Hetero Formulation Division	HETERO

FINISHED PRODUCT SPECIFICATION

Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	Specification No.	FPS/4025881-1-01
Specification Type	Release	Effective Date	21 DEC 2022
Standard Test Procedure No.	STP/4025881-1-01	Supersedes	FPS/4025881-1-00
Pharmacopoeial Status	USP	Reference	-

S.No.	TEST NAME	SPECIFICATION
1.0	Description (Visual inspection)	Colorless to pale yellow, strawberry flavored liquid, filled in 250cc HDPE opaque bottles and child resistant cap with induction sealing wads (FSE).
2.0	Identification	
2.1	By TLC	The R_F value of the principal spot obtained from the sample solution should correspond to that of the principal spot obtained from the standard solution.
2.2	By HPLC	The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the assay.
3.0	Microbiological examination	
3.1	Microbial enumeration tests	
3.1.1	Total aerobic microbial count	Not more than 100cfu per mL
3.1.2	Total combined yeast and molds count	Not more than 10cfu per mL
3.2	Test for specified Microorganisms	
3.2.1	Staphylococcus aureus	Should be absent per mL
3.2.2	Pseudomonas aeruginosa	Should be absent per mL
3.2.3	Salmonella species	Should be absent per 10mL
3.2.4	Escherichia coli	Should be absent per mL
4.0	Deliverable volume	
4.1	Average fill volume	Not less than 240mL

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022

FINISHED PRODUCT SPECIFICATION

Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	Specification No.	FPS/4025881-1-01
Specification Type	Release	Effective Date	21 DEC 2022
Standard Test Procedure No.	STP/4025881-1-01	Supersedes	FPS/4025881-1-00
Pharmacopoeial Status	USP	Reference	-

S.No.	TEST NAME	SPECIFICATION
4.2	Fill volume variation	Should meet the requirements
5.0	pH	Between 3.0 and 4.0
6.0	Related compounds (By HPLC)	
6.1	Zidovudine related compound C (Thymine)	Not more than 3.0%w/w
6.2	Impurity at RRT 0.17	Not more than 0.20%w/w
6.3	Maximum single unknown impurity	Not more than 0.20%w/w
6.4	Total impurities	Not more than 4.0%w/w
7.0	Assay (By HPLC)	
7.1	Zidovudine ($C_{10}H_{13}N_5O_4$), in mg	Not less than 45.00 and Not more than 55.00
7.2	(%) Labeled amount	Not less than 90.0 and Not more than 110.0
8.0	Content of preservative (By HPLC)	
8.1	Sodium benzoate, in mg	Not less than 9.00 and Not more than 11.00
8.2	(%) Labeled amount	Not less than 90.0 and Not more than 110.0

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022

Hetero Formulation Division	HETERO

FINISHED PRODUCT SPECIFICATION			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	Specification No.	FPS/4025881-1-01
Specification Type	Release	Effective Date	21 DEC 2022
Standard Test Procedure No.	STP/4025881-1-01	Supersedes	FPS/4025881-1-00
Pharmacopoeial Status	USP	Reference	-

GENERAL INFORMATION

Market: Cenares (Peru)

Pack Size : 240mL HDPE (With FSE Wad)

In-House Test(s): Identification test by TLC, Content of preservative (By HPLC), Impurity at RRT 0.17, Maximum single unknown impurity, Total impurities.

