

	AUROVITAS PHARMA TAIZHOU CO.,LTD. No.196, Xiangtai Road, China Medical City, Taizhou, Jiangsu Province, China / 安若维他药业泰州有限公司 中国江苏省泰州市 中国医药城祥泰路 196 号
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## RAW DATA SHEET

(In-process / 中间控制)

Product Name / 产品名称: PROLONGED-RELEASE TAMSULOSIN CAPSULES BP 0.4 mg / 坦索罗辛缓释胶囊 BP 0.4 mg

Product Code / 产品编号	SCAVTA1000	A.R. No. / 分析报告编号	AVTIP25000219
Batch No. / 批号	ATM0025012	Batch Size / 批量大小	798.000 KG
Mfg. Date / 生产日期	Nov-2025	Exp. Date / 有效期至	Oct-2027
Specification No. / 质量标准编号	IPS/SCAVTA1000-0	STP No. / 标准检测规程编号	AVT-STP-FP-SCAVTA1A00

## 1) Test Name: Description / 性状

No Data Transfer Methods are configured

## Work Sheet Fields

Instrument (Instrument ID): Semi-micro Balance / 半微量天平(QC-BAL-006)

W.S. Value	6064093(New Usage)	W.S. Field	Balance ID / 天平 ID
Calibrated On	07-Dec-2025	Calibration Due Date	08-Dec-2025
Used From	07-Dec-2025 11:16	Used Up to	07-Dec-2025 11:19
Used For	Description / 性状	Sample Reference No.	AVTIP25000219
Comment(s)	--		

Spread evenly about **1.3826** (1 to 2) g of sample on a butter paper or on a watch glass. Observe the details

in diffuse daylight against white and black background (Colour, Nature of powder, Any extraneous matter).

在黄油纸或表面皿上均匀地涂抹约 1 至 2 g 样品。在白色和黑色背景的漫射日光下观察细节（颜色、粉末性质、任何外来物质）。

## Reference Document(s)

S. No.	Document Code	Document Description
1	AVTIP25000219-性状.pdf	AVTIP25000219-性状.pdf

Q1	White pellets / 白色颗粒
Q2	Off-white pellets / 类白色颗粒
Q3	Does not comply / 不符合规定

Observation: (EWS001\_TI912): Q2

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Observed Quality: Off-white pellets / 类白色颗粒

Pass Limit Description: White to off-white pellets / 白色至类白色颗粒

Result: Pass

1	Analysed By	oakley/继伟.zhou/周	07-Dec-2025 11:57	---
2	Accepted By	sofia / 静.zhang / 张	08-Dec-2025 08:20	---
3	Accepted By	marina / 勉.li / 李	08-Dec-2025 10:11	---
4	Accepted By	elsa/海霞.diao/刁	08-Dec-2025 10:58	---
5	Accepted By	zona/辉.xiao/肖	08-Dec-2025 11:22	---

## 2) Test Name: Water (By KF) / 水分 (KF 法)

No Data Transfer Methods are configured

## Work Sheet Fields

Instrument (Instrument ID): Semi-micro Balance / 半微量天平(QC-BAL-006)			
W.S. Value	6064094 (New Usage)	W.S. Field	Balance ID / 天平 ID
Calibrated On	07-Dec-2025	Calibration Due Date	08-Dec-2025
Used From	07-Dec-2025 11:20	Used Up to	07-Dec-2025 11:32
Used For	Water (By KF) / 水分 (KF 法)	Sample Reference No.	AVTIP25000219
Comment(s)	--		

## Instrument (Instrument ID): KF Moisture Tester / 卡尔费休水分测定仪(QC-KFM-001)

W.S. Value	6064095 (New Usage)	W.S. Field	KF Titrator ID / KF 滴定仪 ID
Calibrated On	07-Dec-2025	Calibration Due Date	08-Dec-2025
Used From	07-Dec-2025 11:20	Used Up to	07-Dec-2025 11:32
Used For	Water (By KF) / 水分 (KF 法)	Sample Reference No.	AVTIP25000219
Comment(s)	--		

Chemical / Reagent Name: Methanol anhydrous / 无水甲醇

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### RAW DATA SHEET

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Product Name / 产品名称: PROLONGED-RELEASE TAMSULOSIN CAPSULES BP 0.4 mg / 坦索罗辛缓释胶囊 BP 0.4 mg

Product Code / 产品编号	SCAVTA1000	A.R. No. / 分析报告编号	AVTIP25000219
Batch No. / 批号	ATM0025012	Batch Size / 批量大小	798.000 KG
Mfg. Date / 生产日期	Nov-2025	Exp. Date / 有效期至	Oct-2027
Specification No. / 质量标准编号	IPS/SCAVTA1000-0	STP No. / 标准检测规程编号	AVT-STP-FP-SCAVTA1A00

W.S. Value	L/M/00225010/03/013 (New Usage)	W.S. Field	Chemicals ID-1/ 化学制品 ID-1
Chemical / Reagent Issue No.	L/M/00225010/03	Batch No.	20241118
Valid up to	03-Dec-2026	Qty. Value	50 ml
Sample Reference No.	AVTIP25000219	Comment(s)	--

Chemical / Reagent Name: HYDRANAL™-容量法滴定剂

W.S. Value	L/H/02125006/08/002(New Usage)	W.S. Field	Chemicals ID-2/ 化学制品 ID-2
Chemical / Reagent Issue No.	L/H/02125006/08	Batch No.	P0640
Valid up to	04-Dec-2026	Qty. Value	3 ml
Sample Reference No.	AVTIP25000219	Comment(s)	--

Determine the “Water Content” on **0.1985** 0.2 g of the crushed powdered beadlets.

测定 0.2 g 粉碎粉末状微丸的“水分”。

#### Reference Document(s)

S. No.	Document Code	Document Description
1	AVTIP25000219-水分.pdf	AVTIP25000219-水分.pdf

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	Water content / 水分含量	W	EWS001_TK366	1.00 % m/m

Formula: (W)

UOM (R): % m/m

No. of Decimals: 2

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Calculated Value: 1.00 % m/m

Pass Limit Description: Not more than 7.0 % m/m / 不超过 7.0 % m/m

Result: Pass

1	Analysed By	oakley/继伟.zhou/周	07-Dec-2025 11:57	---
2	Accepted By	sofia / 静.zhang / 张	08-Dec-2025 08:20	---
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3) Test Name: Each 399.0 mg of blended pellets contains Tamsulosin hydrochloride (C20H28N2O5S, HCl) / 每 399.0 mg 混料微丸含盐酸坦索罗辛 (C20H28N2O5S, HCl)(Group Name: Blend Uniformity (By HPLC) / 混合均匀性 (HPLC 法) )

No Data Transfer Methods are configured

#### Work Sheet Fields

W.S. Value	Refer to AVTIP25000219 Assay (Bypassed)	W.S. Field	INT HPLC ID / INT 液相仪 ID
Comment(s)	N/A		

Column Name: XTERRA RP18

W.S. Value	QLC0226/A016/Q001/U0002 (New Usage)	W.S. Field	INT Column ID / 仪器 色谱柱 ID
Column No.	QLC0226	Sample Reference No.	AVTIP25000219
Comment(s)	--		

W.S. Value	Refer to AVTIP25000219 Assay (Bypassed)	W.S. Field	PMP pH meter ID / pH 计 ID
Comment(s)	N/A		

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Page No.: 4 of 123

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