

## 1 Rilmazafone Hydrochloride Tablets

2 リルマザホン塩酸塩錠

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4 Rilmazafone Hydrochloride Tablets contain not  
5 less than 93.0% and not more than 107.0% of the la-  
6 beled amount of rilmazafone hydrochloride hydrate  
7 ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ ; 547.82).

8 **Method of preparation** Prepare as directed under Tab-  
9 lets, with Rilmazafone Hydrochloride Hydrate.

10 **Identification** To a quantity of powdered Rilmazafone  
11 Hydrochloride Tablets, equivalent to 10 mg of Rilmazafone  
12 Hydrochloride Hydrate, add 5 mL of methanol, shake for  
13 10 minutes, and centrifuge. Filter the supernatant liquid  
14 with a membrane filter with a pore size not exceeding 0.45  
15  $\mu m$ , and use the filtrate as the sample solution. Separately,  
16 dissolve 2 mg of rilmazafone hydrochloride hydrate in 1 mL  
17 of methanol, and use this solution as the standard solution.  
18 Perform the test with these solutions as directed under Thin-  
19 layer Chromatography <2.03>. Spot 10  $\mu L$  each of the sam-  
20 ple solution and standard solution on a plate of silica gel  
21 with fluorescent indicator for thin-layer chromatography.  
22 Develop the plate with a mixture of ethyl acetate, acetonitrile,  
23 water and acetic acid (100) (8:4:3:3) to a distance of  
24 about 10 cm, and air-dry the plate. Examine under ultraviolet  
25 light (main wavelength: 254 nm): the principal spot ob-  
26 tained from the sample solution and the spot from the stand-  
27 ard solution show the same  $R_f$  value.

28 **Uniformity of dosage units** <6.02> Perform the test ac-  
29 cording to the following method: it meets the requirement  
30 of the Content uniformity test.

31 To 1 tablet of Rilmazafone Hydrochloride Tablets add  $V$   
32 mL of water so that each mL contains about 0.2 mg of ril-  
33 mazafone hydrochloride hydrate  
34 ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ ). Add exactly  $2V$  mL of the in-  
35 ternal standard solution, shake vigorously for 10 minutes,  
36 and filter with a membrane filter with a pore size not ex-  
37 ceeding 0.45  $\mu m$ . Discard the first 5 mL of the filtrate, and  
38 use the subsequent filtrate as the sample solution. Sepa-  
39 rately, weigh accurately about 20 mg of Rilmazafone Hy-  
40 drochloride RS (separately determine the water <2.48> in  
41 the same manner as Rilmazafone Hydrochloride Hydrate),  
42 and dissolve in water to make exactly 100 mL. Pipet 10 mL  
43 of this solution, add exactly 20 mL of the internal standard  
44 solution, and use this solution as the standard solution. Then,  
45 proceed as directed in the Assay under Rilmazafone Hydro-  
46 chloride Hydrate.

47 Amount (mg) of rilmazafone hydrochloride hydrate  
48 ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ )

$$49 = M_S \times Q_T / Q_S \times V / 100 \times 1.070$$

50  $M_S$ : Amount (mg) of Rilmazafone Hydrochloride RS  
51 taken, calculated on the anhydrous basis

52 *Internal standard solution*—A solution of propyl parahy-  
53 droxybenzoate in a mixture of water and acetonitrile (1:1)  
54 (3 in 100,000).

55 **Dissolution** <6.10> When the test is performed at 50 rev-  
56 olutions per minute according to the Paddle method, using  
57 900 mL of water as the dissolution medium, the dissolution  
58 rate in 15 minutes of Rilmazafone Hydrochloride Tablets is  
59 not less than 85%.

