

Consumer Group

Type : Raw Material Specification
Title : Talc Powder
Number : RM-008967

Revision 6
Issued Date 2014-08-07 Expiration Date None
Spec Should not be Issued Before Date NA Effective Timeline (days) 0
Geographical Scope Global Specification Category Permanent
Review Interval (Months) 0

Related Information

SCO SCO-614766

Organizations(refer to the Organizations section in GSS)

Organization Type	Organization Name
Marketing Company	J&J Denmark,J&J Sweden,J&J Norway,J&J Finland,J&J Germany,J&J Belgium,J&J Zug,J&J Austria,J&J Indochina,J&J Indonesia,J&J Spain,J&J Ireland,J&J Consumer Poland,J&J Hong Kong,J&J Pakistan,J&J Consumer Japan,J&J Switzerland,J&J South Africa,J&J Consumer India,J&J Brazil,J&J China,J&J Pacific,J&J Thailand,J&J Bolivia,J&J Consumer UK,J&J Egypt SAE,J&J Vietnam,J&J Puerto Rico,J&J Venezuela,J&J Korea,J&J Philippines,J&J Honduras,J&J El Salvador,J&J Nicaragua,J&J Mexico,J&J Central America,J&J Malaysia,J&J Middle East,J&J Costa Rica,J&J Taiwan,J&J Jamaica,J&J Guatemala,J&J Peru,J&J Ecuador,J&J Trinidad,J&J Dominican Republic,J&J Singapore,J&J Chile,J&J Uruguay,J&J Consumer Products USA,J&J Paraguay,J&J Colombia,J&J Panama,J&J Argentina,Consumer & Personal Product Worldwide Company
Product Category	Skin Treatments (Baby),Cosmetics,Lotion & Cream,Cleanser,Body Care,Powder
Manufacturing Location	TPM - KIK (Etobicoke Rexdale) (13 Bethridge Road),Lititz,Mumbai,TPM - SC and C Cosmotech Co Inc (Paranaque City),Sao Jose dos Campos,TPM - Lipang Packing Co Ltd (Shanghai),Jakarta,TPM - VVF (India) Ltd,TPM - SCAL - Shanghai Custom Manufacturing and Aerosol Propellants Co Ltd (Shanghai),Shanghai,TPM - VVF Limited (Baddi),TPM - IDS Manufacturing Co Ltd (Pathumthani),East London,TPM - PT Malidas Sterilindo (Sidoarjo),Manila,TPM - INFASA,Bangkok,Pilar,Cali,TPM - Advanced Testing Laboratory Inc,TPM - NUCRO-Technics Analytical Labs,TPM - PTI - Pharma-Tech Industries (Royston)
Brand	NEUTROGENA,SHOWER TO SHOWER,DESITIN,Johnsons Baby,JOHNSONS
Region	Asia Pacific,Latin America,EAME,North America,Worldwide
Franchise	Baby Care,Adult Skin & Hair Care
Specification Type	Raw Material Specification

Case No: BC666514
Joanne Smith et al.
VS Johnson & Johnson et al.
DEFENDANT'S EXHIBIT 7458

Raw Material Category	CHM - Talc
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Revisions

Rev	State	Description of Change	Reason for Change	Revised By	Issued Date	Expiration Date
0	Obsolete	First Issue	New	Curtis Lee	2009-10-26	None
1	Obsolete	Updating limits for section 2.13-Loss on Drying Updating limits for section 2.35-Free Crystalline Silica as Quartz Adding section 3.1.4-Packaging Clarifying micro requirements for sanitized talc in section 10.0-Testing Frequencies and Requirements	Required updates for the Global Talc spec	Curtis Lee	2010-03-24	None
2	Obsolete	Update supplier information in appendices Replace "Current BIS" with "Current BIS: 1462" for test item "2.11, 2.14, 2.16, 2.17, 2.18, and 2.28" Update requirements in section 2.5-Microbial Requirements, 2.16 Acid Soluble Substances, and 2.30 Limit of Chromium Update methods for section 2.9 Packed Bulk Density, 2.12 Loss on Ignition, 2.15 Water Soluble Substances, and 2.22 MgO Content To clarify what solution is to be used "(Test solution for iron)" was added to sections 2.25-2.28 Section 5.0 was modified to remove redundancies in the statement Section 10.0 was updated to add clarification to the statements See attached Talc Rev 2 Change Summary document for a full change summary	Required updates for the Global Talc specification.	Curtis Lee	2010-12-16	None
3	Obsolete	Add a Body Talc Alternate Source Qualification Guidance as a referenced document and add a note to that affect in the body of the specification (5.0).	Provide guidance for the qualification of an alternate talc ore body and/or milling operation.	Don Hicks	2011-03-24	None
		See attached reference document for detailed list of all changes and rationale. •Converted to datacentric format •Revised General Description to add clarity. •Changed Loose Bulk Density requirement from 0.37-0.55 to 0.35-0.60 g/cm ³ to accommodate test variation. •Deleted Packed Bulk Density requirement as non-value added. •100 mesh Fineness from NLT 99.9% to 99.7% to allow for test variation. Also added wet or dry sieve evaluation. •Added Magnesita as a supplier. •Changed Rio Tinto to Imerys based on 2011 acquisition				

