

1 Miglitol Tablets

2 ミグリトール錠

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4 Miglitol Tablets contain not less than 95.0% and
5 not more than 105.0% of the labeled amount of
6 miglitol ($C_8H_{17}NO_5$; 207.22).

7 **Method of preparation** Prepare as directed under Tab-
8 lets, with Miglitol.

9 **Identification** To a quantity of powdered Miglitol Tab-
10 lets, equivalent to 0.1 g of Miglitol, add 50 mL of a mix-
11 ture of acetonitrile and water (9:1), shake, centrifuge, and
12 use the supernatant liquid as the sample solution. Sepa-
13 rately, dissolve 50 mg of miglitol in a mixture of acetoni-
14 trile and water (9:1) to make 25 mL, and use this solution
15 as the standard solution. Perform the test with these solu-
16 tions as directed under Thin-layer Chromatography <2.03>.
17 Spot 10 μ L each of the sample solution and standard solu-
18 tion on a plate of silica gel for thin-layer chromatography.
19 Develop the plate with a mixture of methanol, ethyl ace-
20 tate and diluted ammonia solution (28) (9 in 10) (2:2:1) to
21 a distance of about 8 cm, and air-dry the plate. Allow the
22 plate to stand in iodine vapors: the principal spot obtained
23 from the sample solution and the spot from the standard
24 solution show a brown color and the same *R_f* value.

25 **Uniformity of dosage units** <6.02> Perform the Mass
26 variation test, or the Content uniformity test according to
27 the following method: it meets the requirement.

28 To 1 tablet of Miglitol Tablets add 20 mL of a mixture
29 of acetonitrile for liquid chromatography and water (4:1),
30 sonicate, cool, and add a mixture of acetonitrile for liquid
31 chromatography and water (4:1) to make exactly *V* mL so
32 that each mL contains about 1 mg of miglitol ($C_8H_{17}NO_5$).
33 Centrifuge this solution, and use the supernatant liquid as
34 the sample solution. Then, proceed as directed in the As-
35 say.

$$36 \quad \text{Amount (mg) of miglitol (C}_8\text{H}_{17}\text{NO}_5\text{)}$$

$$37 \quad = M_S \times A_T/A_S \times V/50$$

38 *M_S*: Amount (mg) of Miglitol RS taken, calculated on
39 the dried basis

40 **Dissolution** <6.10> When the test is performed at 75
41 revolutions per minute according to the Paddle method,
42 using 900 mL of water as the dissolution medium, the
43 dissolution rate in 30 minutes of Miglitol Tablets is not
44 less than 85%.

45 Start the test with 1 tablet of Miglitol Tablets, withdraw
46 not less than 20 mL of the medium at the specified minute
47 after starting the test, and filter through a membrane filter

48 with a pore size not exceeding 0.45 μ m. Discard the first
49 10 mL of the filtrate, pipet *V* mL of the subsequent filtrate,
50 add water to make exactly *V* mL so that each mL contains
51 about 28 μ g of miglitol ($C_8H_{17}NO_5$), and use this solution
52 as the sample solution. Separately, weigh accurately about
53 56 mg of Miglitol RS (separately determine the loss on
54 drying <2.41> under the same conditions as Miglitol), and
55 dissolve in water to make exactly 50 mL. Pipet 5 mL of
56 this solution, add water to make exactly 200 mL and use
57 this solution as the standard solution. Perform the test with
58 exactly 10 μ L each of the sample solution and standard
59 solution as directed under Liquid Chromatography <2.01>
60 according to the following conditions, and determine the
61 peak areas, *A_T* and *A_S*, of miglitol in each solution.

62 Dissolution rate (%) with respect to the labeled amount of
63 miglitol ($C_8H_{17}NO_5$)

$$64 \quad = M_S \times A_T/A_S \times V'/V \times 1/C \times 45$$

65 *M_S*: Amount (mg) of Miglitol RS taken, calculated on
66 the dried basis

67 *C*: Labeled amount (mg) of miglitol ($C_8H_{17}NO_5$) in 1
68 tablet

69 **Operating conditions**—

70 Proceed as directed in the operating conditions in the
71 Assay.

72 **System suitability**—

73 System performance: When the procedure is run with 10
74 μ L of the standard solution under the above operating
75 conditions, the number of theoretical plates and the sym-
76 metry factor of the peak of miglitol are not less than 1000
77 and not more than 1.5, respectively.

78 System repeatability: When the test is repeated 6 times
79 with 10 μ L of the standard solution under the above oper-
80 ating conditions, the relative standard deviation of the
81 peak area of miglitol is not more than 2.0%.

82 **Assay** Weigh accurately the mass of not less than 20
83 Miglitol Tablets, and powder. Weigh accurately a portion
84 of the powder, equivalent to about 0.1 g of miglitol
85 ($C_8H_{17}NO_5$), add 50 mL of a mixture of acetonitrile for
86 liquid chromatography and water (4:1), shake, and add a
87 mixture of acetonitrile for liquid chromatography and wa-
88 ter (4:1) to make exactly 100 mL. Centrifuge this solution,
89 and use the supernatant liquid as the sample solution. Sepa-
90 rately, weigh accurately about 50 mg of Miglitol RS
91 (separately determine the loss on drying <2.41> under the
92 same conditions as Miglitol), and dissolve in a mixture of
93 acetonitrile for liquid chromatography and water (4:1) to
94 make exactly 50 mL, and use this solution as the standard
95 solution. Perform the test with exactly 10 μ L each of the
96 sample solution and standard solution as directed under
97 Liquid Chromatography <2.01> according to the following

98 conditions, and determine the peak areas, A_T and A_S , of
99 miglitol in each solution.

100 Amount (mg) of miglitol ($C_8H_{17}NO_5$) = $M_S \times A_T / A_S \times$
101 2

102 M_S : Amount (mg) of Miglitol RS taken, calculated on
103 the dried basis

104 *Operating conditions—*

105 Detector: An ultraviolet absorption photometer (wave-
106 length: 210 nm).

107 Column: A stainless steel column 4.6 mm in inside di-
108 ameter and 15 cm in length, packed with
109 pentaethylenehexaaminated polyvinyl alcohol polymer
110 beads for liquid chromatography (5 μ m in particle diame-
111 ter).

112 Column temperature: A constant temperature of about
113 40°C.

114 Mobile phase: Dissolve 0.6 g of potassium dihydrogen
115 phosphate and 0.28 g of anhydrous disodium hydrogen
116 phosphate in water to make 1000 mL. To 200 mL of this
117 solution add 800 mL of acetonitrile for liquid
118 chromatography.

119 Flow rate: Adjust so that the retention time of miglitol is
120 about 8 minutes.

121 *System suitability—*

122 System performance: When the procedure is run with 10
123 μ L of the standard solution under the above operating
124 conditions, the number of theoretical plates and the sym-
125 metry factor of the peak of miglitol are not less than 4000
126 and not more than 1.5, respectively.

127 System repeatability: When the test is repeated 6 times
128 with 10 μ L of the standard solution under the above oper-
129 ating conditions, the relative standard deviation of the
130 peak area of miglitol is not more than 1.0%.

131 **Containers and storage** Containers—Tight containers.

132 **Add the following to 9.41 Reagents, Test**
133 **Solutions:**

134 **Miglitol** $C_8H_{17}NO_5$ [Same as the namesake mono-
135 graph]