



Excellence... in sight
Pharmaceutical Division

PHARMACEUTICAL PRODUCT REGISTRATION – CHILIE

ACTIVE INGREDIENTS TEST REPORTS

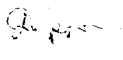
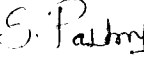
**CERTIFICATE OF ANALYSIS
RAW MATERIAL-GENERAL**

Name of the product : Hydroxy propyl methyl cellulose IP	Batch No/Lot No : ZH20012N11
Name & address of the Manufacturer/Supplier : Dow chemical company - US /Colorcon Asia pvt ltd, Building ,Village Kuksa Bhiewadi-421302	Date of sampling : 06/07/2012
Total Quantity purchased : 25kg	Quantity of sample drawn : 10gms
Date of Manufacturing : 20/08/2011	Report No : ARR – 12/0048 RM No – : 0160P/12-13
Retest Date : 18/08/2016	Released Date : 27/07/2012 Retest Date : 26/07/2013

ANALYSIS

S.NO	TESTS	RESULTS	LIMITS
1.	Description	White powder, almost odorless hygroscopic after drying	White or yellowish white, fibrous or granular powder; hygroscopic after drying
2.	Solubility	It swells in water forming an opalescent, viscous colloidal solution	It should be swells in water forming an opalescent, viscous colloidal solution
3.	Identification a. With heating b. With 1M sodium hydroxide or 1M hydrochloric acid c. With acetic acid and tannic acid d. With sulphuric acid	Above 50°C the solution is cloudy. On cooling the solution is clear. The mixture is remain stable and clear A yellowish white flocculent precipitate is produced this dissolves in 6M ammonia	above 50°C the solution Becomes cloudy or a flocculent Precipitate is formed. On cooling. The solution becomes clear or Slightly opalescent. In either case the solution should be remains clear A yellowish white flocculent Precipitate should be produced This dissolves in 6M ammonia

The product complies/~~Does Not~~ complies as per IP specifications

 27/07/2012	 27/07/2012	 27/07/12
ANALYSED BY QC CHEMIST	CHECKED BY QC SUPERVISOR	APPROVED BY QA SUPERVISOR

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S.NO	TESTS	RESULTS	LIMITS
	and Sodium meta bisulphate	A pink color produced immediately. With in 100 minutes this pink color turns to violet.	A pink color produced Immediately this becomes Violet color with in 100Minutes.
	e. With evaporation	A thin film is produced	A thin film should be produced.
4.	pH (1% solution)	6.89	5.5 – 8.0
5.	Clarity and color of the solution	Clear and colorless	Should be clear and colorless
6.	Viscosity	4200cPs	3000 – 5600cPs
7.	Heavy metals	Less than 20ppm	NMT 20ppm
8.	Chloride	Less than 0.5%	NMT 0.5%
9.	Sulphated Ash	0.11%	NMT 3%
10.	Loss on drying (%)	1.23%	NMT 10.0%
11.	Assay Hydroxy propyl methylcellulose (%)	100.20%	96.0 – 101.0%

The product complies/Does Not complies as per IP specifications		
 27/07/12	 27/07/2012	 27/07/12
ANALYSED BY	CHECKED BY	APPROVED BY
QC CHEMIST	QC SUPERVISOR	QA SUPERVISOR



Certificate 5467244

The Dow Chemical Company

Page 1

Date: 14.10.2011

Certificate of Analysis

Shipped: 30.09.2011

BDP

DOW EUROPE GMBH

Fax:

PORT OF KHAVA SHEVA

KHAVA SHEVA

MA 400000

INDIA

Cust. P.O.: 030/50/40139613

Dlvv Note: 71186194 10

Material: METHOCEL* E4M Premium

Hydroxypropyl Methylcellulose

Spec: 00053936-S

Batch: ZH20012N11

Mfgd:

20.08.2011

Retest Date:

18.08.2016

Ship from: THE DOW CHEMICAL COMPANY

BAY CITY

MI UNITED STATES

It is hereby certified the material indicated above has been manufactured in accordance with the FDA cGMPs, Kosher guidelines, was inspected and tested in accordance with the conditions and the requirements of current USP, EP and JP for Hypromellose as well as the current specific purity criteria for the food additive Hydroxypropyl Methyl Cellulose (E464) and unless agreed otherwise conforms in all respects to the specification relevant thereto.