4	Obsolete	<ul style="list-style-type: none"> •Revised Testing Frequencies and Requirements section to provide additional clarity and global consistency. •Magnesium Oxide: Changed from 29% to 28.2% at the request of LATAM/Magnesita. •Whiteness: 85 to 88% reflectance to align with lowest supplier requirement. •Classified as Micro Risk category 4. •Added Country Specific Loose Bulk Density, Whiteness, and fineness where locally tighter than rest of world. •Added Pre-sanitization micro limits and corresponding test method which are required locally for China. •Added requirement for ID testing upon receipt as per Enterprise policy •Added Trace level monitoring for Neodymium (Nd) in additional requirement section. •Added BIS 1492 requirement for Fineness and Loss on Drying for all products marketed in India. •Identified ERP/SAP codes for Zecco J, Talc Finex, Talc 200J. •Identified optiva codes. •Identified approved sources per region. 	Convert to datacentric format and revise all sections based on latest updates to talc suppliers, requirements, and testing frequencies as requested by the global subject matter experts.	Don Hicks	2012-07-03	None
5	Obsolete	<p>1)Table of Qualitative Attributes – Added: "or Japan MHLW method (X-Ray Diffraction.)" to first sentence. Added: "(Japan MHLW method only for Talc to be marketed in Japan.)"</p> <p>2)Additional Requirements – Deleted: "Trace Level Impurity Monitoring (China market only). On a quarterly basis, Neodymium (Nd) testing with China SFDA method is required for talc raw material. Guidance is none detected." Added: "Trace Level Impurity Monitoring (China market only). On a quarterly basis, Neodymium (ND) testing with China SFDA method is required for talc raw material monitoring purpose. Alert level is 2.5 ppm. An investigation by the Mine/Milling location is recommended if Alert Level is exceeded."</p> <p>3) Revised min range from 98.5 to 98.0 for 200 mesh fineness test parameter.</p> <p>4) Add San Jose Dos Campos to manufacturing location.</p>	<p>1)Added at the request of AP SMP/TT to achieve full compliance with Japan regulatory requirements.</p> <p>2) Added at request of AP SQM to ensure clarity with local China regulatory requirements.</p> <p>3)Revised 200 mesh fineness test parameter to align to Personal Care Product Council.</p> <p>4) Update organizations as per regional RMC.</p>	Gregory Kolibas	2013-10-08	None
6	Issued	RM-008967: Adding comment to arsenic parameter.	See GCC-035537.	Gregory Kolibas	2014-08-07	None

Approvals

Approver	Role	Responsibilities	Date/Time
Hicks Don	Quality Assurance	North America	2014-07-18 11:59:27 AM GMT-5:00
Sahut Armelle	Quality Assurance	EAME	2014-07-24 04:31:53 AM GMT-5:00
			2014-07-22 02:36:15 PM GMT-

Cui Cheng-ji	R&D Operations	North America	5:00
Kulkarni Upendra	Quality Assurance	Asia Pacific	2014-07-18 11:51:34 PM GMT-5:00
Longo Lucy	Specification Office Manager	Worldwide,Raw Material Specification	2014-07-18 12:41:43 PM GMT-5:00
Roberts Joseph	Purchasing	North America	2014-08-07 10:58:37 AM GMT-5:00
Laurenti Fernanda	Quality Assurance	Latin America	2014-07-28 02:31:09 PM GMT-5:00

General Description

Talc is a powdered, selected, natural, hydrated magnesium silicate. Pure talc has the formula $Mg_3Si_4O_{10}(OH)_2$. The talc defined by this specification is a fine white, macro crystalline, lustrous powder which is slippery in feel and adheres to skin. Material meets USP, BIS, BP, and China GB requirements. The material is suitable for use in both topical and oral Cosmetic and OTC Drug products.

