

Certificate

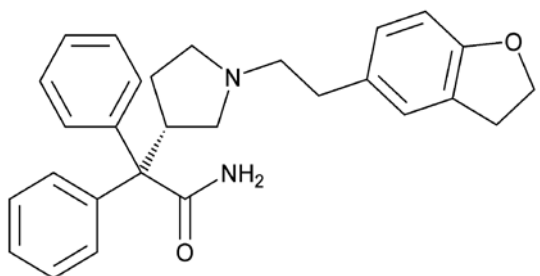
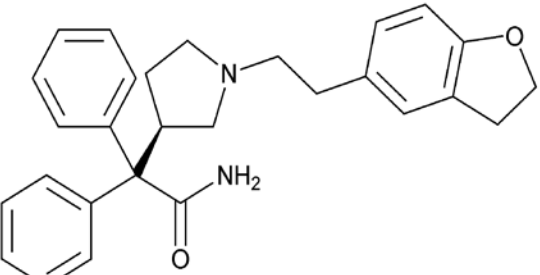
DARIFENACIN CHIRAL PEAK IDENTIFICATION MIXTURE

(A mixture containing darifenacin hydrobromide, (S)-2-{1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide, and about 1% of darifenacin R-isomer, (R)-2-{1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide)

USP Catalog No.: 1164211

USP Lot No.: F04970

Only compendial components as listed in the monograph are shown below.

<i>(S)-2-{1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide</i>	
 <p>• HBr</p>	CAS No.: 133099-07-7
	Molecular Formula: C ₂₈ H ₃₀ N ₂ O ₂ · HBr
	Molecular Weight: 507.46
<i>(R)-2-{1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide</i>	
 <p>• HBr</p>	CAS No.: 1092800-15-1
	Molecular Formula: C ₂₈ H ₃₀ N ₂ O ₂ · HBr
	Molecular Weight: 507.46

LABEL TEXT

For use with specified USP compendial tests.
Not for use as a drug. See SDS prior to use at
www.usp.org/sds.



Lot: F04970

USP REFERENCE STANDARD

DARIFENACIN CHIRAL PEAK IDENTIFICATION MIXTURE 25 mg

(A mixture containing darifenacin hydrobromide, (S)-2-[1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl]-2,2-diphenylacetamide hydrobromide, and about 1% of darifenacin R-isomer, (R)-2-[1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl]-2,2-diphenylacetamide hydrobromide)



Warning! Harmful if swallowed. Causes serious eye irritation.

Do not dry. Keep container tightly closed. Protect from light. Store in a refrigerator.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666

Cat. No. 1164211 Material mfd. in India

Wash thoroughly after handling. Wear eye/face protection. If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Dispose of contents/container in accordance with local/regional/national/international regulations.

Jeri L. Joth

Quality Assurance

Calculation Value

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

LEGAL NOTICE

USP WARRANTS GOOD TITLE TO USP REFERENCE STANDARDS ON DISPATCH FROM USP. THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY WARRANTY THAT THE PRODUCTS, INCLUDING THIS CERTIFICATE, ARE OF MERCHANTABILITY QUALITY. USP'S LIABILITY ARISING OUT OF OR RELATING TO THE SUPPLY OF USP REFERENCE STANDARDS AND THIS CERTIFICATE SHALL IN NO EVENT INCLUDE LOSS OF PROFITS, COST OF PROCURING SUBSTITUTE GOODS OR SERVICES, OR ANY INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES OF ANY KIND, EVEN IF USP IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, USP DOES NOT WARRANT THAT THE USE OR RESALE OF USP REFERENCE STANDARDS, INCLUDING THEIR USE TO PERFORM TESTS AND ASSAYS PUBLISHED BY USP, WILL NOT INFRINGE UNITED STATES OR ANY OTHER PATENTS.

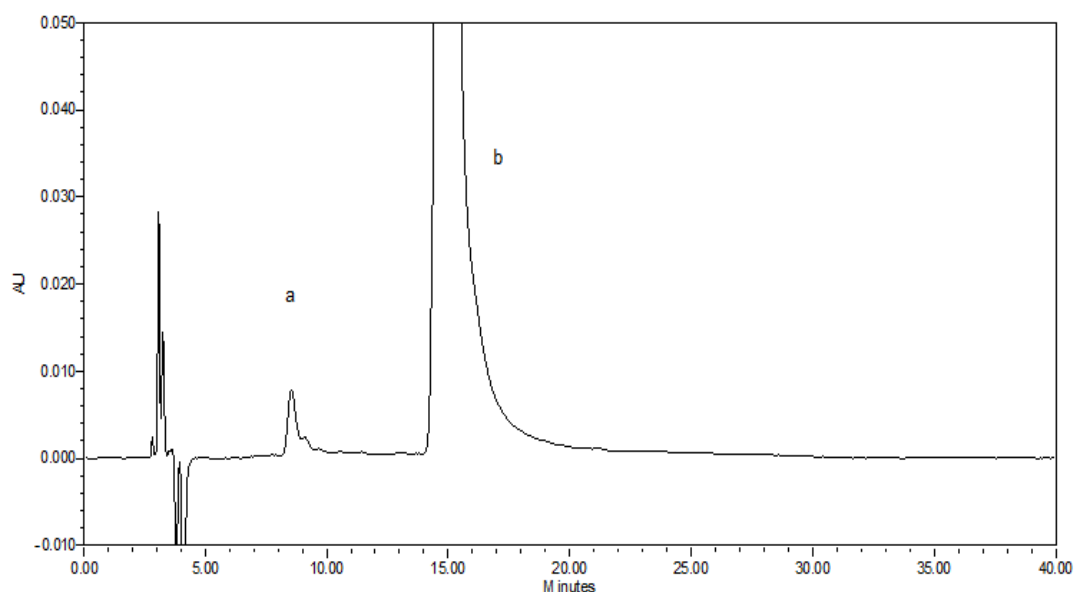
USP Reference Standards are not intended for use as drugs, dietary supplements, or as medical devices.

This certificate may not be reproduced without the express written permission of USP.

Typical Chromatogram

USP Darifenacin Chiral Peak Identification Mixture RS

Catalog Number: 1164211
Lot: F04970
Monograph: Darifenacin Hydrobromide
Publication: PF 42(2)
Test: Enantiomeric Purity
Sample: Darifenacin Chiral Peak Identification Mixture



a - Darifenacin (*R*)-Isomer

b - Darifenacin

This chromatogram is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.