CERTIFICATE OF ANALYSIS

Product: Bentonite Clay

Batch No: 4496602

Expiry Date: February 2026

Test	Method	Specification	Results
Characteristics	BP(93)	As BP (93)	Satisfactory
Identification	BP(93)	As BP (93)	Satisfactory
Loss on Drying	BP(93)	≤ 15%	7.0%
Heavy Metals	BP(93)	≤ 50ppm	< 41.6 mg/kg
Viscosity	In House Method	n/a	552 cps
pH	In House Method	n/a	9.0
Sedimentation Volume	BP(93)	≤ 2ml	<2 ml
Swelling Power	BP(93)	≥ 22ml	22 ml
Coarse Particles	BP(93)	≤ 0.5%	< 0.20%
Alkalinity	BP(93)	Discolours in 5 minutes	Satisfactory

Comments

"The sample complies with the specification for Bentonite in the British Pharmacopoeia 1993"

Allergen Statement

Bentonite Clay

I can confirm, following discussions with our supplier, that the below Allergen information is correct:

ALLERGENS	Product Free From?	Listed Item on Site at manufacturer	Where applicable, is there risk of cross-contamination?
Free from Peanuts and Peanut Derivatives (including possible cross contamination)	YES	NO	NO
Free from other Nut and Nut Derivatives *Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)*	YES	NO	NO
Free from Sesame Seeds and Sesame Seed Derivatives	YES	NO	NO
Free from other Seeds and Seed Derivatives (Poppy Seeds, Cotton Seeds, Sunflower Seeds)	YES	NO	NO
Free from Milk and Milk Derivatives (including lactose)	YES	NO	NO
Free from Egg and Egg Derivatives	YES	NO	NO
Free from Cereals and Derivatives containing OR POTENTIALLY CONTAMINATED WITH Gluten *(wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barley grass)*	YES	NO	NO
Free from Soya and Soya Derivatives	YES	NO	NO
Free from Lupin and Lupin Derivatives	YES	NO	NO
Free from Mustard and Mustard Derivatives	YES	NO	NO
Free from Celery or Celery Derivatives (including Celeriac)	YES	NO	NO
Free from Fish and Fish Derivatives	YES	NO	NO
Free from Molluscs and their Derivatives	YES	NO	NO
Free from Crustaceans and their Derivatives	YES	NO	
Free from Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre	YES	NO	NO

