

CERTIFICATE NUMBER  
**D/22/1307/023**

PARTY NAME & ADDRESS

SHEFA HEALTHCARE PVT. LTD.  
 A-10/1 MIDC TALOJA IND.AREA, TALOJA,  
 NAVI MUMBAI 410208

FDA Maharashtra Approved  
 No.KD/Testing Licence/18/2010

**CERTIFICATE OF ANALYSIS**

THE DRUGS AND COSMETICS ACT 1940 AND THE RULES THEREUNDER  
 FORM 39 [SEE RULE 150 - E(f)]  
 REPORT OF TEST OR ANALYSIS BY APPROVED INSTITUTION

**1. Name of Manufacturer/Party from whom sample received together with his mfg. License No. under the Act & under the Rules made thereunder :**  
 SHEFA HEALTHCARE PVT. LTD. **M. LIC. No**

<b>2. Reference number and date of the letter from the manufacturer/party under which</b> <p style="text-align: center;">11/07/2022</p>	<b>Analysis Required :</b> ECOLI+PSEU+CANDIDA ALBICANS+ ASPERGILLUS BRASILIENSIS AS PER METHOD ASTM E2783-11 EFFICACY TEST
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<b>3. Date of Receipt of sample &amp; quantity :</b> 13/07/2022      1 X 200 ML <p style="text-align: center;">Approximate</p>	<b>4. Name of drug/cosmetic/raw material purporting to be contained in the sample :</b> VIROSIL PHARMA Sample <b>NOT DRAWN</b> by Bee Pharmo Labs Pvt. Ltd.
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**5. Details of raw material/final product in bulk /final product (in finished pack) as obtained from manufacturer/party :**

(a) Original manufacturer's name (in case of raw materials and drugs repacked) :	(b) Batch Number VPS20121	(c) Batch size represented by sample 2000 LTRS.	(d) Date of manufacture, if any 09/2020	(e) Date of expiry, if any 08/2022
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PART ANALYSIS : OTHER TESTS NOT DONE, AS NOT REQUIRED BY THE PARTY.

The Sample's identity and particulars are as supplied by the party and not verified by us, except as mentioned specifically.

**6. RESULTS OF TEST OR ANALYSIS WITH PROTOCOLS OF TEST OR ANALYSIS APPLIED :**  
 AS PER ASTM E 2783-11

1. Description : Clear, colourless liquid in plastic container having typed label on it.
2. Efficacy Test : The sample solution "Virosil Pharm" in its 5% diluted form tested by using ASTM E2783-11 sample showed 100% killing/inactivation of the bacterial species & 99.99% killing/inactivation of the fungal species in 15 min. contact time. Results are as follows :

Sr.No.	Test Organism	Initial control (CFU)	Recovery of organism after the killing/ inactivation contact time of 15 min by "Virosil Pharma"	Percentage killed/ inactivated after the killing/inactivation contact time of 15 min by "Virosil Pharma"
01	Escherichia coli ATCC 8739	31 X 10 <sup>8</sup>	Nil	100%
02	Pseudomonas aeruginosa ATCC 9027	36 X 10 <sup>7</sup>	Nil	100%
03	Candida albicans ATCC 10231	34 X 10 <sup>6</sup>	17 X 10 <sup>2</sup>	99.99%
04	Aspergillus brasiliensis ATCC 16404	25 X 10 <sup>6</sup>	12 X 10 <sup>2</sup>	99.99%

**OPINION :** IN RESPECT OF THE TESTS CARRIED OUT, AS MENTIONED ABOVE, IN THE OPINION OF THE UNDERSIGNED, THE SAMPLE REFERRED TO ABOVE **IS OF STANDARD QUALITY** AS DEFINED IN THE ACT & THE RULES THEREUNDER FOR THE REASONS GIVEN BELOW :  
 THE SUBMITTED SAMPLE COMPLIES WITH THE ABOVE TESTS AS PER ASTM E 2783-11

The opinion is in respect of the tests carried out on the sample, as mentioned above. Certification or endorsement of the product is neither inferred nor implied. Legal liability is limited to the value in the invoice for testing.  
**DATE :** 20/07/2022  
 This Certificate shall not be reproduced except in full, without our written approval.

  
**Signature of person-in-charge of testing**





## RAW DATA SHEET

Issued By:

Date: 15/07/22

Certificate No.: D/22/1307/023

Name of Sample:  
Virosil Pharma

Analysis as per: ASTM E 2783-11

### FOR 10 ml SAMPLE SIZE

#### CONTROL

Add 10 ml water to centrifuge tube

Start vortex for even distribution

At '0' time add 0.1 ml inoculum suspension in above tube

Start the timer within  $\pm 1$  sec of addition of inoculum

At 15 min, remove 1.0 ml aliquot from centrifuge and transfer to 9.0 ml dilution blank (De-engley neutralizing broth)

Prepare 10 fold dilutions of control

Plate out the dilutions in duplicate

Incubate the plates at 30-35°C for bacteria for 3 days and at 20-25°C for fungus for 5 days

Count the colonies using standard plate technique

Take average of plates and proceed for calculations

#### TEST SAMPLE

Procedure is as same as of control, instead of adding water add 10 ml of required diluted test sample in centrifuge tube and proceed further as of control

#### CALCULATIONS

$$\text{Percentage inactivation} = \frac{(\text{positive control cfu/ml}) - (\text{test sample cfu/ml})}{(\text{positive control cfu/ml})} \times 100$$

Analyzed by: Supriya  
(Sign & Date) 20/07/22

Checked By: P  
(Sign & Date) 20/07/22



**RAW DATA SHEET**

Issued By: <u>P</u>	Date: 15/07/22
Certificate No.: D/22/1307/023	
Name of Sample: <u>Virosil Pharma</u>	Analysis as per: <u>ASTM E 2783-11</u>

**RESULTS**

- Diluent used – De – engley Neutralizing Broth
- Sample concentration used – 5%
- Contact time – 15 min
- Media used - Soyabean Casein Dgest Agar (for bacteria)  
 - Soyabean Dextrose Agar with Chloremphenicol (for fungii)

• ~~Contact time~~ 15 ~~min~~ 15/07/22

Sr. no.	Organisms used	Positive control cfu/ml	Test sample cfu/ml	Percentage Inactivation
1.	<i>Escherichia coli</i> ATCC 8739	$31 \times 10^8$	Nil	100%
2.	<i>Pseudomonas aeruginosa</i> ATCC 9027	$36 \times 10^8$	Nil	100%
3.	<i>Aspergillus niger</i> ATCC 16404	$25 \times 10^6$	$12 \times 10^2$	99.99%
4.	<i>Candida albicans</i> ATCC 10231	$34 \times 10^7$	$17 \times 10^2$	99.99%

**CONCLUSION** - Efficacy test for submitted sample complies with respect to above cultures by using time-kill procedure (ASTM E 2783-11) method

Analyzed by: <u>Supriya</u> (Sign & Date) <u>20/07/22</u>	Checked By: <u>P</u> (Sign & Date) <u>20/07/22</u>
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