

CLIENTE: PHARMATECH CHILE SPA

BOLETIN DE ANÁLISIS

Producto Terminado
Análisis N°: 18-47322


Nombre producto	: LAGRIMAS ARTIFICIALES X 10ML HIPROMELC	Fecha de recepción	: 07/02/2018
Forma farmacéutica	: Solución oftálmica	Fecha inicio análisis	: 07/02/2018
Presentación	: Est x fco x 10ml	Fecha término análisis	: 26/02/2018
Serie o Lote	: 7F340	Tiempo de análisis	: 14 Dias
Registro I.S.P. N°	: SDM/1803/15	Muestreado por	: Pharma Isa
Cond. almacenamiento	: T° Ambiente no más de 30°C	Muestreado según P.O.S.:	: CC-01
Fecha EPT	: Info No Disponible	Código producto	: PHTARLF011
Versión met. analítica	: NA	T. del lote o unidad de imp.	: 15.930 Est x fco x 10ml
Procedencia	: India	Cantidad recibida	: 22,00Est x fco x 10ml
Fabricante	: AUROLAB	Contramuestras	: (*)
N° Embarque	: KKLHUA85708300	Fecha manufactura	: 17/06/2017
N° de Factura	: EX1718-0370	Fecha vencimiento	: 30/05/2019

ANALISIS	METODO	ESPECIFICACION	RESULTADOS
Descripción	Cliente	Solución viscosa Clara,incolora.	Solución viscosa Clara,incolora.
Valoración	Cliente	0,595%-0,805%	0,713 %
Esterilidad	Cliente	Estéril	Estéril
Volumen	Cliente	NLT 10 ml	Cumple (10,3 mL)

CALIFICACIÓN : "Cumple Especificaciones"

OBSERVACIONES : 1) Este ensayo fue realizado en presencia de controles microbiológicos de medios de cultivo, ambiente, Gabinete de Bioseguridad y/o Cabina de Flujo Laminar

(*)Las contramuestras se retiran despues del proceso de acondicionamiento.

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Aprobado por
JUAN PABLO ISA PARAM
Firmado 28/02/2018
10:14:15

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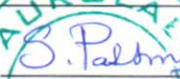
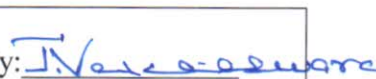
CERTIFICATE OF ANALYSIS

PRODUCT INFORMATION

Product Name : Hypromellose Eye Drops BP 0.7% w/v – 10ml (Lagrimas Artificiales)	Sample received : 40No's
Generic Name : Hypromellose Eye Drops BP 0.7% w/v	Date of Sampling : 17/06/2017
Batch No : 7F340	Date of Completion : 01/07/2017
Manufacturing Date : 2017 - 06	Date of Release : 01/07/2017
Expiry Date : 2019 - 05	Report No : ARF -17/340

ANALYSIS

S. No.	Test Name	Test Result	Acceptance Criteria	Reference to the test method
PHYSICAL ANALYSIS				
1.	Description	Clear, colorless viscous solution	Clear, colorless viscous solution	In-House
2.	Label Checking	Clear & legible	Clear & Legible	In-House
3.	Uniformity of volume (ml)	10.6ml	NLT 10ml	In-House
4.	Specific gravity at 25° C	1.011	1.005 – 1.012 at 25° C	In-House
5.	Refractive index at 25° C	1.3382	1.335 – 1.348 at 25° C	In-House
6.	Viscosity at 25° C (cPs)	50.7 cPs	40cPs – 70cPs at 25° C	In-House
CHEMICAL ANALYSIS				
7.	Identification a. with heating b. with acetic acid and tannic acid	a. The solution is clear on cooling b. A yellowish white flocculent precipitate is produced, which is Dissolved in 6M ammonia Solution.	a. The solution becomes clear on cooling b. A yellowish white flocculent precipitate should be produced. The precipitate should be dissolved in 6M ammonia	BP BP

Analyzed By:  (QC Chemist)	Checked By:  (QC Manager)	Approved By:  (QA Manager)
Date : 01/07/2017	Date : 01/07/2017	Date : 01/07/2017

Lagrimas Artificiales - 10mL

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CERTIFICATE OF ANALYSIS

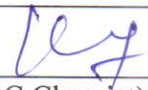
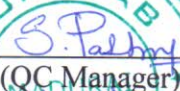
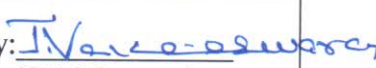
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8.	pH	8.56	8.2 – 8.6	BP
9.	Assay of a. Hydroxy propyl methyl cellulose (%)	0.678%	0.595% - 0.805%	In-House
	b. Chloride (ppm)	4450ppm	4000 – 4900ppm	
10.	Assay of Benzalkonium chloride (%)	0.0105%	0.0090% - 0.0120%	In-House
MICROBIOLOGICAL ANALYSIS				
11	Sterility	No growth	No growth .It has to be sterile.	USP, IP, Ph.Eur.,

This is to certify that the Batch mentioned above complies with BP specification.

Analyzed By:  (QC Chemist)	Checked By:  (QC Manager)	Approved By:  (QA Manager)
Date : 01/07/2017	Date : 01/07/2017	Date : 01/07/2017

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