Chemical names of Related compounds

Zidovudine Related compound C

Thymine (2,4(1H,3H)-Pyrimidinedione,5-methyl)

Impurity at RRT 0.17

5-(Hydroxymethyl)Pyrimidin-2(1H)-one

END OF THE DOCUMENT

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022

Hetero Formulation Division	HETERO

CHANGE HISTORY SHEET

Department	Quality Assurance	Document No.:	FPS/4025881-1-01
Document Title:	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		

Version	Supersedes	S. No.	Changes made
00	Nil	01	New Specification CRN No : CRN-FBPK-21-0245 Date : 23-06-2021
01	00	01	STP No. is revised. CRN No. : CRN-FBQA-22-0363 Date : 07-11-2022

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	13-12-2022	30-12-2022

Hetero Formulation Division	HETERO

FINISHED PRODUCT STABILITY SPECIFICATION

Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	Specification No.	SSS/4025881-1-01
Specification Type	Shelf life	Effective Date	21 DEC 2022
Standard Test Procedure No.	STP/4025881-1-01	Supersedes	SSS/4025881-1-00
Pharmacopoeial Status	USP	Reference	-

S.No.	TEST NAME	SPECIFICATION
1.0	Description (Visual inspection)	Colorless to pale yellow, strawberry flavored liquid, filled in 250cc HDPE opaque bottles and child resistant cap with induction sealing wads (FSE).
2.0	Microbiological examination	
2.1	Microbial enumeration tests	
2.1.1	Total aerobic microbial count	Not more than 100cfu per mL
2.1.2	Total combined yeast and molds count	Not more than 10cfu per mL
2.2	Test for specified Microorganisms	
2.2.1	Staphylococcus aureus	Should be absent per mL
2.2.2	Pseudomonas aeruginosa	Should be absent per mL
2.2.3	Salmonella species	Should be absent per 10mL
2.2.4	Escherichia coli	Should be absent per mL
3.0	pH	Between 3.0 and 4.0
4.0	Related compounds (By HPLC)	
4.1	Zidovudine related compound C (Thymine)	Not more than 3.0%w/w
4.2	Impurity at RRT 0.17	Not more than 0.2%w/w
4.3	Maximum single unknown impurity	Not more than 0.20%w/w
4.4	Total impurities	Not more than 5.0%w/w
5.0	Assay (By HPLC)	
5.1	Zidovudine ($C_{10}H_{13}N_5O_4$), in mg	Not less than 45.00 and Not more than 55.00
5.2	(%) Labeled amount	Not less than 90.0 and Not more than 110.0

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022

Hetero Formulation Division	HETERO

FINISHED PRODUCT STABILITY SPECIFICATION

Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	Specification No.	SSS/4025881-1-01
Specification Type	Shelf life	Effective Date	21 DEC 2022
Standard Test Procedure No.	STP/4025881-1-01	Supersedes	SSS/4025881-1-00
Pharmacopoeial Status	USP	Reference	-

S.No.	TEST NAME	SPECIFICATION
6.0	Content of preservative (By HPLC)	
6.1	Sodium benzoate, in mg	Not less than 8.00 and Not more than 11.00
6.2	(%) Labeled amount	Not less than 80.0 and Not more than 110.0

GENERAL INFORMATION

Market: Cenares (Peru)

Pack Size : 240mL HDPE (With FSE Wad)

In-House Test(s): Content of preservative (By HPLC), Maximum single unknown impurity, Total impurities.

Chemical names of Related compounds

Zidovudine Related compound C

Thymine (2,4(1H,3H)-Pyrimidinedione,5-methyl)

Impurity at RRT 0.17

5-(Hydroxymethyl)Pyrimidin-2(1H)-one

END OF THE DOCUMENT

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022

Hetero Formulation Division	HETERO

CHANGE HISTORY SHEET

Department	Quality Assurance	Document No.:	SSS/4025881-1-01
Document Title:	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		

Version	Supersedes	S. No.	Changes made
00	Nil	01	New Specification CRN No : CRN-FBPK-21-0245 Date : 23-06-2021
01	00	01	STP No. is revised. CRN No. : CRN-FBQA-22-0363 Date : 07-11-2022

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022

STANDARD TEST PROCEDURE

Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

1.0 DESCRIPTION

Take about 100mL of sample in to a dry cylinder. Observe the sample for compliance against the specification.