Exclusive RM for Johnson and Johnson

NA

Grade

NA

RM Origin

Name
Mineral

RM Ingredient / Constituent

INCI/Chemical Name	Cas No.	INCI (EU)	EINECS No.	Monograph ID	Percent Concentration
Talc	14807-96-6	Talc	238-877-9	3119	100

RM Table of Qualitative Attributes

Attributes	Requirement	Test Method Source	Test Method	Comment
Absence of Asbestos	None detected	JNJ	TM7024:	Transmission Electron Microscopy
Carbonate (CO ₃)	Passes Test	Other	NA	Current BIS 1462
				Current USP or Current China SFDA (X-Ray Diffraction and Polarized Light Microscopy) or Japan MHLW method (X-Ray diffraction).None detected by X-Ray Diffraction. None Detected

Absence of Asbestos	None Detected	USP/NF	NA	as fibrous amphibole by Polarized Light Microscopy. (Performed only if detected by X-Ray Diffraction) (Defined to be fibrous serpentine, chrysotile, and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite and actinolite) (China SFDA method only for Talc to be marketed in China.) (Japan MHLW method only for Talc to be marketed in Japan)
Water Soluble Iron	Passes Test	Other	NA	Current BIS 1462 or China GB (GB method only for Talc to be marketed in China.)
Organic Compounds	Passes Test	Other	NA	Current IP
Acidity/Alkalinity	Passes Test	USP/NF	NA	Current USP or IP
Identification	Passes Test	USP/NF	NA	Identification C.
Identification	Passes Test	USP/NF	NA	Identification B.
Identification	Passes Test	USP/NF	NA	Identification A. (China SFDA only for Talc to be marketed in China.)
Appearance	A fine white lustrous powder, slippery in feel, free of uncharacteristic foreign matter, odor, and grittiness.	JNJ	TMWW78010:	Additionally: BIS 1462 also applies for talc to be marketed in India.

RM Table of Quantitative Parameters

Parameters	Unit of Measure	Min	Target	Max	Test Method Source	Test Method	Comment
Acid soluble iron	%	NA	NA	0.7	Other	NA	Current BIS 1462 or China GB (GB only for Talc to be marketed in China.)
Chloride	ppm	NA	NA	250	Other	NA	Current IP
pH-value	N/A	NA	NA	9.5	Other	NA	Current BIS 1462. (pH of solution)
SiO ₂ Content	%	58	NA	NA	Other	NA	Current China GB. Equivalent XRF as alternate.
Magnesium oxide (MgO)	%	28.2	NA	NA	Other	NA	Current China GB, ASTM D717, or BIS 1462. Equivalent XRF as alternate. (BIS required for Talc to be marketed in India.)
Magnesium Content	%	17.0	NA	19.5	USP/NF	NA	Current USP.
Loss on Drying	%	NA	NA	0.5	JNJ	TM7164:	Optional: BIS 1462 (Required for talc to be marketed in India.)
Acid Soluble Substances	%	NA	NA	4.0	Other	NA	Current BIS 1462 or China GB (GB only for Talc to be marketed in China.)
Water Soluble Substances	%	NA	NA	0.1	Other	NA	Current USP or BIS 1462 (BIS only for Talc to be marketed in India.)
							Current USP or BIS 1462. (@