60 Start the test with 1 tablet of Rilmazafone Hydrochloride  
61 Tablets, withdraw not less than 20 mL of the medium at the  
62 specified minute after starting the test, and filter through a  
63 membrane filter with a pore size not exceeding 0.45  $\mu m$ .  
64 Discard the first 10 mL of the filtrate, pipet  $V$  mL of the  
65 subsequent filtrate, add water to make exactly  $V'$  mL so that  
66 each mL contains about 1.1  $\mu g$  of rilmazafone hydrochlo-  
67 ride hydrate ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ ), and use this solu-  
68 tion as the sample solution. Separately, weigh accurately  
69 about 22 mg of Rilmazafone Hydrochloride RS (separately  
70 determine the water <2.48> in the same manner as Ril-  
71 mazafone Hydrochloride Hydrate), and dissolve in water to  
72 make exactly 100 mL. Pipet 5 mL of this solution, add water  
73 to make exactly 100 mL. Then, pipet 5 mL of this solution,  
74 add water to make exactly 50 mL, and use this solution as  
75 the standard solution. Perform the test with exactly 50  $\mu L$   
76 each of the sample solution and standard solution as di-  
77 rected under Liquid Chromatography <2.01> according to  
78 the following conditions, and determine the peak areas,  $A_T$   
79 and  $A_S$ , of rilmazafone in each solution.

80 Dissolution rate (%) with respect to the labeled amount of  
81 rilmazafone hydrochloride hydrate  
82 ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ )  
83  $= M_S \times A_T / A_S \times V' / V \times 1 / C \times 9 / 2 \times$   
84 1.070

85  $M_S$ : Amount (mg) of Rilmazafone Hydrochloride RS  
86 taken, calculated on the anhydrous basis

87  $C$ : Labeled amount (mg) of rilmazafone hydrochloride  
88 hydrate ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ ) in 1 tablet

89 *Operating conditions*—

90 Proceed as directed in the operating conditions in the  
91 Assay under Rilmazafone Hydrochloride Hydrate.

92 *System suitability*—

93 System performance: When the procedure is run with 50  
94  $\mu L$  of the standard solution under the above operating  
95 conditions, the number of theoretical plates and the  
96 symmetry factor of the peak of rilmazafone are not less than  
97 5000 and not more than 1.5, respectively.

98 System repeatability: When the test is repeated 6 times  
99 with 50  $\mu L$  of the standard solution under the above

100 operating conditions, the relative standard deviation of the  
101 peak area of rilmazafone is not more than 2.0%.

102 **Assay** Weigh accurately the mass of not less than 20 tab-  
103 lets of Rilmazafone Hydrochloride Tablets, and powder.  
104 Weigh accurately a portion of the powder, equivalent to  
105 about 2 mg of rilmazafone hydrochloride hydrate  
106 ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ ), add 10 mL of water and exactly  
107 20 mL of the internal standard solution, shake vigorously  
108 for 10 minutes, and filter through a membrane filter with a  
109 pore size not exceeding 0.45  $\mu m$ . Discard the first 5 mL of  
110 the filtrate, and use the subsequent filtrate as the sample so-  
111 lution. Separately, weigh accurately about 20 mg of Ril-  
112 mazafone Hydrochloride RS (separately determine the wa-  
113 ter <2.48> in the same manner as Rilmazafone Hydrochlo-  
114 ride Hydrate), and dissolve in water to make exactly 100  
115 mL. Pipet 10 mL of this solution, add exactly 20 mL of the  
116 internal standard, and use this solution as the standard solu-  
117 tion. Then, proceed as directed in the Assay under Ril-  
118 mazafone Hydrochloride Hydrate.

119 Amount (mg) of rilmazafone hydrochloride hydrate  
120 ( $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$ )

$$121 = M_s \times Q_T / Q_S \times 1 / 10 \times 1.070$$

122  $M_s$ : Amount (mg) of Rilmazafone Hydrochloride RS  
123 taken, calculated on the anhydrous basis

124 *Internal standard solution*—A solution of propyl parahy-  
125 droxybenzoate in a mixture of water and acetonitrile (1:1)  
126 (3 in 100,000).

127 **Containers and storage** Containers—Well-closed con-  
128 tainers.

129 **Add the following to 9.01 Reference**

130 **Standards (1):**

131 **Rilmazafone hydrochloride RS**

132 **Add the following to 9.41 Reagents,**

133 **Test Solutions:**

134 **Rilmazafone hydrochloride hydrate**

135  $C_{21}H_{20}Cl_2N_6O_3 \cdot HCl \cdot 2H_2O$  [Same as the namesake mono-  
136 graph]

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