2.0 IDENTIFICATION

2.1 By TLC

Chemicals & Reagents

Methanol	:	AR Grade
Butyl alcohol	:	AR Grade
n-heptane	:	AR Grade
Acetone	:	AR Grade
Ammonium hydroxide	:	AR Grade
Water	:	Purified water

Chromatographic conditions

TLC plate	:	Silica plate coated with 0.25 mm layer of chromatographic silica gel mixture containing a fluorescent indicator having an optimal intensity at 254nm
Development chamber	:	20 x 20cm
Detection/Visualization	:	Examine the plate under short wave length UV light.

Preparation of Diluent

Prepare a mixture of methanol and water in the ratio of 75:25%v/v.

	Prepared By	Checked By	Approved By
Name	T. Uma Shankar	D.Kishore	Rajesh.Durgi
Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Preparation of Developing solvent

Prepare a mixture of butyl alcohol, n-heptane, acetone and ammonium hydroxide in the ratio of 40:30:30:10%v/v/v/v.

Preparation of Standard solution

Weigh and transfer about 25mg of Zidovudine working standard into a 5mL clean dry volumetric flask, add 3mL of methanol and sonicate to dissolve. Make up to volume with diluent and mix.

Preparation of Sample solution

Transfer 5.0mL of sample into a 10mL clean dry volumetric flask, add about 6mL of diluent and sonicate for 5 minutes with intermediate shaking. Make up to volume with diluent and mix.

Procedure

Apply separately 5µL each of standard solution and sample solution to a TLC plate. Allow the spots to dry. Allow the chromatogram to develop until the solvent front has moved about three quarters of the length of the plate. Remove the plate from the chamber, mark the solvent front and allow the solvent to evaporate. Observe the plate under short wave length UV light.

Observation

The R_F value of the principal spot obtained from the sample solution corresponds to that of the principal spot obtained from the standard solution.

2.2 By HPLC

For Chemicals & Reagents, Preparation of Mobile phase, Diluent, Chromatographic conditions, preparation of Standard solution, preparation of Sample solution, Procedure and Evaluation of system suitability- proceed as directed under "Assay".

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Observation

The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the Assay.

3.0 MICROBIOLOGICAL EXAMINATION

Perform the test on sample as per General test procedure No. GP074.

4.0 DELIVERABLE VOLUME

Perform the test on sample as per General test procedure No. GP118 and follow the acceptance criteria as given for multiple unit container.

5.0 pH

Chemicals & Reagents

Potassium chloride : AR Grade
Water : Purified water

Preparation of 0.12 M Potassium chloride

Accurately weigh and transfer about 0.895g of potassium chloride into a 100mL volumetric flask. Dissolve and dilute to mark with water.

Preparation of Sample solution

Prepare a mixture containing 15mL of sample (equivalent to 150mg of Zidovudine) and 5mL of 0.12M potassium chloride (3:1).

Determine the pH of sample solution as per General test procedure No. GP002.

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

6.0 RELATED COMPOUNDS (By HPLC)

For Chemicals & Reagents, Preparation of Mobile phase, Preparation of diluent, chromatographic conditions, Preparation of resolution solution, Preparation of standard solution and Preparation of sample solution - proceed as directed under 'Assay'.

Preparation of Placebo solution

Accurately transfer 10mL of placebo solution into a 100mL volumetric flask, add about 60mL of diluent and sonicate for 10 minutes with occasional shaking. Make up to the volume with diluent and mix.

Dilute 5mL of the above solution to 50mL with diluent and mix. Filter a portion of the solution through 0.45µm membrane filter and discard first 3 mL of the filtrate.

Procedure

Separately inject 10µL of Diluent, Placebo solution, Resolution solution, Standard solution (five injections) and Sample solution into the chromatographic system. Record the chromatograms and measure the peak responses.

Evaluation of System suitability

The resolution between Zidovudine related compound C and Zidovudine peak is not less than 4.0, the tailing factor for Zidovudine peak is not more than 2.0 from resolution solution.