Loss on Ignition	%	NA	NA	7.0	Other	NA	1075C+-25C to constant weight) (BIS required for talc to be marketed in India.)
Free Crystalline Silica as Quartz	%	NA	NA	0.5	CTFA	NA	CTFA Method J6-1 (XRD)
Limit of Chromium	ppm	NA	NA	2	Other	NA	AA or ICP using current USP/NF test solution for iron. Maximum Acceptable Level.
Limit of Chromium	ppm	NA	NA	0.5	Other	NA	AA or ICP using current USP/NF test solution for iron). Alert level - See notes in Additional Information section.
Limit of Cadmium	ppm	NA	NA	2	Quantitative	NA	AA or ICP using USP/NF test solution for iron.
Limit of Lead	ppm	NA	NA	10	USP/NF	NA	Current USP, ICP (Test solution for iron.), or Current BIS 1462. (BIS method only for Talc to be marketed in India.)
Limit of Aluminum	%	NA	NA	2.0	USP/NF	NA	Current USP or ICP
Limit of Arsenic	ppm	NA	NA	2	Other	NA	Current BIS 1462 or ICP (Test solution for iron) (BIS required for talc marketed in India.). Note: Arsenic limit of NMT 1.5 PPM applies to all Talc Powder to be marketed in Sri Lanka.
Limit of Iron	%	NA	NA	0.25	USP/NF	NA	Current USP or ICP (Test solution for iron.)
Limit of Mercury	ppm	NA	NA	0.5	Other	NA	AA or ICP using current USP/NF test solution for iron.
Limit of Nickel	ppm	NA	NA	10	Other	NA	AA or ICP using current USP/NF test solution for iron.
Limit of Chromium	ppm	NA	NA	1	Other	NA	AA or ICP using current USP/NF test solution for iron. Action Level - See notes in Additional Information section.
Loose Bulk Density	g/cm ³	0.35	NA	0.60	JNJ	TM-000846:	See Additional Requirements section for specific limits by supplier.
Fineness	%	99.7	NA	NA	JNJ	TM7167:	through 100mesh (150um) (Wet or Dry). BIS 1462 additionally required for talc marketed in India.
Limit of Calcium	%	NA	NA	0.9	USP/NF	NA	Current USP or ICP
Fineness	%	98.0	NA	NA	JNJ	TM7167:	through 200mesh (75um) (Wet or Dry). BIS 1462 additionally required for talc marketed in India.
Fineness	%	100	NA	NA	JNJ	TM7167:	through 60mesh (250um) (Wet or Dry). BIS 1462 additionally required for talc marketed in India.

Whiteness	%	88	NA	NA	Other	NA	Current China GB or Supplier's TM. See Additional Requirements section for specific requirements by supplier.
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RM Microbiology

Name	Unit of Measure	Limit	Test Method	Comment
Candida Albicans	Absent / 1 g	0	TM-000869:	Sanitized Talc Powder Only. Aerobic enrichment.
Clostridium spp	Absent / 1 g	0	TM-000869:	Sanitized Talc Powder Only. Anaerobic enrichment.
Gram Negative Rods	Absent / 1 g	0	TM-000869:	Sanitized Talc Powder Only. Aerobic enrichment.
Staphylococcus Aureus	Absent / 1 g	0	TM-000869:	Sanitized Talc Powder Only. Aerobic enrichment. See Additional Requirements section for pre-sanitized country specific limits.
Total Aerobic Micro Count (TAMC)	Cfu/g	100	TM-000869:	Sanitized Talc Powder Only. (1:10 dilution) See Additional Requirements section for pre-sanitized country specific limits.
Total Yeast and Mold Count (TCYM)	Cfu/g	10	TM-000869:	Sanitized Talc Powder Only. (1:10 dilution) See Additional Requirements section for pre-sanitized country specific limits.

Micro Risk Category

4

Storage and Transport Conditions

Transportation

Protect from moisture. Where used, pallets to comply with J&J STD-005.

Storage

Store in dry environment.

RM Suppliers and TradeNames

TradeName	Manufacturing Sourced Supplier	Distributor	Packaging Size & Type	Shelf Life Months	Comments	Reference Numbers
	Guiguang Talc Dev Co	Name: N A			Mine: Guiguang Zhizhu in Long Sheng County, Guangxi Province. Ore Name: Guangxi. Mine Owner: Guiguang Talc Development	RMQ #: NA

