Rev. No.	00
Effective Date	01-07-2020
Valid Upto	01-07-2023

July 1, 2020

PRODUCT REGULATORY DATASHEET

Name of the Product: Cellulose Capsule Shells

Product brand name: ACGcaps HR, ACGcaps HL & ACGcaps HI

SCOPE: This datasheet is applicable only to product listed above.

SECTION 1: MANUFACTURING SITE INFORMATION

This product shall be manufactured at any facility of ACG Associated Capsules Pvt. Ltd. unless specified or limited by regulations or customer restrictions.

Our manufacturing facilities operate under license and surveillance of FDA (State and Central Government of India).

All manufacturing and associated activities comply with appropriate excipient GMP requirements based on the IPEC Good Manufacturing Practices guideline for bulk pharmaceutical excipients.

Each manufacturing site is designed to comply with appropriate additional local and regional regulatory requirements.

GMP certificate for each facility can be accessed from our website.

SECTION 2: PRODUCT INFORMATION

All raw materials used in the above product meet the applicable pharmacopeial/regulatory requirements.

Sr. No.	Ingredient	Applicable standard
1	HPMC/Hypromellose	Ph. Eur + USP + IP
2	Colorants	EU 231/2012+ CFR+BIS as applicable*
3	Iron Oxides (Yellow & Red)	EU 231/2012 + USPNF + CFR
4	Iron Oxide (Black)	EU 231/2012 + CFR
5	Titanium Dioxide or Opacifier	Ph. Eur + USP + IP + EU 231/2012 + CFR
6	Additives	Ph. Eur + USP + IP

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CIN No. : U24239MH1961PTC012061 I GST No. : 27AAACA4769K1ZD

Suitability of colorants*

An important part of the capsule shell is the colorants. These are governed by regulations (certifications/restrictions) of the country of use.

Colorants for capsules are selected based on their suitability for finished dosage form in intended country of use.

Accordingly, for products supplied in India, the colorants meet the BIS requirement.

Products to be consumed in the European Union use colors that conform to the (EU) 231/2012 laying down specifications for food additives.

Where applicable as in products to be consumed in USA, the colorants are certified by FDA in accordance with 21CFR part 73 & 74 for Food and Drug.

Designated Additive List of Japan forms the base when selecting and approving colors for use in capsules meant for Japan.

The quantity of colour additive used in above product is in accordance with ADI as per WHO/FAO as applicable.

Globally accepted colorants such as Iron Oxides where used meet the acceptance criteria of regulated markets such as US, EU, Japan, in addition to the Indian regulations. Elemental iron content does not exceed 5 mg per day according to 21CFR part-73.120 for food and part 73.1200 for drug.

SECTION 3: PHYSICAL / CHEMICAL INFORMATION

Product composition and specification can be made available on request to regulatory.acpl@acg-world.com

SECTION 4: REGULATORY INFORMATION

4.1 TSE/BSE INFORMATION

HPMC/Hypromellose used in the manufacturing of Cellulose Capsules Shells is extracted from wood pulp. It does not contain or contact any product of animal origin.

Accordingly, Cellulose Capsules Shells are not concerned by the requirements regarding TSE/BSE of regulation (EC) No.999/2001 and amendments thereof, EMEA/410/01 & USFDA 9 CFR Part 94.23

Further, ingredient used in above product is not derived from material of animal origin.

Therefore, above product does not pose any TSE/BSE risk.

4.2 GMO INFORMATION

Cellulose Capsules Shells are not subjected to or nor derived from any technique of genetic modification as defined in Article 2(2) of European Directive 2001/18/EC.

Ingredients used in the manufacture of the above product are not subjected to or nor derived from any technique of genetic modification as defined above.

Ingredients used in manufacturing of the above product are traceable to their source.

The product does not contain any GMOs (Genetically Modified Organisms).

Based on above, Cellulose Capsules Shells comply with EC 298/2008 (formerly 1829/2003) & EC1830/2003 on genetically modified food and feed.

