



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, BADDI- NALAGARH ROAD, DISTT.- SOLAN-174101 (H.P.)

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Healtuss-TR	A.R. No.	FG/G/24A0166
Generic Name	Terbutaline Sulphate, Ambroxol Hydrochloride, Guaiphenesin & Menthol Syrup	Sample Quantity	14 Bottles
Batch No.:	AGL40509	Sample Received on	09/05/2024
Batch Size:	24000 Bottles	Analysis Date	09/05/2024
Mfg. Date.	05/2024	Release Date	17/05/2024
Exp. Date	04/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result																							
1.	Description	Orange colour syrup filled in 100 ml amber colour PET bottle sealed with ROPP aluminium cap.	Orange colour syrup filled in 100 ml amber colour PET bottle sealed with ROPP aluminium cap.																							
2.	Identification	In the assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.	Complies																							
3.	Weight per ml	Between 0.800 gm/ml to 1.200 gm/ml	1.122 gm/ml																							
4.	pH	Between 4.0 to 6.0	5.37																							
5.	Average filled Volume	Not less than 100.0 ml	101.0 ml																							
6.	Uniformity of filled Volume	Not less than 95.0 ml	Min:- 100.0 ml Max:- 102.0 ml																							
7.	Assay:																									
	Each 5 ml contains:	<table><tr><th>Claim</th><th>Limit</th><th>mg</th><th>%</th></tr><tr><td>Terbutaline Sulphate IP</td><td>1.25 mg</td><td>Between 90.00 % to 110.00 % of stated amount (Between 1.125 mg to 1.375 mg)</td><td>1.227 mg</td><td>98.19%</td></tr><tr><td>Ambroxol Hydrochloride IP</td><td>15 mg</td><td>Between 90.00 % to 110.00 % of stated amount (Between 13.5 mg to 16.5 mg)</td><td>14.854 mg</td><td>99.03%</td></tr><tr><td>Guaiphenesin IP</td><td>50 mg</td><td>Between 90.00 % to 110.00 % of stated amount (Between 45.0 mg to 55.0 mg)</td><td>51.909 mg</td><td>103.82%</td></tr><tr><td>Menthol IP</td><td>0.5 mg</td><td>Between 90.00 % to 110.00 % of stated amount (Between 0.45 mg to 0.55 mg)</td><td>0.52167 mg</td><td>104.33%</td></tr></table>	Claim	Limit	mg	%	Terbutaline Sulphate IP	1.25 mg	Between 90.00 % to 110.00 % of stated amount (Between 1.125 mg to 1.375 mg)	1.227 mg	98.19%	Ambroxol Hydrochloride IP	15 mg	Between 90.00 % to 110.00 % of stated amount (Between 13.5 mg to 16.5 mg)	14.854 mg	99.03%	Guaiphenesin IP	50 mg	Between 90.00 % to 110.00 % of stated amount (Between 45.0 mg to 55.0 mg)	51.909 mg	103.82%	Menthol IP	0.5 mg	Between 90.00 % to 110.00 % of stated amount (Between 0.45 mg to 0.55 mg)	0.52167 mg	104.33%
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Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	17/05/2024	17/05/2024	17/05/2024



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8.	Microbial Limit Tests:		
a.	Total aerobic microbial count	NMT 100 cfu/ml	20 cfu/ml
b.	Total yeast and mould count	NMT 10 cfu/ml	Less than 10 cfu/ml
c.	Pathogens: Escherichia coli	Should be absent/ml	Absent/ml

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Harveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	17/05/2024	17/05/2024	17/05/2024