Feature	Units	Results	Limits	
		ZH20012N11	Minimum	Maximum
Apparent Viscosity	mPa.s	4,572	2,663	4,970
Brookfield				
2% in water, @ 20degC				
Loss on Drying	%	1.7	----	5.0
Residue on Ignition	%	0.2	----	1.5
Ash, Sulfated	%	0.2	----	1.5
pH, 2% in Water	-	6.0	5.0	8.0
Assay, Methoxyl	%	28.8	28.0	30.0
Assay, Hydroxypropoxyl	%	8.5	7.0	12.0
Appearance		Passes		
Opalescence				
Appearance		Passes		
solution color				

This Batch, based on audit testing and process control, is certified to be NMT 20 ppm heavy metals (as Pb) and also meets all specification requirements for harmonized identification tests, residual solvents and microbiological limits.

Batch (Lot) Number manufactured location: 2N = Midland, MI; 24 = Plaquemine, LA

Julie Wright, FORTEFIBER, METHOCEL Quality Systems Specialist

For inquiries please contact Customer Service at 1-800-232-2436 (USA).

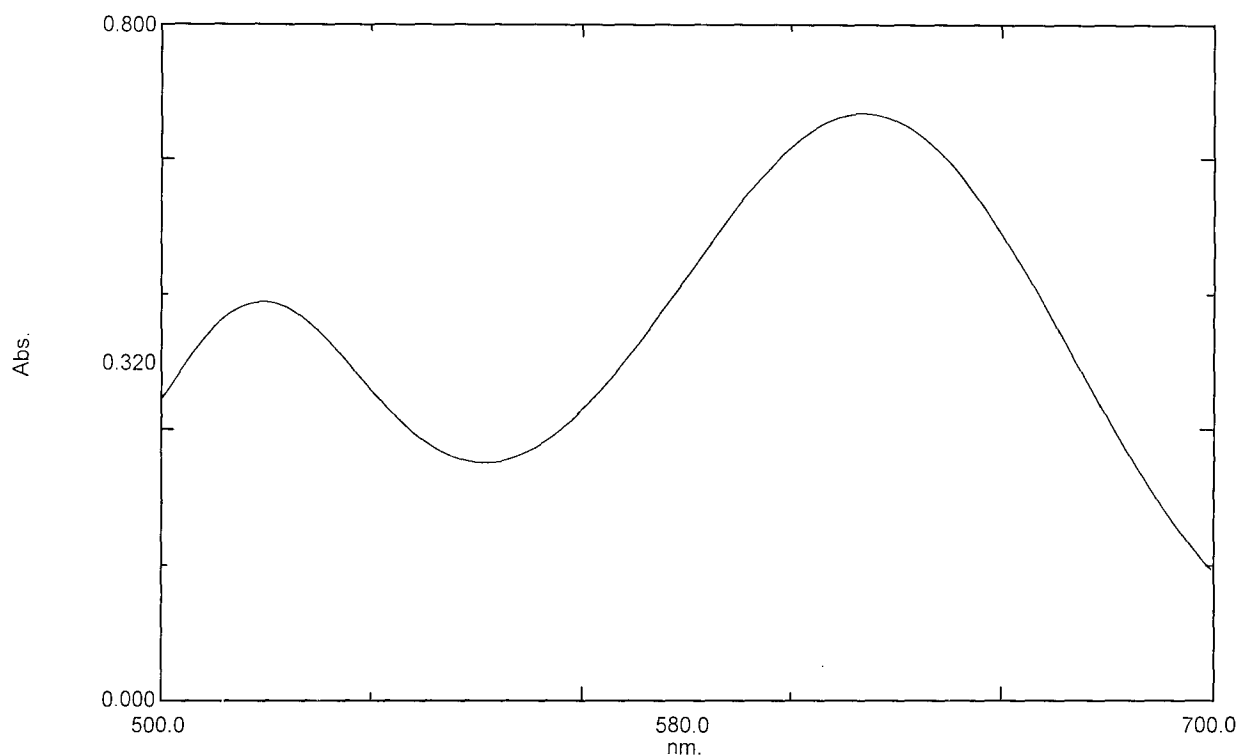
* Trademark of The Dow Chemical Company

AUROLAB PHARMACEUTICAL REPORT

 aurolab

07/16/2012 10:45:44 AM

DATA :ZH20012N11 HPMC Raw material Sample



Measurement Properties

Wavelength Range (nm.): 500.00 to 700.00
Scan Speed: Fast
Sampling Interval: 1.00
Auto Sampling Interval: Disabled
Scan Mode: Single

