



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/24A0508
Generic Name	Terbutaline Sulphate, Ambroxol Hydrochloride, Guaiphenesin & Menthol Syrup	Sample Quantity	14 Bottles
Batch No.:	AGL41143	Sample Received on	03/12/2024
Batch Size:	24000 Bottles	Analysis Date	03/12/2024
Mfg. Date.	11/2024	Release Date	18/12/2024
Exp. Date	10/2026	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	1.1270 gm/ml		
4.	pH	Between 4.0 to 6.0	5.40		
5.	Average filled Volume	Not less than 100.0 ml	100.92 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:	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)	1.250 mg	100.00%
	Ambroxol Hydrochloride IP	15 mg	Between 90.00 % to 110.00 % of stated amount (Between 13.5 mg to 16.5 mg)	14.686 mg	97.91%
	Guaiphenesin IP	50 mg	Between 90.00 % to 110.00 % of stated amount (Between 45.0 mg to 55.0 mg)	50.876 mg	101.75%
	Menthol IP	0.5 mg	Between 90.00 % to 110.00 % of stated amount (Between 0.45 mg to 0.55 mg)	0.477 mg	95.40%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	18/12/2024	18/12/2024	18/12/2024



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8.	Microbial Limit Tests:		
a.	Total aerobic microbial count	NMT 100 cfu/ml	35 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	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	18/12/2024	18/12/2024	18/12/2024