



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

NAFDAC Public Assessment Report (NAPAR)

**Abacavir (as sulfate)/dolutegravir (as sodium)/lamivudine 60 mg/
5 mg/30 mg dispersible tablets**

Abacavir sulfate/dolutegravir sodium/lamivudine 60 mg/5 mg/30mg

A4-101779

Phillips Pharmaceuticals Nigeria Limited

This report reflects the scientific assessment for the approval of abacavir/dolutegravir/lamivudine 60 mg/5 mg/30 mg dispersible tablets. The product was licenced in December 2025.

PART 1: ABSTRACT

Abacavir (as sulfate)/dolutegravir (as sodium)/lamivudine dispersible tablets, manufactured at Cipla Limited, Pithampur, Madhya Pradesh, India, was granted marketing authorization by NAFDAC for the treatment of HIV/AIDS on 18 December 2025.

Abacavir (as sulfate)/dolutegravir (as sodium)/lamivudine is currently indicated for treatment of HIV infection in infants and children aged from 4 weeks and weighing 3 to 25 kg.

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 abacavir/dolutegravir/lamivudine 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 abacavir/dolutegravir/lamivudine dispersible tablets 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 abacavir/dolutegravir/lamivudine have been presented in part 5 of this report.

The detailed steps taken to approve abacavir/dolutegravir/lamivudine by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of abacavir/dolutegravir/lamivudine dispersible tablets.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Abacavir (as sulfate)/dolutegravir as sodium)/lamivudine 60 mg/ 5 mg/30 mg dispersible tablets	Abacavir sulfate/dolutegravir sodium/lamivudine 60 mg/5 mg/ 30 mg	Film-coated dispersible tablet Pink, oval, film-coated, dispersible tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'C' debossed (stamped into) on one side and are plain on the other side	Round, opaque, white plastic (HDPE) bottle containing 30 or 90 tablets. It also contains a desiccant (drying material). The bottle has an aluminium/plastic foil seal printed with "SFYP" in black and a white, childproof plastic (polypropylene) screw cap	1 x 30 tablets 1 x 90 tablets

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



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Abacavir (as sulfate)/dolutegravir (as sodium)/lamivudine 60 mg/5 mg/30 mg dispersible tablets

5.1.2 Therapeutic indication

Abacavir/dolutegravir/lamivudine dispersible tablet is indicated for the treatment indicated for treatment of HIV infection in infants and children aged from 4 weeks and weighing 3 to 25 kg.

5.1.3 Applicant

Phillips Pharmaceuticals Nigeria Limited, 122-132 Afprint Industrial Estate, Apapa-Oshodi Expressway Iyana-Isolo, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Film-coated dispersible tablet

Pink, oval, film-coated, dispersible tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'C' debossed (stamped into) on one side and are plain on the other side

5.1.5 Storage

Do not store above 30°C. Store in the original container.

In-Use Period

90's HDPE container

Should be used within 30 days, once opened.

When the bottle is first opened the "Discard after date" should be written on the bottle label in the place provided

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Round, opaque, white plastic (HDPE) bottle containing 30 or 90 tablets. It also contains a desiccant (drying material). The bottle has an aluminium/plastic foil seal printed with "SFYP" in black and a white, childproof plastic (polypropylene) screw cap.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredients, abacavir sulfate, dolutegravir sodium, and lamivudine, are manufactured by Laurus Labs Limited, Plot No. 21, Jawaharlal Nehru Pharma City, Parawada, Anakapalli – 531021 Andhra Pradesh, India; Laurus Labs Limited, Plot Nos. 18 & 21, Jawaharlal Nehru Pharma City, Parawada, Anakapalli – 531021, Andhra Pradesh, India, and Laurus Labs Limited, Plot No. 18, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam – 531021, Andhra Pradesh, India, respectively.

The API specifications is based on in house, and this have been adequately validated.

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 abacavir/dolutegravir/lamivudine dispersible tablets include mannitol, microcrystalline cellulose, sodium starch glycolate, povidone, crospovidone, aspartame, calcium sulfate dihydrate, colloidal silicon dioxide, magnesium stearate and ferric oxide red, all being controlled by acceptable specifications, while strawberry cream flavour and opadry II (pink) are in-house controlled.

None of the excipients are derived from human or animal origin except for magnesium stearate. TSE / BSE free certificates have been provided for magnesium stearate.

5.4 Drug Product

5.4.1 Drug product manufacturer

Cipla Limited, Plot Nos. 9 & 10, Indore Special Economic Zone, Phase II, Pithampur, District Dhar, Madhya Pradesh, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, delivers the intended performance, and is safe, in terms of efficacy to the reference product Triumeq PD[®] currently licensed by ViiV Healthcare. Wet granulation was selected as the method of manufacture for both the layers. Various experiments were performed to select and optimize the concentration of excipients and process parameters to obtain tablets of desired characteristics. Based on the satisfactory data of optimization trials, the formula was finalized. Appropriate in-process controls were set to ensure batch-to-batch reproducibility. Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product, Triumeq PD[®] (ViiV Healthcare) and abacavir/dolutegravir/lamivudine 60 mg/5 mg/30 mg dispersible tablets.