06/06/18

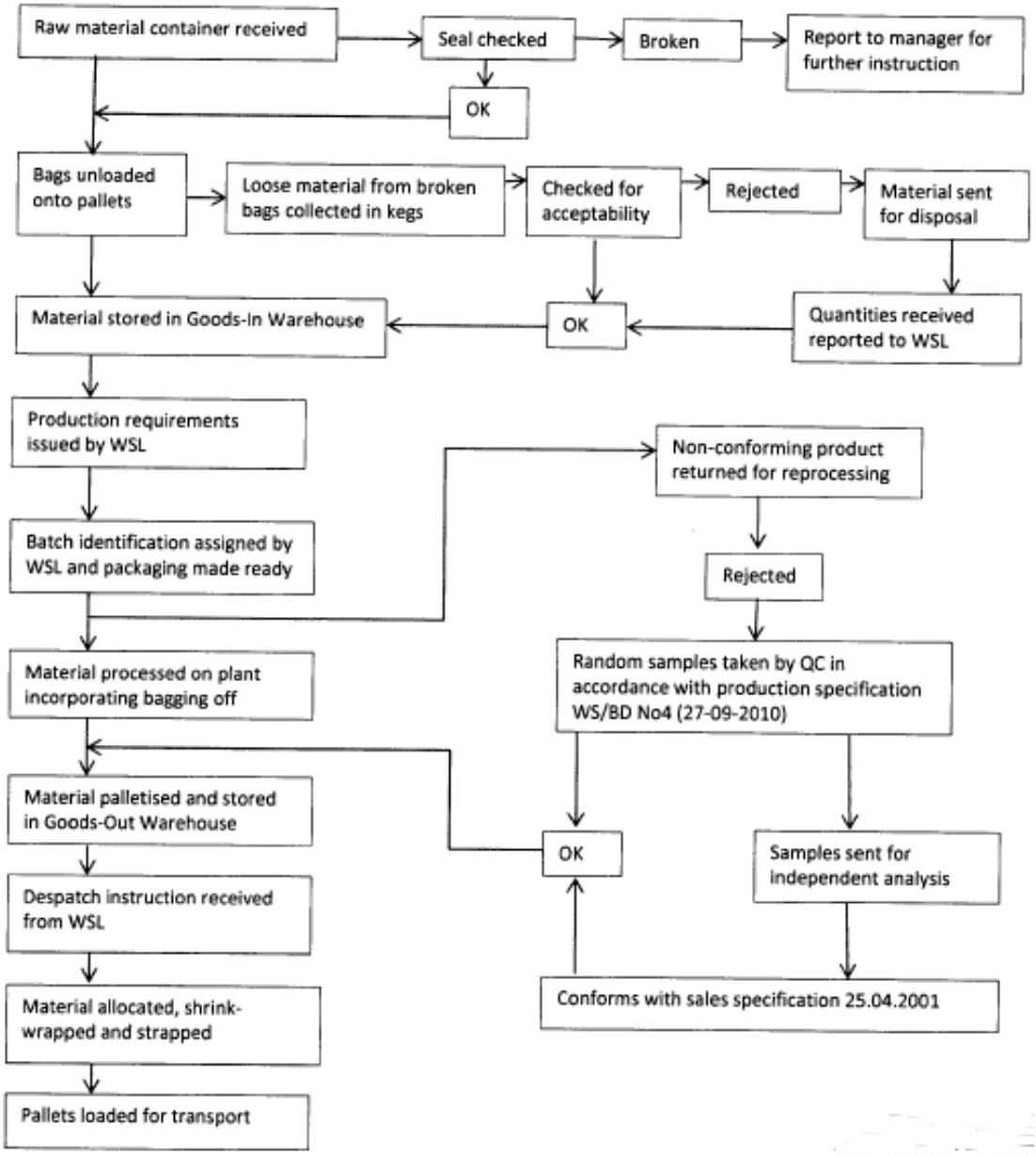
Flow Chart and Country of Origin Statement

Bentonite Clay

We confirm, following discussions with our supplier, that the above product origin is **Germany**

Please find the below Flow Chart for your reference:

Bentonite / Bentopharm Process Chart



GMO and Vegan Statement

Bentonite Clay

Dear Sir/Madam,

We can confirm, following discussions with the supplier, that the product origin is Vegan Suitable and

GMO-Free, as provided by our supplier. Hoping this meets with your requirements.

06/06/18

Object of analysis: Bentonite Clay #

Results:

Parameter	*Test specification*	*Result*
Identification		
1. Identity A	a gelatinous white precipitate is formed	conforms
2. Identity B	the apparent volume of the sediment is not less than 22 ml after 2 hours	conforms (32 ml)
3. Identity C	gives the reaction of silicates	conforms
Purity		
4. Alkalinity	decolourisation of bluish solution within 5 min	conforms
5. Coarse particles	max. 0.5 %	< 0.5 %
6. Heavy metals	max. 50 ppm	< 50 ppm
7. Loss on drying	max. 15 %	8.90 %
8. Microbial contamination	TAMC: 10^3 cfu/g; max. acceptable limit (Ph.Eur. 2.6.12): 2000	conforms (410 cfu/g)
Functionality-related characteristics		
9. Swelling power with water	see test identity B	conforms
10. Sedimentation volume	the volume of the clear supernatant liquid is not greater than 2 ml after 24 hours	conforms
Escherichia coli	-	not detectable /g

The sample conforms to Ph. Eur. 8.8, monograph Bentonit (8.0/0467)
According to the client, the monograph Bentonite in British Pharmacopeia 2017 conforms to the Ph.Eur. 8.8 monograph with regard to content. Therefore, the sample also conforms to BP 2017.

