National Agency for Food & Drug Administration & Control (NAFDAC)

Public Assessment Report (PAR)

Royadium injection 150 mg/2mL

Alpha- Beta Arteether injection 150 mg/2mL

A4-101502

Akroyal Biotech Limited

This report reflects the scientific assessment for the approval of Royadium injection. The product was licenced on 27 August 2025

PART 1: ABSTRACT

Royadium injection containing Alpha beta arteether, manufactured at Orley Laboratories Private Limited,1817, G.I.D.C. Industrial Estate, Phase-III, Vatwa, Ahmedabad-382445, India was granted marketing authorization by NAFDAC for the treatment of malaria on 27 August 2025.

Royadium injection is indicated for complicated and uncomplicated P. falciparum malaria, including cerebral malaria. It is indicated as second-line treatment of chloroquine resistant malaria.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of Royadium injection by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of Royadium injection have been shown in part 2 of this report. The Summary of Product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of Royadium injection has been presented in Part 5 of this report.

The detailed steps taken to approve Royadium injection by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of Royadium injection

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Royadium injection	Alpha - beta Arteether	Liquid Yellow colour oily solution filled in amber glass ampoule	amber glass ampoule	3 ampoules x 2 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

See: https://greenbook.nafdac.gov.ng/

PART 4: LABELLING

Primary label

Secondary label

PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Royadium injection

Alpha- Beta Arteether 150mg/2mL

5.1.2 Therapeutic indication

Royadium injection is indicated for complicated and uncomplicated P. falciparum malaria, including cerebral malaria. It is indicated as second-line treatment of chloroquine resistant malaria.

5.1.3 Manufacturer/applicant

Akroyal Biotech limited, House 4, Clifford O. Avenue, Plot 656 Arab Road Kubwa, Abuja 901101 FCT - Abuja Nigeria

5.1.4 Pharmaceutical form

Liquid

Yellow colour oily solution. Available as 3 ampoules x 2mL

5.1.5 Storage

Store below 30°C. Protect from moisture and light.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Royadium injection is a yellow colour oily solution filled in 2 mL amber glass ampoule in 3 ampoules per pack.

5.2 Drug Substance

5.2.1 Manufacturer

The active pharmaceutical ingredient, alpha beta arteether is manufactured by Triveni Interchem Private Limited, 134, Pancharatna, Char Rasta, G.I.D.C.,Vapi - 396195, Gujarat, India

The API specifications are pharmacopeial based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of Royadium injection include Ethyl Oleate, benzyl alcohol, butylated hydroxy, toluene butylated, hydroxy anisole and propyl gallate, all being controlled by acceptable specifications. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Orley Laboratories PVT Limited.1817, G.I.D.C. Industrial Estate, Phase-III, Vatwa, Ahmedabad-382445, India.

5.4.2 Pharmaceutical development

The objective is to develop a safe, effective, and stable parenteral formulation of Royadium injection that delivers the required therapeutic activity against chloroquine resistant plasmodium falciparum malaria and cerebral malaria cases.

The manufacturing method used involved, sterile filtration, yield optimization and suitability of scale – up to commercial production. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on in-house methods. The finished product specifications include description, identification, extractable volume, particulate matter, BET, sterility test, and assay. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH as long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing of the product. The product proved to be quite stable at these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 24 months and Store below 30°C. Protect from moisture and light. have been accepted.

5.5 Conclusion

Based on the assessment of data on quality, safety and efficacy, the benefit–risk profile of Royadium injection was acceptable for the following indication: ‘complicated and uncomplicated P. falciparum malaria, including cerebral malaria. It is indicated as second-line treatment of chloroquine resistant malaria’ and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant Akroyal Biotech limited, House 4, Clifford O. Avenue, Plot 656 Arab Road Kubwa, Abuja 901101 FCT - Abuja Nigeria,submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Royadium injection.

The following are the steps for the registration of Royadium injection

November 2024	Date of receipt of application
June 2025	Date of conclusion of assessment
July 2025	Date of inspection
27 August 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Royadium injection.