

Certificate of Analysis

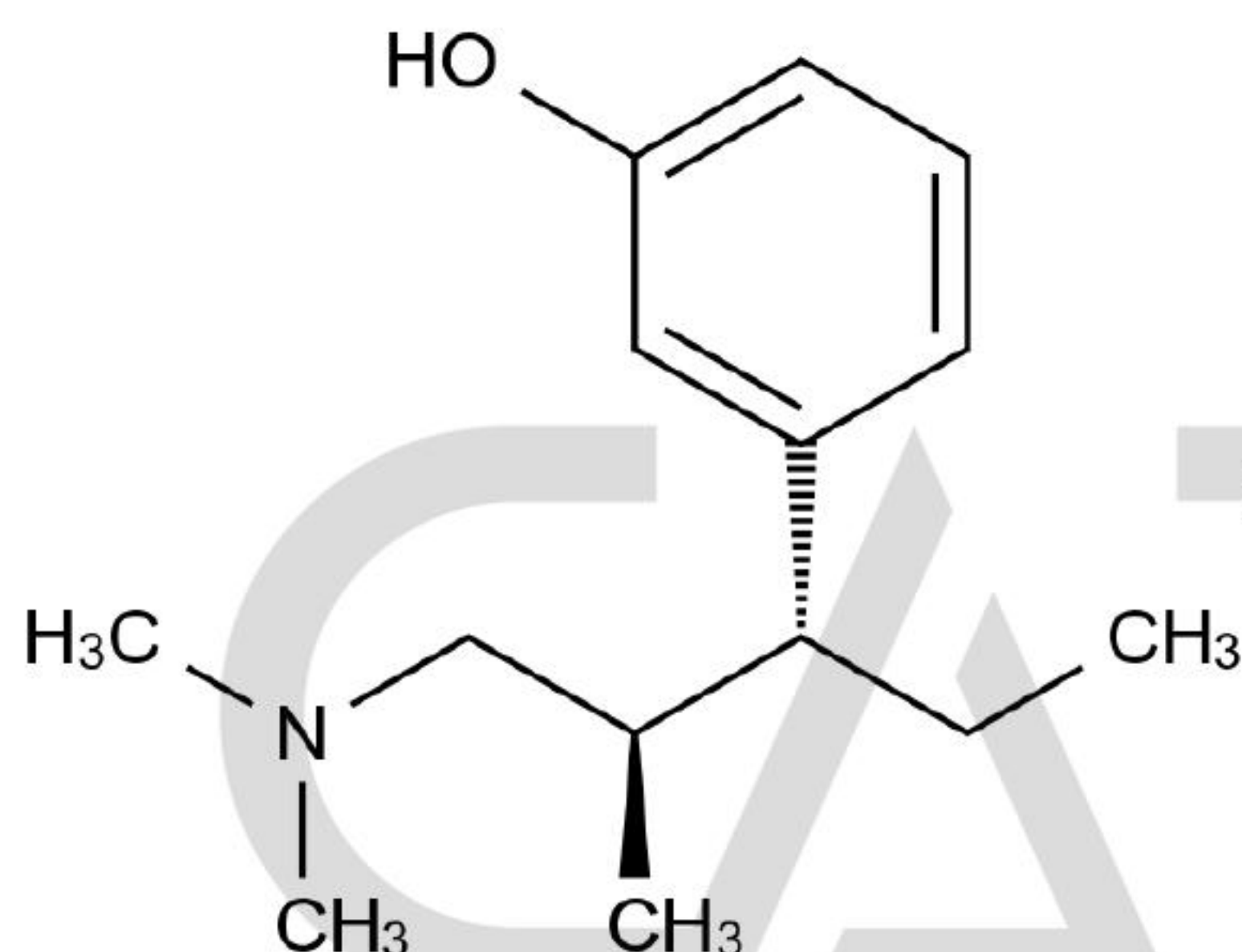
Reference Material & Standard

Product Name:	Tapentadol Hydrochloride	Catalogue Number:	CCAD303902
Synonyms:	N/A	Lot Number:	0412-RF-0028
CAS Number:	175591-09-0	Expiry Date:	Apr 15, 2028
Molecular Formula:	C ₁₄ H ₂₃ NO HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	221.34 36.46		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.473%
Loss on Drying	TGA	0.0906%
Assay		99.4%
Uncertainty		±2.0%

Comment:

1. The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$$

Loss on Drying is considered as absolute effect, HPLC purity is considered as relative effect.

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by:

Nice

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Apr 16, 2024

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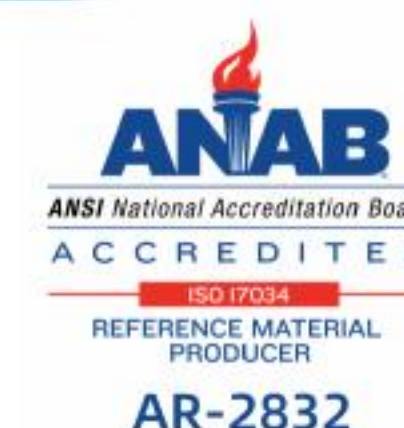
Add: 3rd Floor, Building B, No.179, Guangpu Rd East, Huangpu District, Guangzhou, China

Tel: +86-20-81960175

Email: supports@cato-chem.com

Web: <https://www.cato-chem.com>

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