THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR OPTIFRESHTM (POLYVINYL ALCOHOL 1.4 % W/V AND POVIDONE 0.6 % W/V) OPTHALMIC SOLUTION (EYE DROPS)

Version number 1.0
21 August, 2023

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1. Introduction

Optifresh ophthalmic solution is a clear, colorless to slightly yellowish solution containing the 14 mg polyvinyl alcohol and 6 mg povidone per each mL. Polyvinyl Alcohol and Povidone ophthalmic solution exerts a mechanical, not a pharmacological action. The viscosity and lubricating enhancing agent is polyvinyl alcohol. Optifresh ophthalmic solution lowers the surface tension at the surface of the corneal epithelium, providing a lubricant layer that enhances patient comfort. Also, can help to restore normal tear film tonicity and to act as a wetting agent for lipid-, aqueous- and mucin-deficient eyes. Optifresh ophthalmic solution is approved in Tanzania for use in all ages.

Product details

Registration number	TAN 23 HM 0249
Brand name	Optifresh
Generic name, strength, and form	Polyvinyl Alcohol -14mg/ml Povidone- 6mg/ml
ATC classification	Artificial tears and other indifferent preparations, ATC code: S01AX20
Distribution category	POM
Country of origin	India
Associated product	N/A
Marketing Authorization Holder	Jamjoom Pharmaceuticals Plot No. ME1:3, Phase V, Industrial City P.O. Box 6267 Jeddah-21442 Kingdom of Saudi Arabia
Local Technical Representative	Phillips Pharmaceutical (Tanzania) Limited Plot No. 111 Nyerere Road, Vingunguti Industrial Area 737 Dar-Es-Salaam

1.1 Assessment procedure

The application for registration of Optifresh was submitted on DD/MM/YYYY. The product underwent full assessment. Assessment was completed in 4 (four) rounds of evaluation and the product was registered on 01/06/2023.

1.2 Information for users

Visual description of the finished product	Clear ,Colourless to slightly Yellowish solution free from any visible particles
Primary packing material	LDPE bottle fitted with LDPE nozzle and HDPE screw cap
Secondary packing materials	Printed carton box
Shelf-life and storage condition	36 months, Do not store above 30 °C. Use within 4 weeks of opening
Route of administration	Ocular

Therapeutic indications	As a lubricant and artificial tear in dry eye and other ocular irritation syndromes

2. Labelling and product information

Summary of product characteristics
The SmPC included all the relevant information to ensure correct and safe use of the medicine by healthcare providers. The complete SmPC can be accessed here.

Package insert/leaflet
The package insert is confirmed to be derived from the SmPC and contains sufficient data for the end user. Since the product is POM, the package insert contains full prescribing information as per SmPC.

Container labels
The product label information is presented in English. Details in the secondary pack label include:

Brand name: Optifresh

Composition: Polyvinyl Alcohol -14mg/ml and Povidone- 6mg/ml

Pack size: 10 mL

Manufacturing details: batch number, manufacturing date, and expiry date

Storage conditions: Do not above 30°C

Manufacturer address: physical address of release site

Unique identifier: Not applicable

Special warnings/precautions or instructions for use: Not applicable

The details of the primary pack include:

Brand name and strength: Optifresh

Manufacturing details: batch number, manufacturing date and expiry date

Name of manufacturer: Jamjoom Pharmaceuticals Co.

The content of the primary and secondary labels was aligned to the requirements of the Part V of the Compendium: Guidelines on Format and Content of Product Labels for Medicinal products. The label contains sufficient information for proper identification of the medicine and post marketing follow up of the product.

Mock labels are appended as annex I.

3. Scientific discussion

Quality of Active Pharmaceutical Ingredients

Information on quality of the API was submitted in form of DMF.

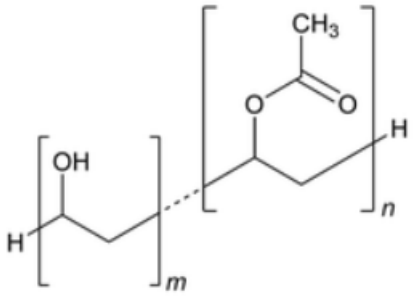
General Information

Polyvinyl Alcohol API is compendia in USP.

Molecular formula:
$[CH_2CH(OH)]_n$

Chemical name:
Polyvinyl alcohol

Structure:



General properties

Polyvinyl Alcohol is a white to cream coloured granules or white to cream coloured powder**.** Freely soluble in water at room temperature. Discussion on polymorphism is not provided and is not required as API dissolved in the final product.

Manufacture

Polyvinyl Alcohol API manufacturer is Merck KGaA Frankfurter Str. 25064271 Darmstadt Germany. The manufacturing complies with GMP requirements as evidenced by the GMP certificates issued by <state the issuing authority>. Polyvinyl Alcohol API is manufactured by chemical synthesis using conventional techniques. Sufficient controls of quality of materials and in-process checks were employed throughout the manufacturing process.