Talc 200 J	Name: (Guangxi China) City: Guangxi Country: China	City: N A Country: N A	NA	36	Company. Grinding Facility: Guiguang Talc Development Company Ltd. in Lingui, Guilin, China. Approved source only for NA, AP, and EMEA Region.	ERP/SAP #: 5000687 Optiva #: RAW90015477
Grade 25 USP	Name: Imerys Talc America Inc (Houston TX United States) City: Houston Country: United States	Name: N A City: N A Country: N A	NA	36	Mine: Guiguang Zhizhu in Long Sheng County, Guangxi Province, China. Ore Name: Gunagxi # 2a. Mine Owner: Guiguang Talc Development Company. Grinding Facility: Imerys Talc America, Inc. in Houston, TX USA. Approved source only for NA Region.	RMQ #: NA ERP/SAP #: NA Optiva #: NA
TALMAG PHARMA-S	Name: MAGNESITA REFRATÁRIOS S/A (BR 36949) (Brumado Brazil) City: Brumado Country: Brazil	Name: N A City: N A Country: N A	NA	36	Mine: Cabeceiras near Brumado, Brazil. Ore Name: Pharma-S. Mine Owner: Magnesita. Grinding Facility: Magnesita near Brumado. Approved source only for LATAM Region	RMQ #: NA ERP/SAP #: NA Optiva #: NA
					Mine: Chainpura in Bhilwara, Rajasthan, India. Ore	

Zecco 200J	Name: Golcha Group (Dausa India) City: Dausa Country: India	Name: N A City: N A Country: N A	NA	36	Name: 2C105CH and 2C106CH. Mine Owner: Golcha Group - Udaipur Mineral Development Syndicate Pvt. Ltd. Grinding Facility: Golcha Group in Dausa, India. Approved source only for AP/EMEA Region.	RMQ #: NA ERP/SAP #: NA Optiva #: RAW90206217
Zecco 200J	Name: Golcha Chemintac Co Ltd (Rayong Thailand) City: Rayong Country: Thailand	Name: N A City: N A Country: N A	NA	36	Mine: Chainpura in Bhilwara, Rajasthan, India. Ore Name: 2C105CH and 2C106CH. Mine Owner: Golcha Group - Udaipur Mineral Development Syndicate Pvt. Ltd. Grinding Facility: Golcha Chemintac Co. Ltd. in Rayong, Thailand. Approved source only for AP/EMEA Region.	RMQ #: NA ERP/SAP #: 5005775,5007765 Optiva #: RAW90206217
Talc Finex	Name: Golcha Group (Rajasthan India) City: Rajasthan	Name: N A City: N A	NA	36	Mine: Ghewaria in Bhilwara, Rajasthan, India. Ore Name: Talc FNX. Mine Owner: Golcha Group - Udaipur Mineral Development Syndicate Pvt. Ltd. Grinding Facility:	RMQ #: NA ERP/SAP #: 5004435

	Country: India	Country: N A		Udaipur Mineral Development Syndicate Pvt. Ltd., Ghewaria Plant in Bhilwara, Rajasthan, India. Approved source only for AP/EMEA Region.	Optiva #: RAW90015480
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Acceptance

The specified material must meet all the requirements outlined in this specification. Any nonconformance to these requirements may result in rejection of the entire lot. A Certificate of Analysis (COA) shall be submitted with each receipt. The COA will contain material Manufacturing Site (Supplier), date of manufacture, retest and/or expiration date (if applicable), and actual test results of the lot for all qualitative attributes, quantitative parameters and microbiological requirements listed above. The Manufacturing Site (J&J or External Manufacturer) will review the submitted COA for conformance to requirements.

Change Control

There shall be no change in the Supplier's Finished Product (including manufacturing site and process, starting materials, material composition, or packaging) without prior notification to, and written approval from, Johnson & Johnson. This notification shall be made proactively to guarantee a complete re-qualification (as appropriate) prior to the necessity for producing finished goods with the modified or new raw material.

Packaging

Shall be packaged in containers or bulk suitable to protect the contents from loss, contamination and deterioration in normal shipment and storage. The supplier is responsible for delivery of uncontaminated material. Evidence of contamination will cause rejection of the shipment.

Identification

Each single unit shall have an identification label. The minimum required information on this label is: name of material, name of qualified supplier, supplier batch code and Lot No., J&J Raw Material code & Purchase Order Number, gross and net weight, date of manufacturing, date of expiration (if applicable), caution advise about handling and storage and usage regarding safety (if applicable) and Drum Sequence Number (if applicable).

Safety Warnings

When this material is no longer needed or past its expiration date, dispose of it in accordance with local regulatory requirements. Hazardous waste determinations shall be based on requirements in the region where the material is first designated a waste. For additional safety and personal protection details, please refer to the supplier's MSDS.