The relative standard deviation for peak areas of sodium benzoate and Zidovudine from five replicate injections of standard solution is not more than 2.0%

The relative retention times are about 0.12 for Zidovudine related compound C and 0.55 for Sodium benzoate with respect to Zidovudine.

Examine the placebo chromatogram for any extraneous peaks and disregard corresponding peaks observed in the chromatogram of the sample solution.

The Limit of Quantification (LOQ) for Thymine is about 0.018ppm.

The Limit of Quantification for Zidovudine is about 0.120ppm.

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Note : The peak at RRT about 0.20 is of placebo, disregard corresponding peak observed in the chromatogram of sample solution.

Calculations

% of Zidovudine related compound C

$$= \frac{A_{T1}}{A_{S1}} \times \frac{W_{S1}}{200} \times \frac{2}{100} \times \frac{100}{10} \times \frac{50}{5} \times \frac{5}{L} \times \frac{P_1}{100} \times 100$$

Where,

A_{T1} = Area of Zidovudine related compound C peak in sample solution
A_{S1} = Average area of Zidovudine related compound C peak obtained from five replicate injections of standard solution
W_{S1} = Weight of Zidovudine related compound C working standard taken, in 'mg'
P_1 = % Purity of Zidovudine related compound C used (on as is basis)
L = Label claim of Zidovudine, in 'mg/5mL'

% of Impurity at RRT 0.17

$$= \frac{A_{T2}}{A_S} \times \frac{W_S}{50} \times \frac{10}{100} \times \frac{100}{10} \times \frac{50}{5} \times \frac{5}{L} \times \frac{P}{100} \times 100$$

Where,

A_{T2} = Area of Impurity at RRT 0.17 peak in sample solution
A_S = Average area of Zidovudine peak obtained from five replicate injections of standard solution
W_S = Weight of Zidovudine working standard taken, in 'mg'
P = % Purity of Zidovudine working standard used (on as is basis)
L = Label claim of Zidovudine, in 'mg/5mL'

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

% of Maximum single unknown impurity

$$= \frac{A_{TMSUI}}{A_S} \times \frac{W_S}{50} \times \frac{10}{100} \times \frac{100}{10} \times \frac{50}{5} \times \frac{5}{L} \times \frac{P}{100} \times 100$$

Where,

A_{TMSUI} = Area of Maximum single unknown impurity peak in sample solution
A_S = Average area of Zidovudine impurity peak obtained from five replicate injections of standard solution
W_S = Weight of Zidovudine working standard taken, in 'mg'
P = % Purity of Zidovudine working standard used (on as is basis)
L = Label claim of Zidovudine, in 'mg/5mL'

% of Total unknown impurities

$$= \frac{A_{TTUI}}{A_S} \times \frac{W_S}{50} \times \frac{10}{100} \times \frac{100}{10} \times \frac{50}{5} \times \frac{5}{L} \times \frac{P}{100} \times 100$$

