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MINISTRYOFHEALTH

TANZANIAMEDICINES ANDMEDICALDEVICESAUTHORITY

PUBLIC ASSESSMENT REPORT FOR FICOCYTE (FILGRASTIM 30 MU/0.5 mL) SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

Version number 1
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1. Introduction

Ficocyte is a generic medicine of Neupogen. Ficocyte is an Immunostimulants medicine belonging to L03AA02 ATC code group description> group. Ficocyte exerts its activity by <briefly describe the mechanism of action>. Ficocyte is approved in Tanzania for use in adults or children.

1.1 Product details

Registration number	TAN 21 HM 0094
Brand name	Ficocyte
Generic name, strength and form	Filgrastim
ATC classification	L03AA02, Granulocyte colony-stimulating factor
Distribution category	POM
Country of origin	Vietnam
Associated product	State any other product of formulation, strength or site that is linked or associated with the product if applicable
Marketing Authorization Holder	Nanogen Pharmaceutical Biotechnology Co., Limited Lot I – 5C Saigon Hitech Park, Tang Nhon Phu A Ward, District 9, HCM City VIETNAM Tel: +84 08 37309931/ 37309940 Email: info@nanogenpharma.com
Local Technical Representative	Atlas Phamacy P.O. Box 34123, Dar es Salaam, Tel: +255 2667111 Email: atlas@tz2000.com / vitusatlas@tz2000.com

1.2 Assessment procedure

The application for registration of Ficocyte was submitted on <2012>. The product underwent full assessment. Assessment was completed in four rounds of evaluation. Ficocyte was registered on 29th March, 2021

1.3 Information for users

Visual description of the finished	clear, colorless solution

product	
Primary packing material	0.5 mL colorless glass prefilled syringe, with needle available, plastic plunger
Secondary packing materials	Carton box
Shelf-life and storage condition	24 months Store in the refrigerator at 2ºC – 8ºC. Do not freeze. Protect from light.
Route of administration	SC/IV injection
Therapeutic indications	FICOCYTE is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy FICOCYTE is indicated for the mobilisation of peripheral blood progenitor cells (PBPC)In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an ANC of _ 0.5 x 109/L, and a history of severe or recurrent infections, long term administration of FICOCYTE is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. FICOCYTE is indicated for the treatment of persistent neutropenia (Absolute neutrophil count (ANC) less than or equal to 1.0 x109/L) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

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: Ficocyte

Composition: Filgrastim 30 MU/0.5 mL, Benzyl Alcohol 0.9% as preservative

Pack size: 1 x 0.5 mL pre-filled syringe

Manufacturing details: <batch number, manufacturing date, expiry date>

Storage conditions: Store in the refrigerator at 2ºC – 8ºC. Do not freeze. Protect from light

Manufacturer address: Nanogen Pharmaceutical Biotechnology Co., Limited, Lot I – 5C Saigon Hitech Park, Tang Nhon Phu A Ward, District 9, HCM City,VIETNAM

Unique identifier: NA

Special warnings/precautions or instructions for use: NA

The details of the primary pack include:

Brand name and strength: Ficocyte (Filgrastim 30 MU/0.5 ml)

Manufacturing details: <batch number, manufacturing date, expiry date>

Name of manufacturer: Nanogen Pharmaceutical Biotechnology Co., Limited

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.

Describe any approved deviation to the requirements and the justification for the deviation.

Mock labels are appended as annex I

3. Scientific discussion

Quality of Active Pharmaceutical Ingredient(s)

Information on quality of the API was submitted in form of Full details.

General properties

Filgrastim API is compendia in USP/BP.

Molecular formula: C845H1339N223O243S9

Chemical name: is a recombinant human granulocyte-colony stimulating factor (G-CSF) produced in E. coli as a non-glycosylated protein containing an N-terminal methionyl extension

Structure:

Critical physico-chemical properties of the API were Clear colourless odourless transparent colourless liquid with moleqular weight ranged from 18 to 20 kDa and pH of 3.5 to 4.5

Manufacture

The API manufacturing site, Life Technologies, 5791 Van Allen Way, Carlsbad, CA, USA 92008 was noted to comply with WHO GMP requirements as evidenced by the GMP certificate issued by <state the issuing authority>. Filgrastim API is manufactured by fermentation 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 in-house standards and ICHQ3A. The parameters monitored during quality control are: appearance, pH, total protein, identification, molecular weight, purity, host cell and vector derived DNA, host cell derived protein, potency, sterility and bacterial endotoxin. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The re-test period of Filgrastim API is 12 months when packed in bottles and stored at -20^{o}C/ 65% RH.

Quality of the Finished Pharmaceutical Product

Formulation

Ficocyte is a clear, colorless solution packed in colorless glass pre-filled syringe with needle in a plastic plunger. Describe the diluent, measuring devices or any delivery device if applicable. Ficocyte contains Filgrastim and other ingredients listed here after Sodium acetate trihydrate, Benzyl alcohol, Polysorbate 80 and water for injection. The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, Edition 8th in terms of function and quantities.

Ingredient, Benzyl alcohol is of safety concern therefore appropriate warnings were included in the product label.

Manufacture

The finished product was manufactured at Nanogen Pharmaceutical Biotechnology Co. Limited, Lot I – 5C Saigon Hitech Park, Tang Nhon Phu A Ward, District 9, HCM City, Vietnam. The compliance of the site to TMDA GMP standards was confirmed through site inspection/desk-review> on <date of GMP compliance>.

Specifications

The FPP is non-compendia. The manufacturer controls the quality of the finished product as per in-house and ICHQ3B requirements. The parameters monitored during quality control are: appearance, identification, volume, pH, clarity of solution, purity, molecular weight, potency, Benzyl alcohol, sterility, bacterial endotoxin and abnormal toxicity. Compliance to the standard was established using batch analysis data and stability data.

Stability and container closure system

Stability studies were conducted on three batches of the finished product stored at 2ºC – 8ºC for 24 months and <accelerated conditions> for <number> months. Based on the stability data presented, the approved shelf-life is 24 months when stored in colorless glass prefilled syringe at 2ºC – 8ºC.

Safety and efficacy information

NA

4. Benefit-Risk Assessment and Conclusion

On basis ofthe 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. Ficocyte 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

NA

PART 5: CHANGE HISTORY

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

Annex I: Mock up label