Specifications

The API specifications were set as per USP standards and ICHQ3A. The parameters monitored during quality control are: description, solubility, identification, limit of methanol (methyl alcohol), limit of methyl acetate, loss on drying, residue on ignition, acid value, viscosity, water insoluble substances, pH, degree of hydrolysis. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The re-test period of Polyvinyl Alcohol API is 24 months when packed in polyethylene bottle with storage condition 'stored in its original, unopened container under normal warehousing conditions'.

Povidone

Information on quality of the API was submitted in form of CEP.

General Information

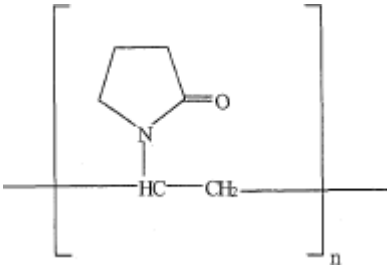
Povidone API is compendia in Ph.Eur., BP, USP.

Molecular formula: $(C_6H_9NO)_n$

Chemical name:

2-Pyrrolidone, 1 -ethenyl-, homopolymer

Structure:



General properties

Polyvinylpyrrolidone is a white to creamy white, odorless hygroscopic powder, which soluble in water, alcohol, or chloroform. Discussion on polymorphism is not provided and is not required as API dissolved in the final product.

Manufacture

Povidone API manufacturer is ISP Technologies Inc (Site 1: Vuilding 4501, Texas City, Texas 77592, U.S.A and Site 2: 455, North Main Street, Cavert City, KY 42029, U.S.A). The manufacturing complies with GMP requirements as evidenced by the GMP certificates submitted. Povidone API is manufactured by chemical synthesis using conventional techniques. Sufficient controls of quality of materials and in-process checks were employed throughout the manufacturing process.

Specifications

The API specifications were set as per Ph. Eur standards and ICHQ3A. The parameters monitored during quality control are: Description, solubility, identification, K-Value, lead, 2-pyrrolidone, peroxides, formic acid, limit of aldehydes, limit of hydrazine, nitrogen content, residue on ignition, vinylpyrrolidinone, water (KF), pH, and microbiological examination. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The shelf-life period of Povidone API is 36 months when packed in original container with storage condition 'Do not store above 25 ^{o}C'.

Quality of the Finished Pharmaceutical Product

Formulation

Optifresh is a clear, colorless to slightly yellowish solution, free from visible contamination, filled in 10 mL LDPE opaque bottles

Optifresh contains the polyvinyl alcohol and povidone and other ingredients listed here after: chlorobutanol hemihydrate, sodium chloride, sodium hydroxide, hydrochloric acid, water for injection. The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, 8th Edition in terms of function and quantities.

Manufacture

The finished product manufacturers are Jamjoom Pharmaceuticals Company, Plot No. ME1:3, Phase V, Industrial City,P.O. Box 6267, Jeddah-21442,Kingdom of Saudi Arabia. The compliance of the sites to TMDA GMP standards was confirmed through site inspection on 01-02/05/2016.

Specifications

The FPP is non-compendia. The manufacturer controls the quality of the finished product as per in-house standards and ICH requirements. The parameters monitored during quality control are:

Description, identification, filled volume, pH, osmolality, density, assay- polyvinyl alcohol, povidone, and chlorobutanol, particulate matter, sterility, antimicrobial effectiveness testing. Compliance to the standard was established using batch analysis data and stability data.

Stability and container closure system

Stability studies were conducted on 3(three) batches of the finished product stored at 30 ± 2°C & RH: 35 ± 5% RH for 36 months and 40± 2°C & RH: 25% ± 5% RH for 6 months. Based on the stability data presented, the approved shelf-life is 36 months when stored in Low Density Polyethylene (LDPE) Bottle with storage condition 'Do not store above 30 ºC'

After opening of bottle, the product is demonstrated through in-use stability study physically and chemically stable for 30 days when store at temperature not above 30°C.

4. Benefit-Risk Assessment and Conclusion

On basis of the data submitted, the current state of knowledge and compliance to Good Manufacturing Practice, the benefit of the product outweighs the risks associated with its use when used in accordance to the summary of product characteristics. Optifresh is recommended for registration.

5. Post-approval updates

Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date

Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response

Re-registration applications

Application for renewal of registration was submitted on <DDMMYYYY>. The application was finalized in <number> rounds of evaluation. The product was confirmed to still be compliant to

the standards of quality, safety and efficacy, hence registration was renewed on <DDMMYYYY>.

PART 5: CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

Annex I: Mock up labels;

Primary pack label;

Secondary pack label:

Africa

Effective date: 03/10/2022