# Blonanserin Tablets

ブロナンセリン錠

Blonanserin Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of blonanserin ($C_{23}H_{30}FN_3$: 367.50).

**Method of preparation** Prepare as directed under Tablets, with Blonanserin.

**Identification** To an amount of powdered Blonanserin Tablets, equivalent to 1.3 mg of Blonanserin, add 1 mL of water to moisten. Then, add 60 mL of methanol, shake for 20 minutes, add methanol to make 100 mL, and centrifuge. Determine the absorption spectrum of the supernatant liquid as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits maxima between 234 nm and 238 nm, between 251 nm and 255 nm and between 312 nm and 316 nm.

**Uniformity of dosage units** *<6.02>* Perform the test according to the following method: it meets the requirement of the Content uniformity test.

To 1 tablet of Blonanserin Tablets add $V$/25 mL of water to disintegrate, then add 3$V$/5 mL of methanol, and sonicate for 10 minutes. Further, shake for 20 minutes, add methanol to make exactly $V$ mL so that each mL contains about 40 $\mu$g of blonanserin ($C_{23}H_{30}FN_3$). Centrifuge this solution, pipet 8 mL of the supernatant liquid, add exactly 2 mL of the internal standard solution, and use this solution as the sample solution. Separately, weigh accurately about 40 mg of Blonanserin RS, previously dried at 105℃ for 2 hours, and dissolve in methanol to make exactly 100 mL. Pipet 4 mL of this solution, add exactly 10 mL of the internal standard solution, add methanol to make 50 mL, and use this solution as the standard solution. Then, proceed as directed in the Assay under Blonanserin.

Amount (mg) of blonanserin ($C_{23}H_{30}FN_3$)
$= M_S \times Q_T / Q_S \times V / 1000$

$M_S$: Amount (mg) of Blonanserin RS taken

*Internal standard solution*—A solution of isoamyl benzoate in methanol (1 in 8000).

**Dissolution** *<6.10>* When the test is performed at 50 revolutions per minute according to the Paddle method, using 900 mL of a solution prepared by adding 0.05 mol/L disodium hydrogen phosphate TS to 0.05 mol/L potassium dihydrogen phosphate TS and adjusted to pH 6.0 as the dissolution medium, the dissolution rates of a 2-mg tablet and a 4-mg tablet in 30 minutes are not less than 75% and the dissolution rate of a 8-mg tablet in 60 minutes is not less than 75%.

Start the test with 1 tablet of Blonanserin Tablets, withdraw not less than 30 mL of the medium at the specified minute after starting the test, and filter through a membrane filter with a pore size 0.45 $\mu$m. Discard not less than 20 mL of the first filtrate, pipet $V$ mL of the subsequent filtrate, add the dissolution medium to make exactly $V'$ mL so that each mL contains about 2.2 $\mu$g of blonanserin ($C_{23}H_{30}FN_3$). Pipet 4 mL of this liquid, add exactly 1 mL of 0.1 mol/L hydrochloric acid TS, and use this solution as the sample solution. Separately, weigh accurately about 20 mg of Blonanserin RS, previously dried at 105℃ for 2 hours, and dissolve in methanol to make exactly 200 mL. Pipet 4 mL of this solution, add a mixture of the dissolution medium and 0.1 mol/L hydrochloric acid TS (4:1) to make exactly 250 mL, and use this solution as the standard solution. Perform the test with exactly 40 $\mu$L each of the sample solution and standard solution as directed under Liquid Chromatography *<2.01>* according to the following conditions, and determine the peak areas, $A_T$ and $A_S$, of blonanserin in each solution.

Dissolution rate (%) with respect to the labeled amount of blonanserin($C_{23}H_{30}FN_3$)
$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 9$

$M_S$: Amount (mg) of Blonanserin RS taken
$C$: Labeled amount (mg) of blonanserin ($C_{23}H_{30}FN_3$) in 1 tablet

*Operating conditions*—
Proceed as directed in the operating conditions in the Assay under Blonanserin.
*System suitability*—
System performance: When the procedure is run with 40 $\mu$L of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of blonanserin are not less than 8000 and not more than 2.0, respectively.
System repeatability: When the test is repeated 6 times with 40 $\mu$L of the standard solution under the above operating conditions, the relative standard deviation of the peak area of blonanserin is not more than 2.0%.

**Assay** Weigh accurately the mass of not less than 20 Blonanserin Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 4 mg of blonanserin ($C_{23}H_{30}FN_3$), add 4 mL of water to moisten, add 60 mL of methanol, and sonicate for 10 minutes. Further, shake for 20 minutes, add methanol to make exactly 100 mL, and centrifuge. Pipet 8 mL of the supernatant liquid, add exactly 2 mL of the internal standard solution, and use this solution as the sample solution. Separately, weigh accurately about 40 mg of Blonanserin RS, previously dried at 105℃ for 2 hours, and dissolve in methanol to make exactly 100 mL. Pipet 4 mL of this solution, and add exactly 10 mL of the internal standard solution, add methanol to make 50 mL, and use this solution

as the standard solution. Proceed as directed in the Assay under Blonanserin.

$$\text{Amount (mg) of blonanserin } (C_{23}H_{30}FN_3) = M_S \times Q_T / Q_S \times 1/10$$

$M_S$: Amount (mg) of Blonanserin RS taken

*Internal standard solution*—A solution of isoamyl benzoate in methanol (1 in 8000).

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

***Add the following to 9.01 Reference Standards (1).***

Blonanserin RS