4.3 RESIDUAL SOLVENTS INFORMATION

Cellulose Capsules Shells do not contain any Class I & II solvents as per CPMP/ICH/283/95 & current edition USP General Chapter <467> on Residual Solvents.

The following class III solvents are likely to be present in our product.

Sr.No.	Name of Solvent	Specification Limit
1.	Isopropyl Alcohol	Less than 5000 ppm
2.	Ethyl Alcohol	Less than 5000 ppm
3.	N-Butyl Alcohol	Less than 5000 ppm

Other residual solvents are not used in manufacturing process.

4.4 ALLERGEN INFORMATION

ALLERGEN	*Y/N	Comments
Gluten containing cereals and products (wheat, barley, rye, oat, kamut, spelt and their hybridised strains)	N	
Crustaceans and products, thereof	N	
Eggs and products, thereof	N	
Fish and products, thereof	N	
Peanuts and products, thereof	N	
Tree nuts and products, thereof	N	
Soybeans and products, thereof	N	
Milk and products (including lactose), thereof	N	
Nuts and products (almond, hazelnut, walnut, cashew, pecan nut, pistachio nut, Brazil nut, macadamia nut and Queensland nut), thereof	N	
Celery and products, thereof	N	
Mustard and products, thereof	N	
Sesame and products, thereof	N	
Sulfite (E220 – 228) and sulphur dioxide [>= 10 ppm SO_2]	N	
Lupin and products, thereof	N	
Molluscs and products, thereof	N	
Colorants	N	Suitable colorants are used based on customer request only.
Antioxidants	N	
Preservatives	N	Based on customer request

*Y = YES, N = NO

Reference:

US FDA Guidance for Industry - Food Allergen Labelling and Consumer Protection.

Commission Regulation – 2007/68/EC.

Regulation (EU) No 1169/2011 on the provision of food information to consumers.

4.5 ELEMENTAL IMPURITIES INFORMATION

Cellulose Capsules Shells comply with ICH Q3D and other applicable Guideline for elemental impurities. Elemental impurities are monitored as per reduced monitoring program for Class 1 and Class 2A by using validated test methods outlined in the current edition of USP General Chapter <233>. Elemental impurities compliance statement can be made available on request.

Therefore, Cellulose Capsules Shells meet the limit of Class 1 and Class 2A elements as listed below:

Elemental Impurity	Symbol	Class IPEC	Limit (ppm)
Arsenic (inorganic)	As	1	1
Lead	Pb	1	1
Cadmium	Cd	1	0.5
Mercury (inorganic)	Hg	1	0.1
Cobalt	Co	2A	5
Nickel	Ni	2A	20
Vanadium	V	2A	10

4.6 KOSHER/HALAL INFORMATION

Ingredients used in the manufacturing of Cellulose Capsules Shells are Kosher and halal certified in accordance with the applicable requirements.

4.7 VEGETARIAN INFORMATION

Cellulose Capsules Shells do not contain nor contact any product of animal origin. Further no other ingredients of animal origin are used to manufacture the above product.

Therefore, Cellulose Capsules Shells are suitable for vegetarian diet.

4.8 IRRADIATION FREE INFORMATION

Statement can be made available on request to **regulatory.acpl@acg-world.com**

4.9 NANO MATERIAL INFORMATION

Cellulose Capsules Shells manufactured by us are not considered as nanomaterials as per definition outlined in EC directive 1169/2011.

Additionally, ingredients used in the above product are neither manufactured as nanomaterial nor use nanotechnology.

4.10 MELAMINE INFORMATION

The basic raw material used in the manufacturing of Cellulose Capsules Shells is Hydroxypropyl Methylcellulose (HPMC).

Hydroxypropyl Methylcellulose (HPMC) is not covered under “Guidance for industry pharmaceutical component at risk for melamine contamination” issued by USFDA dated August- 2009.

Other ingredients used in above product are not covered in melamine guidance.