Test methods:

- Testing of Bentonit
According to Ph. Eur. 8.8, monograph Bentonit (8.0/0467)

Identification

1. Identity A

2. Identity B

3. Identity C

Purity

4. Alkalinity

5. Coarse particles

6. Heavy metals

7. Loss on drying

8. Microbial contamination

Functionality-related characteristics

9. Swelling power with water (see identity B)

10. Sedimentation volume

- Determination of Escherichia coli according to Ph.Eur. current edition 8.8, 2.6.12 und 2.6.13

Bentonite Clay Information Sheet

Information regarding Bentonite Clay to satisfy the requirements of Cosmetic Regulation EU2017/1224

- Bentonite Clay is mechanically milled, bagged, irradiated if required, it is analysed using approved third parties
- The raw material is mined in the USA and imported into the UK by the supplier for production as given above. UK is the Country of Origin.
- Bentonite Clay is produced without the use of any metal catalysts or reagents. The finished material contains less than 50ppm of heavy metal and further testing for lead and Arsenic can be carried out to comply with Food Additive 2008/84/EC regulations.
- Specification and SDS are attached as separate documents. No SDS is required as the material is exempt from REACH and non-hazardous. The SDS attached is compliant with EC2015/830, EC1272/2008 and EC2020/878 and is offered as a courtesy to our customers.
- Certificate of analysis and irradiation certificate, if required, is available for every batch.
- Bentonite Clay is exempt from REACH under Annex V Paragraph 7 of the regulation, as a non-hazardous natural mineral.
- Bentonite clay is a substance of "unknown or variable composition, Complex reaction product or Biological material" (UVCB according to REACH and CLP regulations). The purity of the material is 100% w/w which includes the impurities associated with a UVCB.
- Bentonite Clay does not contain any Nanomaterials, SVHC, CMR, VOCs, Glycols or Methylisothiazolinone.
- The material is produced without contact with any GMO materials, products containing GMOs or pathways where GMO materials have been produced.
- Bentonite Clay has never been tested on animals.
- Bentonite Clay is not known to contain any hormones, allergens (EC/1169/2011), Collagen, gelatine, tallow or natural rubber (2003/32/EC), or palm oil.
- Bentonite Clay is not derived from, nor has come into contact with any materials or machinery that has been exposed to hormones BSE/TSE, bovine, porcine, caprine, ovine, deer, elk, mink or feline material. (2003/32EC)
- It does not involve the use of solvents in the manufacture, or preservatives including parabens.
- Bentonite Clay (E558) can be used by all religious groups, vegetarians and vegans.
- Bentonite Clay has an unlimited shelf-life subject to the appropriate storage in dry conditions, away from direct sunlight and excess of temperatures. A retest after five years is recommended. (Excludes irradiated material)

Revision: 12 Date: Jan 2021

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1. Product identifier
Product name: Bentopharm
EC No: 215-108-5
CAS No: 1302-78-9
REACH registration No: Exempt. Natural Mineral
Type of product: Mineral

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of substance / mixture:
Agricultural, Cosmetics, Food/feedstuff additives, Paper industry, Pharmaceuticals.
Function or use category: Absorbents and adsorbents, Filler, Viscosity adjusters

1.2.2 Uses advised against:
Restrictions on use: There are no restricted uses.

1.3. Details of the supplier of the safety data sheet
Company:
Madar Corporation Limited

19-20 Sandleheath Industrial Estate
Fordingbridge
SP6 1PA
01425 655555
technical@madarcorporation.co.uk

Emergency telephone number:
+44 (0) 1425 655555(Mon-Fri 9am – 5pm)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
Classification according to regulation (EC) No. 1272/2008 (CLP)
Not classified

Adverse physicochemical, human health and environmental effects
To our knowledge, this product does not present ant particular risk, provided it is handles in accordance with good occupational hygiene and safety practice.

