9 de Mayo de 2017

A la Dirección técnica de Alpes Chemie S.A.

El titular que suscribe certifica que el producto **Cosopt** solución oftálmica con principio activo clorhidrato de dorzolamida 20 mg/ml (+) maleato de timolol 5 mg/ml (registro ISP Nro. F-1875/14) el cual se exporta a Chile a la empresa Alpes Chemie S.A., utiliza el material de empaque primario aprobado por el ISP bajo resolución Nro. 001342 del día 21.02.2007.

El fármaco dispone de un sistema de goteo uniforme, donde no escurre excedente y la gota es extraída de forma vertical al goteo.
La solución oftálmica de clorhidrato de dorzolamida y maleato de timolol se suministrará en un recipiente (OCUMETER® PLUS) que consta de un cuerpo moldeado de plástico por inyección de una sola pieza, cierre inferior y un único conjunto de tapa de 2 piezas.
El cuerpo del envase se moldea a partir de una resina de polietileno de alta densidad (HDPE), que proporciona rigidez al recipiente, una punta cuentagotas oftálmica sellada, un accesorio de rosca para ajuste de la tapa y una región flexible que se puede presionar para que una gota sea dispensada.

Por favor verificar el documento anexo: Common Technical Document Page y 3.2.P.7 Container Closure System

Lilian Patricia Bento Sabeh

Atentamente,
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Common Technical Document Page
Section 3.2.P.7 (Annotated Page)

7. Container Closure System

7.1 Description

The components for the OCUMETER™ PLUS container closure system are molded and assembled by either Betts UK Limited, United Kingdom; Rexam Pharma, France; or by Nypro, France. The assembled OCUMETER™ PLUS components are sterilized by gamma irradiation at IONISOS, Zone Industrielle de l'Aubree, 72300 SABLE SUR SARTHE, France using a validated load pattern and sterilization cycle.

Dorzolamide hydrochloride and timolol maleate ophthalmic solution will be supplied in a container consisting of a single piece injection molded plastic body, bottom closure, and a unique 2-piece cap assembly. See Reference for diagrams of the OCUMETER™ PLUS dispensing container. The body is molded from high density polyethylene (HDPE) resin, PURELL 5037L (formerly LUPOLEN 5031 L), which provides a rigid storage container, a sealed ophthalmic dropper tip, a threaded fitting for a cap, and a flexible region that can be depressed to cause a drop to be dispensed. PURELL 5037L is supplied by BASELL (formerly Elenac) and has been tested for conformance to the requirements of the EP and USP chapters. The bottom closure and the inner part of the 2-piece cap is molded from the same HDPE as the body. The bottom closure is mechanically inserted after filling and heat-sealed.

The outer cap is molded from either CYCOLOY C1204HF, supplied by GE Plastics Europe, CYCOLAC S701-281699F, supplied by GE Plastics Europe, or from a blend of 68% POLYSTYROL 168N, 29% POLYSTYROL 427D, supplied by BASF, Germany, and 3% Masterbatch STYRENE MS4294 (3% White Color Concentrate), supplied by Silvergate Plastics LTD, United Kingdom. The design of the two-piece cap mechanism makes puncturing automatic as the patient unscrews the cap in the normal counter-clockwise manner. This activates the container by creating an opening in the sealed internal tip membrane. This is accomplished through the use of a conically shaped piercing point within the cap. After first opening the bottle, the two parts of the cap mechanism are locked and the cap functions as a normal cap in providing a mechanical seal during the usage period. The container provides a drop size range of 35 to 41 mg/drop.

Updated Common Technical Document Page
Section 3.2.P.7 (Clean Page)

7. Container Closure System

7.1 Description

The components for the OCUMETER™ PLUS container closure system are molded and assembled by either Betts UK Limited, United Kingdom; Rexam Pharma, France; or by Nypro, France. The assembled OCUMETER™ PLUS components are sterilized by gamma irradiation at IONISOS, Zone Industrielle de l'Aubree, 72300 SABLE SUR SARTHE, France using a validated load pattern and sterilization cycle.

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