Additional Requirements

NOTES:

- Additional requirements may be performed as required by local regulatory requirements.
- Reduced testing may be justified via data generated by receiving site or independent lab.
- Alert Level - QA Management and the Supplier to be made aware of exceeding this historical level.
- Action Level - QA Management and Supplier to be made aware of exceeding this level. Lab investigation and Mine/Milling site sourcing location and process investigation recommended.

- BIS: Bureau of India Standard
- China GB: China national standard
- USP/NF: United States Pharmacopeia/National Formulary
- IP: Indian Pharmacopeia
- ICP: Inductively Coupled Plasma
- AA: Atomic Absorption spectrometry
- XRF: X-Ray Fluorescence
- XRD: X-Ray Diffraction
- PLM: Polarized Light Microscopy
- TEM: Transmission Electron Microscopy

PACKAGING:

- Bulk shipments of Talc Powder to use Johnson & Johnson approved railcars or bulk powder trailers designed to protect contents from loss, moisture, microorganisms, contamination, and deterioration in normal shipment and storage. Bulk shipping containers to use uniquely numbered tamper evident seals.
- Bags of Talc Powder to use Johnson & Johnson approved paper and/or poly lined bags designed to protect contents from loss, moisture, microorganisms, contamination, and deterioration in normal shipment and storage. Pallets may be stretch wrapped.
- Super sacks of Talc Powder to use Johnson & Johnson approved super sacks designed to protect contents from loss, moisture, microorganisms, contamination and deterioration in normal shipment and storage.

ACCEPTABLE TALC SANITIZATION METHODS (WHERE APPLICABLE)

The following forms of sanitization are currently considered approved for Talc sanitization following qualification/validation and approval by Johnson & Johnson:

- Dry Heat Sterilization
- Steam Sterilization
- Gamma or E-beam irradiation is to be used only on an interim basis.

APPROVED INDEPENDENT TESTING FACILITIES

RJ Lee Group, Inc.
350 Hochberg Road
Monroeville, PA 15146
1-724-325-1776

J&J INDEPENDENT AUDITS:

- Quarterly, samples from a finished Talc lot representing each ore body/grinding facility combination are sent to a J&J authorized independent lab for full testing. Includes XRD, PLM, & TEM for asbestos and full elemental analysis. Excludes Micro. Data reported to J&J as confirmatory testing on health of ore body.

CHANGE CONTROL:

Any changes to Ore Bodies, Mining, Milling, Sanitization, or Processing requires comprehensive assessment by internal subject matter experts and external consultants as appropriate. Such changes require an update to this specification and an Authorization For Product Release (APR). See reference document 'Body Powder Talc Alternative Source Qualification Guidance' for specific direction.

SPECIFIC SUPPLIER PROCESS CONTROL REQUIREMENTS**Loose Bulk Density**

- Talc 200J for J&J Thailand Plant: 0.45-0.48 g/cu cm
- Talc Zecco 200J for J&J Thailand Plant: 0.45-0.55 g/cu cm
- Talc 200J for J&J China Plant: 0.37-0.48 g/cu cm

Whiteness

- Talc 200J: NLT 90.0 percent
- Talc Finex: NLT 90.0 percent

COUNTRY SPECIFIC ADDITIONAL REQUIREMENTS**Microbiology Requirements for Pre-Sanitized Talc (China Market Only)**

- Total Aerobic Micro Count: 500 cfu/g (GB Method)
- Total Yeast & Mold Count: 100 cfu/g (GB Method)
- Coliform: Absent / 1 g (GB Method)
- Pseudomonas: Absent / 1 g (GB Method)
- Staphylococcus: Absent / 1 g (GB Method)

Trace Level Impurity Monitoring (China market only)

- On a quarterly basis, Neodymium (Nd) testing with China SFDA method is required for talc raw material for monitoring purposes. Alert level is 2.5ppm. An investigation by the Mine/Milling location is recommended if Alert Level is exceeded.

Test Method Options (India market only)

- Where available, BIS TM's to be used for Talc which is to be marketed in India.

Receiving Site RM Sampling

NA

Receiving Site RM Testing Frequencies and Requirements

Attributes	Test Frequency	Annual Re-Test	Comment
NA	NA	NA	See testing frequencies and requirements attachment for testing requirements for ore and post milling stages.