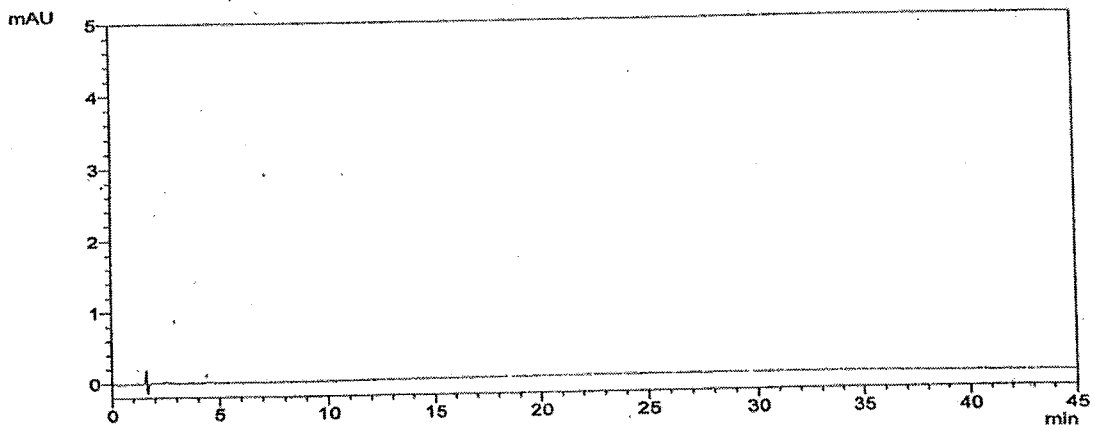
Where,

A_{TTUI} = Area of total unknown impurity peaks in sample solution
A_S = Average area of Zidovudine peak obtained from five replicate injections of standard solution
W_S = Weight of Zidovudine working standard taken, in 'mg'
P = % Purity of Zidovudine working standard used (on as is basis)
L = Label claim of Zidovudine, in 'mg/5mL'

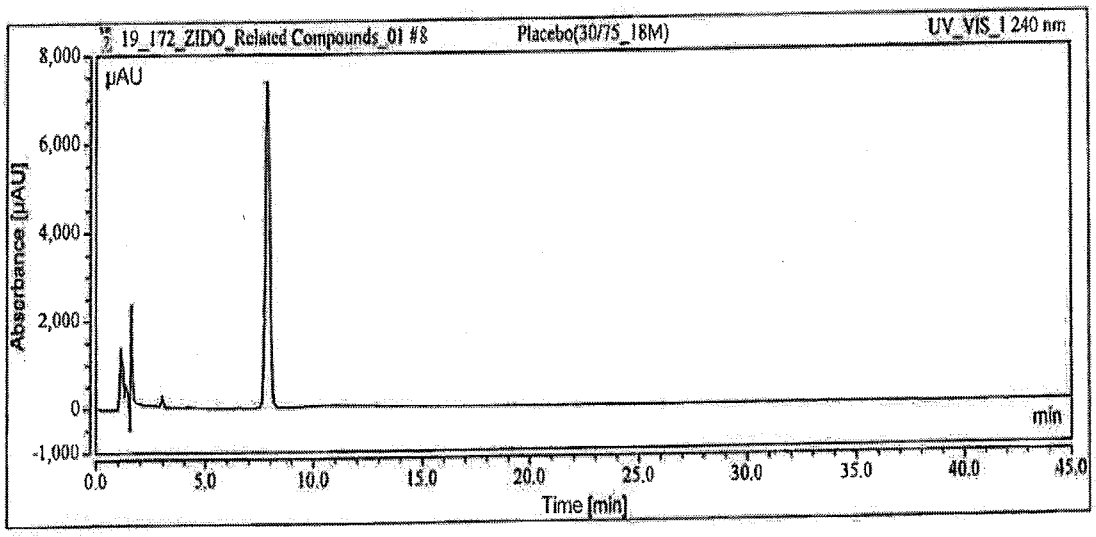
% of Total impurities = % of Zidovudine related compound C + % of Impurity at RRT 0.17 + % of Total unknown impurities