5.4.3 Specification

The finished product specification tests include test for description, identification of the APIs (HPLC, HPLC with PDA detector) and colorants, water content (KF), dissolution (HPLC detection), uniformity of dosage units (by content uniformity), assay (HPLC), degradation products (HPLC), residual solvents, fineness of dispersion, dispersion time and microbial limits. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH at long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 24 months and 'Do not store above 30°C' have been accepted.

5.5 Assessment of bioequivalence

The following bioequivalence study has been performed in 2022 according to internationally accepted guidelines.

The objective of the study was to compare the bioavailability of abacavir/dolutegravir/ lamivudine 60 mg/5 mg/30 mg dispersible tablet manufactured by Cipla Limited, India (test drug) with the reference formulation Triumeq PD[®] (ViiV Healthcare), and to assess bioequivalence.

The bioequivalence study was conducted using a single-dose, open-label, randomized, two-treatment crossover study in 66 healthy subjects under fasting conditions. Subjects received a single dose of either the test product (abacavir/dolutegravir/lamivudine 60 mg/5 mg/30 mg, Batch No. ID20166) or the reference product (Triumeq PD[®], Batch No. 2P3T), with a 10-day washout period between treatments. The tablets were dispersed in 20 mL of water prior to administration. Blood samples were collected pre-dose and at 27 time points up to 72 hours post-dose during each study period. Plasma concentrations of abacavir, dolutegravir and lamivudine were determined using validated LC-MS/MS methods. Pharmacokinetic parameters including AUC, C_{max} and t_{max} were assessed for bioequivalence. Data from 65 subjects were included in the pharmacokinetic and bioequivalence analyses.

Arithmetic mean and geometric mean values of the pharmacokinetic variables for abacavir, dolutegravir and lamivudine as well as statistical results are summarised in the following tables:

Abacavir

Pharmacokinetic Parameter	Test formulation (T) arithmetic mean ± SD (geometric mean)	Reference (R) arithmetic mean ± SD (geometric mean)	log-transformed parameters	
			Ratio T/R (%)	Conventional 90% CI (ANOVAlog)
t _{max} (h)	0.74 ± 0.59	0.75 ± 0.50	–	–
C _{max} (ng/mL)	748 ± 266 (704)	673 ± 255 (629)	112.0	103.2 – 121.6
AUC _{0-t} (ng·h/mL)	981 ± 384 (918)	944 ± 384 (883)	104.0	99.4 – 108.7
AUC _{0-inf} (ng·h/mL)	985 ± 386 (922)	948 ± 385 (887)	104.0	99.4 – 108.7

Dolutegravir

Pharmacokinetic Parameter	Test formulation (T) arithmetic mean ± SD (geometric mean)	Reference (R) arithmetic mean ± SD (geometric mean)	log-transformed parameters	
			Ratio T/R (%)	Conventional 90% CI (ANOVAlog)
t _{max} (h)	1.37 ± 0.86	1.06 ± 0.64	–	–
C _{max} (ng/mL)	630 ± 116 (620)	721 ± 143 (707)	87.7	85.2 – 90.3
AUC _{0-t} (ng·h/mL)	10968 ± 2762 (10593)	11286 ± 2962 (10870)	97.5	95.6 – 99.4
AUC _{0-inf} (ng·h/mL)	11597 ± 3177 (11133)	11864 ± 3294 (11376)	97.9	95.8 – 100.0

Lamivudine

Pharmacokinetic Parameter	Test formulation (T) arithmetic mean $\pm$ SD (geometric mean)	Reference (R) arithmetic mean $\pm$ SD (geometric mean)	log-transformed parameters	
			Ratio T/R (%)	Conventional 90% CI (ANOVAlog)
$t_{\max}$ (h)	1.38 $\pm$ 0.71	1.45 $\pm$ 0.65	–	–
$C_{\max}$ (ng/mL)	378 $\pm$ 120 (359)	341 $\pm$ 110 (324)	110.8	103.8 – 118.4
AUC _{0-t} (ng·h/mL)	1669 $\pm$ 461 (1612)	1534 $\pm$ 485 (1464)	110.1	105.3 – 115.2
AUC _{0-inf} (ng·h/mL)	1710 $\pm$ 471 (1651)	1572 $\pm$ 493 (1502)	109.9	105.1 – 115.0

The results of the study show that preset acceptance limits of 80 -125 % are met by both AUC and $C_{\max}$ values regarding Abacavir/dolutegravir/lamivudine. Accordingly, the test tablet, Abacavir/dolutegravir/lamivudine dispersible tablets meets the criteria for bioequivalence with regard to the rate and extent of absorption and is therefore bioequivalent to the reference Triumeq PD[®] (ViiV Healthcare).

5.6 Conclusion

Based on the assessment of data on quality, bioequivalence, safety and efficacy, the benefit–risk profile of abacavir/dolutegravir/lamivudine dispersible tablet was acceptable for the following indication: 'indicated for treatment of HIV infection in infants and children aged from 4 weeks and weighing 3 to 25 kg', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Phillips Pharmaceuticals Nigeria Limited, 122-132 Afprint Industrial Estate, Apapa-Oshodi Expressway Iyana-Isolo, Lagos State, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of abacavir/dolutegravir/lamivudine dispersible tablet.

The following are the steps for registration

February 2025	Date of receipt of application
October 2025	Date of conclusion of assessment
October 2025	Date of inspection
18 December 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of abacavir (as sulfate)/dolutegravir (as sodium)/lamivudine 60 mg/5 mg/ 30 mg dispersible tablets.