Ropinirole Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	28–Jun–2019
Official Date	01–Jul–2019
Expert Committee	Chemical Medicines Monographs 4
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 4 Expert Committee has revised the Ropinirole Extended-Release Tablets monograph. The purpose for the revision is to add *Dissolution Test 4* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution tests.

- *Dissolution Test 4* was validated using the BDS Hypersil C18 brand of L1 column. The typical retention time for ropinirole is about 2.2 min.

The revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

The Ropinirole Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Claire Chisolm, Scientific Liaison (301-230-3215 or cnc@usp.org).

▲**Table 6**▲ (RB 1-Jul-2019) *(continued)*

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Ropinirole methylene dimer[d]	1.82	1.0	0.5
Propylidene ropinirole[e, f]	1.96	2.0	—
Any individual unspecified degradation product	—	1.0	0.2
Total degradation products	—	—	1.5

[a] 4-[2-(Propylamino)ethyl]indolin-2-one.
[b] 4-[2-(Dipropylamino)ethyl]-1-(hydroxymethyl)indolin-2-one.
[c] *N*-[2-(2-Oxoindolin-4-yl)ethyl]-*N*-propylpropan-1-amine oxide.
[d] 4-[2-(Dipropylamino)ethyl]-3-({4-[2-(dipropylamino)ethyl]-2-oxo-2,3-dihydro-1*H*-indol-3-yl}methyl)-2,3-dihydro-1*H*-indol-2-one.
[e] (*Z*)-4-[2-(Dipropylamino)ethyl]-3-propylideneindolin-2-one.
[f] Process impurity included in the table for identification only. Process impurities are controlled in the drug substance and are not to be reported or included in the total impurities for the drug product.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.
- **LABELING:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Ropinirole Hydrochloride RS
  USP Ropinirole Related Compound B RS
  4-[2-(Dipropylamino)ethyl]indoline-2,3-dione hydrochloride.
  $C_{16}H_{22}N_2O_2 \cdot HCl$ 310.82

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