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Blank Chromatogram



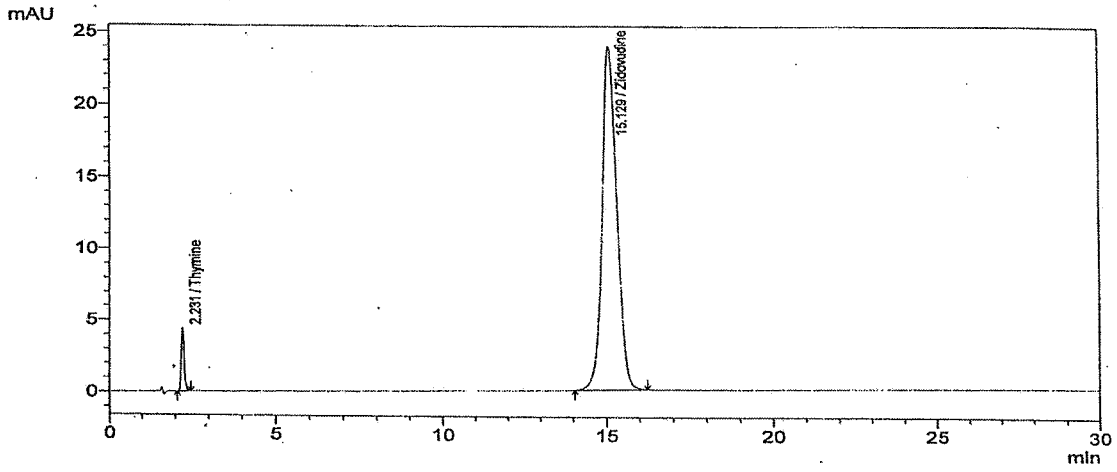
Placebo Chromatogram



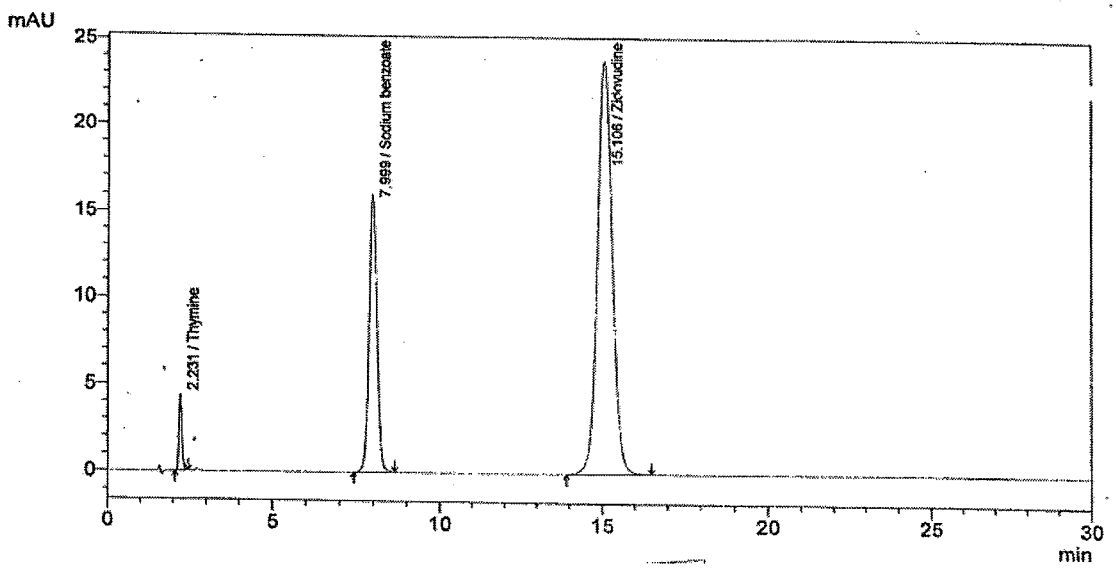
STANDARD TEST PROCEDURE

Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Resolution Chromatogram

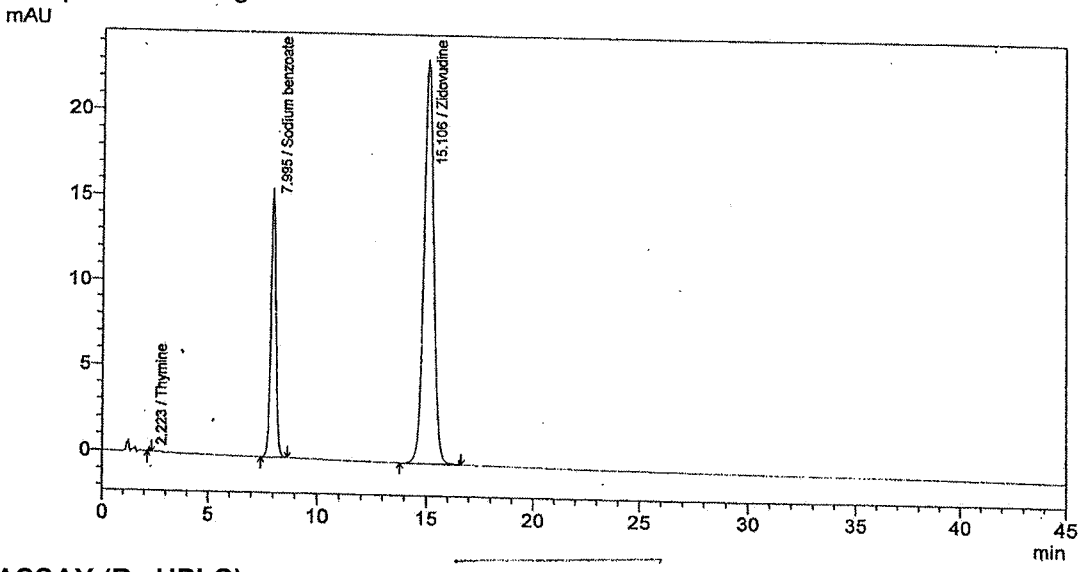


Standard Chromatogram



STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Sample Chromatogram



7.0 ASSAY (By HPLC)

Chemicals & Reagents

Sodium acetate trihydrate	: AR Grade
Methanol	: HPLC Grade
Acetonitrile	: HPLC Grade
Glacial acetic acid	: AR Grade
Water	: Milli-Q-Grade

Preparation of Buffer

Weigh accurately about 5.44g of Sodium acetate trihydrate into a beaker containing 1000mL of water and sonicate to dissolve. Filter through 0.45µm membrane filter.

Preparation of Solvent mixture

Prepare a mixture of methanol and acetonitrile in the ratio of 90:10%v/v.

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
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Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Preparation of Mobile Phase

Prepare a degassed mixture of buffer, solvent mixture and glacial acetic acid in the ratio of 900:100:02%v/v/v.

Preparation of Diluent: Use mobile phase as diluent

Chromatographic conditions

Column	:	Hypersil ODS, 100 x 4.6mm, 5-µm
Flow Rate	:	1.0mL/minute
Wavelength	:	240nm
Column oven temperature	:	Ambient
Injection volume	:	10µL
Run time	:	30 minutes for the resolution and standard solution.
	:	45 minutes for the diluent, placebo and sample solution.