Testing Frequency Definitions

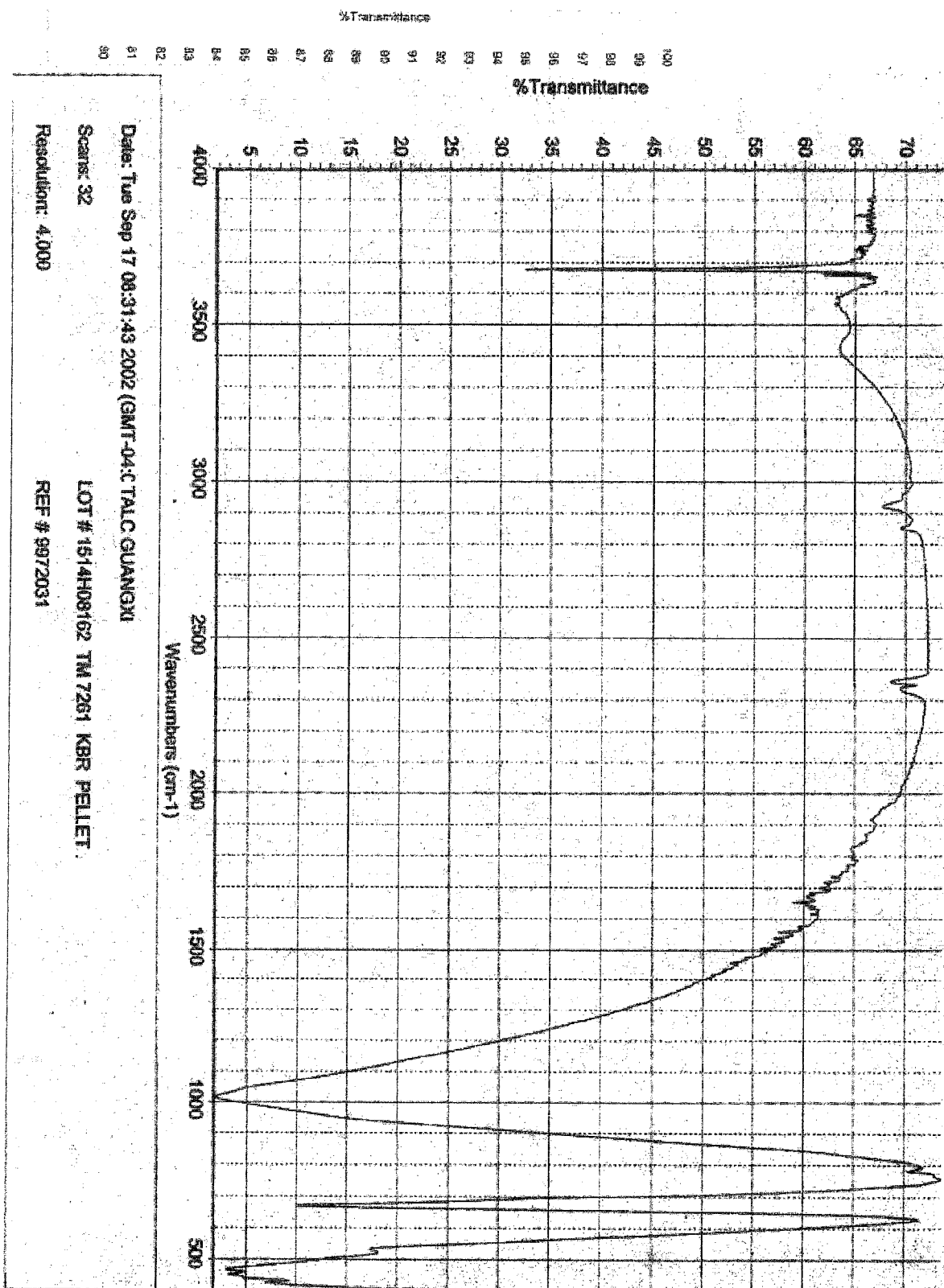
Annual Re-Test	Test performed annually on lots in inventory to assure continued conformance to the specification. Frequency interval is from last test date.
Every Delivery	Specific test to be performed on every delivery by the Receiving Site unless, qualified for reduced testing per the local SOP.
Every Delivery-Not Eligible for RT	Specific test to be performed on every delivery by the Receiving Site. The test is not eligible for Reduced Testing.
C of A	Result to be taken from the supplier's Certificate of Analysis. No testing by the receiving site is required. This option should only be selected in exceptional cases such as residual solvents certification, where the design evaluation during the R&D qualification stage confirms the reliability of the raw material.
Supplier Attestation Letter Received. No Testing Required	Supplier certifies that the parameter in question has been met in accordance with Johnson and Johnson's requirement. The parameter need to be identified on the supplier's CoA in order to meet this requirement.
Annual Audit Testing	Testing for this parameter is required on an annual basis only.