Therefore, Cellulose Capsules Shells are free from melamine contamination.

4.11 GLUTEN INFORMATION

Samples of Cellulose Capsules Shells are analyzed for Gluten content by Elisa Reader as per our monitoring program and it is found below the detection limit of 10 ppm.

Hence, we confirm that our product Cellulose Capsules Shells is Gluten free.

4.12 AFLATOXIN INFORMATION

Samples of Cellulose Capsules Shells are analysed for total Aflatoxin -B1, B2, G1, G2 & M1 by LC MS as per our monitoring program and it is found below the detection limit of 1 ppb.

Hence, we confirm that our product Cellulose Capsules Shells does not contain total Aflatoxins.

4.13 RESIDUAL PESTICIDE INFORMATION

Samples of Cellulose Capsules Shells are analysed for pesticide residues by GC MS as per EU 555/2018 and it is found below the detection limit.

Hence, we confirm that our product Cellulose Capsules Shells does not contain any pesticide residue and are safe and fit for human consumption.

4.14 PAH & PCB INFORMATION

Samples of Cellulose Capsules Shells are analyzed for Polycyclic aromatic hydrocarbons (PAH) & Polychlorinated biphenyl (PCB) and it is found below the detection limit of 1 ppb.

Hence, we confirm that our product Cellulose Capsules Shells does not contain Polycyclic aromatic hydrocarbons (PAH) & Polychlorinated biphenyl (PCB).

4.15 DIOXIN INFORMATION

Samples of Cellulose Capsules Shells are analyzed for dioxin content and it is found below the detection limit of 1ppb.

Hence, we confirm that our product Cellulose Capsules Shells does not contain dioxin.

4.16 NUTRITIONAL INFORMATION

Nutritional information can be available on request to regulatory.acpl@acg-world.com

4.17 OTHER REGULATORY INFORMATION

An additional regulatory information can be made available on request to regulatory.acpl@acg-world.com

SECTION 5: MISCELLANEOUS PRODUCT INFORMATION

5.1 BATCH NUMBERING

A typical batch number consists of system generated (SAP) 10 digits, where first 4 digits indicate the manufacturing location while the remaining 6 digits are serial numbers.

Example: 1100000278

1100 – Dahanu facility

5.2 BATCH DEFINITION

A specific quantity of material produced in a series of process and expected to be homogeneous within specified limit.

SECTION 6: REVISION HISTORY

Effective Date: 01.07.2020

Changes since last revision: -

Sr. No	Revision No.	Nature of Change	Effective date
1.	00	New product regulatory data sheet	01.07.2020

SECTION 7: CONTACT INFORMATION

For frequently asked questions refer http://apps.acg-world.com/faq/external/

For further details click on below link: http://apps.acg-world.com/products

ABBREVIATIONS

FDA = Food and Drug Administration

IP = Indian Pharmacopoeia

USP = United States Pharmacopeia

EP / Ph. Eur = European Pharmacopoeia

BIS = Bureau of Indian Standards

ADI = Acceptable Daily Intake

WHO/FAO = World Health Organization & Food & Agriculture Organization

GMO = Genetically Modified Organism

GMP = Good Manufacturing Practices

CFR = Code of Federal Regulations

EU = European Union

US = United States

NF = National Formulary

HPMC = Hydroxypropyl methylcellulose

IPEC = International Pharmaceutical Excipient Council

mg = milligram

TSE = Transmissible spongiform encephalopathy.

BSE = Bovine spongiform encephalopathy

EC = European Commission

EMEA: European Medicines Evaluation Agency

ICH: International Council for Harmonization

DISCLAIMER

The information contained herein, to the best of our knowledge, is true and accurate. Recommendations or suggestions are made without warranty or guarantee since the Regulations are subject to amendments & addendum. Any information contained herein is intended as guidance for use in our products and the actual should be verified before use.

Regards

Vrushali Salve

Asst. Executive-Global Regulatory Affairs