2.2. Label elements
Labelling according to Regulation (EC) No. 1272/2008 (CLP)
No labelling applicable

2.3 Other hazards
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

SECTION 3: COMPOSTION/INFORMATION ON INGREDIENTS

3.1 Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Bentonite	(CAS-No.) 1302-78-9 (EC-No.) 215-108-5 (REACH-no) Exempt. Natural Mineral	≥ 99.95	Not classified

3.2 Mixtures
Not applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:
First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact: Wash skin with plenty of water.
First-aid after eye contact: Rinse eyes with water as a precaution.
First-aid measures after ingestion: Call a physician or poison control centre. Call a poison centre or doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed:
No additional information available

4.3. Indication of any immediate medical attention and special treatment needed:
Treat symptomatically

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media:
Suitable extinguishing media: Water spray, Dry powder, Foam

5.2. Special hazards arising from the substances or mixture:
Hazardous decomposition products in case of fire: No hazardous thermal decomposition products

5.3. Advice for firefighters:
Protection during firefighting: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:
6.1.1. For non-emergency personnel
Emergency procedures: Ventilate spillage areas.

6.1.2 For emergency responders
Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: “Exposure controls/personal protection”

6.2. Environmental precautions:
Avoid release to the environment

6.3. Methods and material for containment and cleaning up:

Methods for cleaning-up: Mechanically recover the product
Other information: Dispose of materials or solid residues at an authorised site.

6.4. Reference to other sections:

For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling:

Precautions for safe handling: Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities:

Storage conditions: Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters:

No additional information available

8.2. Exposure controls:

Appropriate engineering controls:
Ensure good ventilation of the work station

Materials for protective clothing:
Normal work clothes are appropriate

Hand protection:					
Protective gloves					
Type	**Material**	**Permeation**	**Thickness (mm)**	**Penetration**	**Standard**
Disposable gloves, Reusable gloves	Polyvinylchloride (PVC)				EN ISO 374

Eye protection:			
Safety glasses			
Type	**Use**	**Characteristics**	**Standard**
Safety glasses, Safety goggles	Fine dust	clear, With side shields	EN 166

Skin and body protection:
Wear suitable protective clothing

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Physical state	:	Solid
Appearance	:	Micronised powder.
Colour	:	Light grey. light green.
Odour	:	odourless.
Odour threshold	:	No data available
pH	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	> 450 °C EU Method A.1
Freezing point	:	Not applicable
Boiling point	:	Not Applicable
Flash point	:	Not Applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable.
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	2.6 (at 20°C)
Density	:	1 – 1.4 g/cm³ Measured as bulk density
Solubility	:	No data available
Partition coefficient n-octanol/water (Log Pow)	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	Not applicable

9.2. Other information:
No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:
The product is non-reactive under normal conditions of use, storage and transport

10.2. Chemical stability:
Stable under normal conditions

10.3. Possibility of hazardous reactions:
No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid:
None under recommended storage and handling conditions (see section 7)

10.5. Incompatible materials:
No additional information available

10.6. Hazardous decomposition products:
Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXOLOGICAL INFORMATION

11.1. Information on toxicological effects:
Acute toxicity (oral): Not classified
Acute toxicity (dermal): Data not available (Bentonite is almost insoluble and has a low absorption through the skin)
Acute toxicity (inhalation): Not classified
Additional information: Classification is not warranted

Bentopharm (1302-78-9)	
LD50 oral rat	> 2000 mg/kg (wt/wt) (OECD 420, rat)
LC50 inhalation rat (mg/l)	> 5.27 mg/l (OECD 436, rat)

Skin corrosion/irritation: Not classified
Serious eye damage/irritation: Slightly irritant but not relevant for classification (Conclusive but not sufficient for classification)
Additional information: Based on available data, the classification criteria are not met

Respiratory or skin sensitisation: Not classified (Conclusive but not sufficient for classification)
Additional information: Based on available data, the classification are not met

Germ cell mutagenicity: Not classified(Based on available data criteria are not met
Additional information: Based on available date criteria are not met

Carcinogenicity: Not classified(inconclusive data)
Additional information: Based on available data, the classification criteria are not met.

