

Certificate

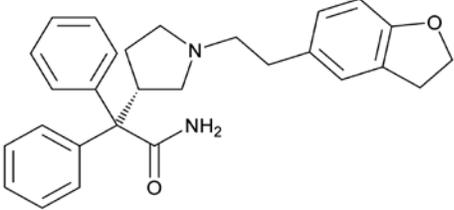
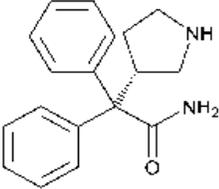
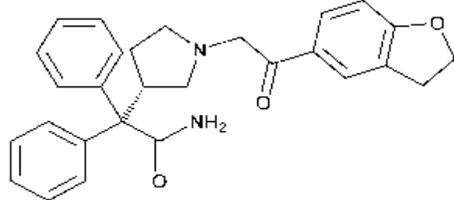
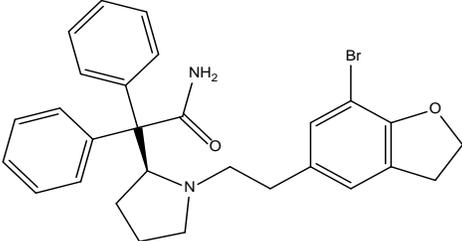
DARIFENACIN PEAK IDENTIFICATION MIXTURE

(A mixture consisting of Darifenacin Hydrobromide (99%), Dealkyl darifenacin (0.3%), Ketodarifenacin (0.2%), and 7-Bromo darifenacin (0.3%))

USP Catalog No.: 1164222

USP Lot No.: F04980

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

<i>(S)</i> -2-{1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide	
 $\cdot \text{HBr}$	CAS No.: 133099-07-7
	Molecular Formula: $\text{C}_{28}\text{H}_{30}\text{N}_2\text{O}_2 \cdot \text{HBr}$
	Molecular Weight: 507.46
<i>(S)</i> -2,2-Diphenyl-2-(pyrrolidin-3-yl)acetamide (Dealkyl darifenacin)	
	CAS No.: 134002-25-8
	Molecular Formula: $\text{C}_{18}\text{H}_{20}\text{N}_2\text{O}$
	Molecular Weight: 280.36
<i>(S)</i> -2-{1-[2-(2,3-dihydrobenzofuran-5-yl)-2-oxoethyl]pyrrolidin-3-yl}-2,2-diphenylacetamide (Ketodarifenacin)	
	CAS No.: 133034-07-8
	Molecular Formula: $\text{C}_{28}\text{H}_{30}\text{N}_2\text{O}_3$
	Molecular Weight: 440.54
<i>(S)</i> -2-{1-[2-(7-Bromo-2,3-dihydro-1-benzofuran-5-yl)ethyl]pyrrolidin-yl}-2,2-diphenylacetamide (7-Bromo darifenacin)	
	CAS No.: N/A
	Molecular Formula: $\text{C}_{28}\text{H}_{29}\text{BrN}_2\text{O}_2$
	Molecular Weight: 505.44

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.



USP REFERENCE STANDARD

DARIFENACIN PEAK IDENTIFICATION MIXTURE 25 mg

(A mixture consisting of darifenacin hydrobromide (99%), dealkyl darifenacin (0.3%), ketodarifenacin (0.2%), and 7-Bromo darifenacin (0.3%))



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. 1164222 Material mfd. in India

Wash thoroughly after handling. Wear eye protection/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

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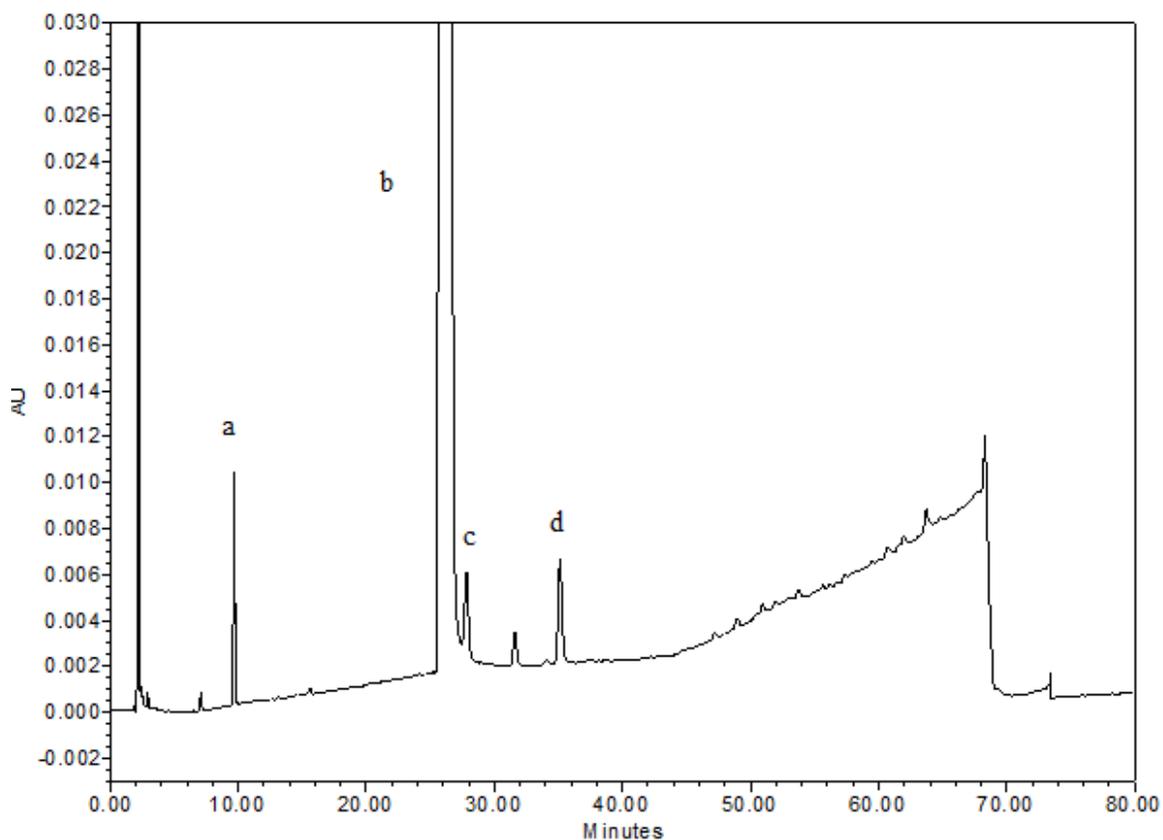
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Typical Chromatogram

USP Darifenacin Peak Identification Mixture RS

Catalog Number: 1164222
Lot: F04980
Monograph: Darifenacin Hydrobromide
Publication: PF 42(2)
Test: Organic Impurities
Sample: Darifenacin Peak Identification Mixture



- a - Dealkyl darifenacin
- b - Darifenacin
- c - Ketodarifenacin
- d - 7-Bromo darifenacin

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