No.	Wavelength	Absorbance	Description
1	635.0	0.694	Sample
2			

Instrument Properties

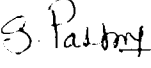
Instrument Type: UV-1800 Series
Measuring Mode: Absorbance
Slit Width: 1.0 nm
Light Source Change Wavelength: 350.0 nm
S/R Exchange: Normal

Attachment Properties

Attachment: None

Analysed By : 

Date : 16/7/2012

Approved By : 

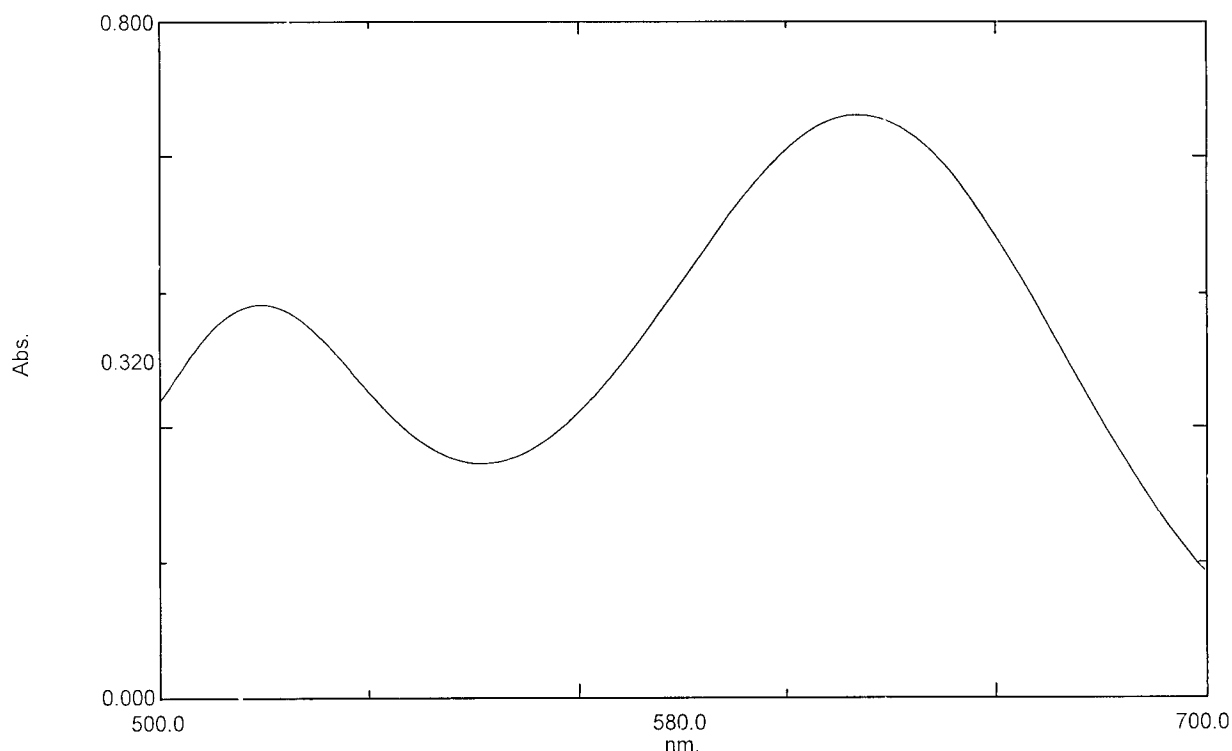
Date : 16/07/12

AUROLAB PHARMACEUTICAL REPORT



07/16/2012 10:40:45 AM

DATA :ZH20012N11 HPMC Raw material Std



Measurement Properties

Wavelength Range (nm.): 500.00 to 700.00
Scan Speed: Fast
Sampling Interval: 1.00
Auto Sampling Interval: Disabled
Scan Mode: Single

No.	Wavelength	Absorbance	Description
1	635.0	0.689	std
2			

Instrument Properties

Instrument Type: UV-1800 Series
Measuring Mode: Absorbance
Slit Width: 1.0 nm
Light Source Change Wavelength: 350.0 nm
S/R Exchange: Normal

Attachment Properties

Attachment: None

Analysed By : *RZ*

Date : 16/7/2012

Approved By : *S. Parney*

Date : 16/07/12