



Regulatory Information Sheet

Japanese Precedence of Use Levels for Iron Oxides in Oral Administration Dosage Forms

The precedence of use levels shown in the table below are listed in the Japanese Pharmaceutical Excipients Directory (JPED) 2016 (Japanese Version) for the use of iron oxides in oral administration dosage forms.

Iron Oxide	Precedence of Use Level
Red Iron Oxide	95.4 mg per day
Yellow Iron Oxide	5.67 mg per day
Black Iron Oxide	1.539 mg per day

These represent the maximum daily dosage of each oxide that a patient should consume from the use of a particular dosage form based on previously approved applications in Japan.

These levels need to be carefully assessed when formulating products intended to be marketed in Japan. Calculations should be done to determine the specific amount of iron oxide present on a dosage form. This needs to be multiplied by the number of recommended doses per day to determine the daily dosage and assess this level against the listed levels.

If an application results in the amount of iron oxide exceeding these levels, it may be necessary to supply the MHLW with additional supporting safety information which justifies that the levels used are safe. This can be done, providing appropriate safety data is available. However, it may result in some delays in the approval/registration of the drug in Japan.

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