Bentopharm (1302-78-9)	
IARC group	3 - Not classifiable

Reproductive toxicity: Not classified (Based on available data, the classification are not met)

STOT- single exposure: Not classified (Based on available data, the classification criteria are not met)
Additional information: Based on available data, the classification criteria are not met

STOT- related exposure: Not classified (Based on available data, the classification criteria are not met)
Additional information: Based on available data, the classification criteria are not met

Aspiration hazard: Not classified (Based on available data, the classification criteria are not met)
Additional information: Based on available data, the classification criteria are not met

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity:

Ecology – general: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment

Hazardous to the aquatic environment, short-term (acute): Not classified

Hazardous to the aquatic environment, long-term (chronic): Not classified

Not rapidly degradable

Bentopharm (1302-78-9)	
LC50 fish 1	16000 mg/l Freshwater fish (rainbow trout)
LC50 other aquatic organisms 1	> mg/l
EC50 other aquatic organisms 1	81.6 mg/l Freshwater invertebrates (Dungeness crab)
EC50 other aquatic organisms 2	24.8 mg/l Freshwater invertebrates (dock shrimp)
EC50 72h algae (1)	> 100 mg/l Freshwater Algae

12.2. Persistence and degradability:

No additional information available

12.3. Bio accumulative potential:

Bentopharm (1302-78-9)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil:

No additional information available

12.5. Results of PBT and vPvB assessment:

Bentopharm (1302-78-9)
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

12.6 Other adverse effects:

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Waste treatment methods: Dispose of contents/container in accordance with licensed collector's sorting instructions

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user:
Overland transport
Transport by sea: Not regulated
Air transport: Not regulated
Inland waterway transport: Not regulated
Rail transport: Not regulated

14.7. Transport in bulk according to annex II of marpol and the IBC Code:
Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:
15.1.1. EU-Regulations
No REACH Annex XVII restrictions
Bentopharm is not on the REACH Candidate List
Bentopharm is not on the REACH Annex XIV List
Bentopharm is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 Jult 2012 concerning the export and import of hazardous chemicals
Bentopharm is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations
No additional information available

15.2. Chemical safety assessment:
No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

Indication of changes:			
Section	**Changed item**	**Change**	**Comments**
1.3			Typing correction

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BLV	Biological limit value
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

Data Sources: manufacturer's evaluation, Industrial Minerals Association, ECHA (European Chemicals Agency)

Product Specification

Product Name: Bentonite Clay (Standard (B20) & Superfine & Superfine Extra)

Product: Natural Bentonite Clay

Form: Micronised Powder

Specification: BP 1993 EP 1990

Definition:
Bentonite is a natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some of the aluminium and silicon atoms may be replaced by other atoms such as magnesium and iron.
Characteristics: Complies to BP & EP Monograph
Identification test A, B & C: Complies to BP & EP Monograph
Alkalinity: Complies to BP & EP Monograph
Coarse Particles: Complies to BP & EP Monograph (nmt 0.5% on 75 micron sieve)
Sedimentation Volume: Complies to BP & EP Monograph (nmt 2ml)
Swelling Power: Complies to BP & EP Monograph (nlt 22ml)
Heavy Metals: Complies to BP & EP Monograph (Limit test A for heavy metals)
Loss on Drying: Complies to BP & EP Monograph (nmt 15%)