance, please write a letter identifying the type of substance. Please use the following letters:

A: Active substances

F: Dyes

K: Preservatives

X: Flavouring

C: Other inactive

Substances