Preparation of Zidovudine related compound C (Thymine) stock solution

Accurately weigh and transfer about 20mg of Thymine into a 200mL volumetric flask. Add about 150mL of diluent and sonicate to dissolve. Dilute to volume with diluent and mix.

Preparation of Zidovudine standard stock solution

Accurately weigh and transfer about 50mg of Zidovudine working standard into a 50mL volumetric flask. Add about 30mL of diluent and sonicate to dissolve. Dilute to volume with diluent and mix.

Preparation of Sodium benzoate standard stock solution

Accurately weigh and transfer about 20mg of Sodium benzoate working standard into a 100mL volumetric flask. Add about 60mL of diluent and sonicate to dissolve. Dilute to volume with diluent and mix.

Preparation of Resolution solution

Transfer 10.0mL of Zidovudine standard stock solution and 2.0mL of Zidovudine related compound C standard stock solution into a 100mL volumetric flask, dilute to volume with diluent and mix.

STANDARD TEST PROCEDURE

Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Preparation of Standard solution

Transfer 10.0mL each of Zidovudine standard stock solution, Sodium benzoate standard stock solution and 2.0mL of Zidovudine related compound C stock solution into a 100mL volumetric flask, dilute to volume with diluent and mix.

Preparation of Sample solution

Accurately transfer 10mL of oral solution into a 100mL volumetric flask, add about 60mL of diluent and sonicate for 10 minutes with intermediate shaking. Make up to the volume with diluent and mix.

