

GENERAL CONFORMITY CERTIFICATION

This General Conformity Certification is being provided pursuant to section 14(a) of the Consumer Product Safety Act as amended, 15 U.S.C. 2063(a), and section 102(a)(1) of the Consumer Product Safety Improvement Act of 2017 for products contained in child-resistant packaging in accordance with the Poison Prevention Packaging Act and implementing regulations. See 16 C.F.R. § 1700.14.

Identification of the product covered by the certificate.	CRESEMBA ® (isavuconazonium sulfate) Capsules for oral administration • 186 mg isavuconazonium sulfate / capsule in an aluminum blister (equivalent to 100 mg of Isavuconazole / capsule), seven (7) capsules per blister sheet
Regulation(s), rule(s), ban(s), and/or standard(s) to which this product is being certified:	(NDC 0469-0520-14) 16 C.F.R. § 1700.14(a) (10)
Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:	Astellas US Technologies, Inc. 1 Astellas Way Northbrook, IL 60025 Phone number: 224-205-8800
Individual maintaining test records upon which this certification is based:	Astellas US Technologies, Inc. 1 Astellas Way Northbrook, IL 60025 Email: medinfo.us@astellas.com Phone number: 224-205-8800
Date and place where this product was manufactured:	Each manufactured lot is labeled with the National Drug Code (NDC) number and a unique lot number which are used to identify the date and place of manufacture. For additional information, please email medinfo.us@astellas.com
Date and place where this product was tested for compliance with the regulation(s), rule(s), ban(s) and/or standard(s) cited above and test report(s) on which certification is based:	1001 Forest Trail Sugar Grove, IL USA 60554 Test Report: • 1371-143, dated February 18. 2015
Third-party laboratory that conducted testing upon which this certification is based: Effective date:	Bitner Associates, Inc. 1001 Forest Trail Sugar Grove, IL USA 60554 708-738-5598 October 1, 2018
Literate date.	00.000.1, 2010