

CERTIFICATE OF ANALYSIS

Page 1 of 1

Product Name	Rheollose® HVP - CARMELLOSE SODIUM EP 10.0 (CARBOXYMETHYLCELLULOSE SODIUM)		
Lot No	CMC Na/25040097		
T.R. No.	BD/TR/0097-A/2025		
Lot Size	101.00 kg		
Mfg. Date	April-25		
Re.Test.Date	April-28		
			Date of Analysis : 22/04/2025

SR. NO.	TESTS	SPECIFICATION	RESULTS	REFERENCE METHOD
---------	-------	---------------	---------	------------------

A. CHEMICAL TESTS

1.	Appearance	A White or almost white, granular powder, hygroscopic after drying.	White, odorless, hygroscopic powder.	EP
2.	Solubility	Practically insoluble in acetone, in anhydrous ethanol and in toluene. It is easily dispersed in water giving colloidal solutions.	Complies	EP
3.	Identification Tests:-			
	Test (A) By chemical	A blue, cotton-like precipitate is produced.	Complies	EP
	Test (B) By chemical	No Precipitate is formed.	Complies	
	Test (C) Sodium test	The solution prepared from the sulfated ash in the test for heavy metals should give the reaction of sodium.	Complies	
4.	Appearance of solution	Solution S is should not more opalescent than reference suspension III (2.2.1) and should not more intensely colored than reference solution Y6 (2.2.2, Method II)	Complies	EP
5.	pH of Solution[1.0 % w / v]	6.0 to 8.0	7.04	EP
6.	Viscosity In 2% Water Solution, By brook field LVDV, Spindle no: 3, at 20 rpm and 25°C	1500 – 3000 cP	2104 cP	EP
7.	Sodium Glycolate	Maximum 0.4 %	Complies	EP
8.	Chloride	Maximum 0.25 %	Complies	EP
9.	Heavy Metals	Maximum 20 ppm	Complies	EP
10.	Loss on drying	Maximum 10.0 %	6.80 %	EP
11.	Sulfated Ash	20% to 33.3%	25.49 %	EP
12.	Assay (on dried basis)	6.5% to 10.8% of sodium (Na)	8.15 %	EP


B. PHYSICAL TESTS

1.	Particle Size	Not less than 95% Passing through 60 Mesh	100.00 %	In House
----	---------------	---	----------	----------

C. MICROBIAL LIMITS: (Additional Test)

1.	Total Aerobic microbial Count	Not more than 1000 CFU/g	Complies	EP
2.	Total yeasts and molds Count	Not more than 100 CFU/g	Complies	

Remark: The Product passes as per EP 10.0, IH Specifications.

	Designation	Stamp	Signature	Date
Prepared by :	Q.C. Chemist		<i>Isarala P.</i>	22/04/2025
Reviewed & Approved by :	Manager Q.C./QA		<i>P. Desai</i>	22/04/2025

METAPHARMACEUTICAL

N DE LOTE:

0320525

Q.C. 20/05/2025