Dilute 5mL of the above solution to 50mL with diluent and mix. Filter a portion of the solution through 0.45µm membrane filter and discard first 3 mL of the filtrate.

Note: Standard and Sample solutions are stable up to 48 hours at room temperature (≅ 25°C).

Procedure

Separately inject 10µL of Diluent, Resolution solution, Standard solution (five injections) and Sample solution into the chromatographic system. Record the chromatograms and measure the peak responses.

Evaluation of System suitability

The resolution between Zidovudine related compound C and Zidovudine peak should not be less than 4.0, the tailing factor for Zidovudine peak is not more than 2.0 from resolution solution.

The relative standard deviation for peak areas of sodium benzoate and Zidovudine from five replicate injections of standard solution is not more than 2.0%

The relative retention times are about 0.12 for Zidovudine related compound C and 0.55 for Sodium benzoate with respect to Zidovudine.

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

Calculation

Zidovudine, in mg/5mL

$$= \frac{A_T}{A_S} \times \frac{W_S}{50} \times \frac{10}{100} \times \frac{100}{10} \times \frac{50}{5} \times \frac{P}{100} \times 5$$

(%) Labeled amount

$$= \frac{\text{Content of Zidovudine, in 'mg/5mL'}}{\text{Label claim of Zidovudine, in 'mg/5mL'}} \times 100$$

Where,

A_T = Area of Zidovudine peak in sample solution
A_S = Average area of Zidovudine peak obtained from five replicate injections of standard solution
W_S = Weight of Zidovudine working standard taken, in 'mg'
P = % Purity of Zidovudine working standard used (on as is basis)

8.0 CONTENT OF PRESERVATIVE (By HPLC)

For Chemicals & Reagents, Preparation of mobile phase, Preparation of diluent, Chromatographic conditions, Preparation of resolution solution, Preparation of standard solution, Preparation of sample solution, Procedure and evaluation of system suitability - proceed as directed under 'Assay'.

Calculation

Sodium benzoate, in mg/5mL

$$= \frac{A_T}{A_S} \times \frac{W_S}{100} \times \frac{10}{100} \times \frac{100}{10} \times \frac{50}{5} \times \frac{P}{100} \times 5$$

STANDARD TEST PROCEDURE			
Product / Material Name	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		
Product / Material Code	4025881	STP No.	STP/4025881-1-01
Reference	-	Effective Date	21 DEC 2022
Pharmacopoeial Status	USP	Supersedes	STP/4025881-1-00

(%) Labeled amount

$$= \frac{\text{Content of Sodium benzoate, in 'mg/5mL'}}{\text{Label claim of Sodium benzoate, in 'mg/5mL'}} \times 100$$

Where,

A_T = Area of Sodium benzoate peak in sample solution
A_S = Average area of Sodium benzoate peak obtained from five replicate injections of standard solution
W_S = Weight of Sodium benzoate working standard taken, in 'mg'
P = % Purity of Sodium benzoate working standard used (on as is basis)

END OF THE DOCUMENT

Hetero Formulation Division	HETERO

CHANGE HISTORY SHEET

Department	Quality Assurance	Document No.:	STP/4025881-1-01
Document Title:	Zidovudina 50mg/5mL solucion oral (Zidovudine Oral Solution USP 50mg/5mL)		

Version	Supersedes	S. No.	Changes made
00	Nil	01	New STP CRN No : CRN-FBPK-21-0245 Date : 23-06-2021
01	00	01	Based on H-OOS-FBQC-22-0052/PA1 &PA2 STP revised. In Related compounds by HPLC test method 1) Under Evaluation of system suitability Note point has been incorporated. 2) Specimen chromatograms has been included. CRN No. : CRN-FBQA-22-0363 Date : 07-11-2022

	Prepared By	Checked By	Approved By
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Designation	Officer-QA	DGM-QC	Manager-QA
Sign & Date	13-12-2022	19-12-2022	20-12-2022