Incoming Inspection at the Receiving Site

The Receiving Site will statistically sample every delivery and conduct full testing per this specification. If justified by the Receiving Site, a reduced testing protocol can be executed with the following minimum requirements for every delivery: Appearance, ID, Assay (for active ingredients) and Full conformance of the C of A to this specification. Items on reduced testing must be certified by the supplier in the C of A. Full testing must be conducted on a minimum of one lot per year by the Receiving Site.

Reference Documents

Name	Description
Doc-0596403	NA
Doc-0596404	NA
Doc-0596405	NA
Doc-0596406	Revision 4 Change Summary



TESTING FREQUENCIES AND REQUIREMENTS

Stage	Oversight Strategy	Supplier	J&J Plant or TPM
Ore	<ul style="list-style-type: none"> Ore testing provides general oversight of the mining process and the quality of the actively mined ore body. Periodic Ore testing eliminates the need for full testing of each incoming Talc Powder lot. While awaiting results of ore lot testing, the selected ore lot may be used for milling/grinding, but the milled lots will be quarantined until ore tests have been satisfactorily completed. 	<ul style="list-style-type: none"> Ore testing is performed by the supplier for each discrete ore lot, or based on a pre-defined time period, not to exceed quarterly. Ore samples for testing are taken from post milled talc. All testing conducted with exception of Bulk Density, Fineness, Whiteness, and Microbiological. (Note: Suppliers are exempted from the use of TEM if it is not locally available.) Testing performed by supplier and/or approved contract lab. 	<ul style="list-style-type: none"> Ore lot C of A for full testing is received and reviewed for compliance versus specification. May be sent with, or separate from, finished Talc powder lot.
Post Milling	<ul style="list-style-type: none"> Each milled lot is to be tested for requirements that are associated with the quality of the milling operation. Each milled lot is to be linked on the C of A to its parent ore lot where practical. While awaiting results of ore lot testing, milled lots associated with the ore lot will be quarantined until ore tests have been satisfactorily completed. 	<p><u>Each Milled Lot Produced:</u></p> <ul style="list-style-type: none"> Supplier typically performs in-process testing for Fineness, Whiteness, Bulk Density, and Appearance to monitor process. Minimally tested for Fineness, Whiteness, Bulk Density, and Appearance. Testing items or methods required by local regulations are to be additionally performed by the supplier. (Refer to local or regional SOP.) Testing performed by supplier and/or approved contract lab. C of A created w/ linkage to ore lot and provided with each milled powder lot shipment. Microbial results are required to be reported for all sanitized talc. 	<p><u>Each Milled Lot Received:</u></p> <ul style="list-style-type: none"> Ensure that C of A documents are available to demonstrate compliance to all requirements. Confirm linkage of milled lot C of A to quarterly ore lot testing with satisfactory results. Minimally tested upon receipt for Appearance, ID, and Microbiology (if sanitized by supplier) requirements. All other requirements to be certified via C of A. In lieu of C of A, testing may be performed by the site or designated independent lab. Testing requirements required by local regulations are to be additionally performed as applicable. (Refer to "Additional Requirements" section.
J&J Ore Body Oversight Monitoring Assessment	<ul style="list-style-type: none"> Confirmatory testing of quarterly milled talc samples by single independent laboratory to assess current health of mine. This data is not used for lot by lot release decision making. The sampled milled lot may be released prior to completion of this confirmatory testing. OOS results are to be considered for possible investigation. 	<ul style="list-style-type: none"> Not Applicable 	<ul style="list-style-type: none"> Quarterly, samples of milled Talc lots from each mine/milling operation combination are sent to a single J&J authorized independent lab for full testing. Includes XRD, PLM, & TEM for asbestos and full elemental analysis. Excludes ID & Micro. Data reported to J&J as confirmatory testing. Where practical, a Talc Powder lot that is linked to a supplier's ore lot testing should be selected for independent lab testing.