

Henan Huaer Dental Biotechnology Co.LTD

Inspection report of silicone rubber impression materials

Product name	silicone rubber impression materials	Product source	Henan Huaer Dental Biotechnology Co. LTD
Colour number	A:white B:red brown	Lot number	2019102505
Specification	10 kg / barrel	Production date	2019/10/2
Product quantity	150 kg	Test date	2019/11/3
Inspection standard	ISO 4823-2015		
Requirements for characteristics and properties		Standard requirement	Result
Mixing time		120~300	225
Working time		>4.0	4.44
Consistency		>36	41
Linear dimensional change		<1.5	0.69
Compatibility with gypsum		-	Complied
Elastic recovery		>96.5	97.73
Strain-in-compression		0.8~20	4.52
The testing process is shown in the attached table Note: Except for special requirements, the above tests are conducted at room temperature. 			
Conclusion: The product was based on ISO 4823-2015 and the results were in accordance with the regulations.			

Tester : *Misa*

Reviewer: *Selinda*

【Mixing time】

Proportion and mix the required volume of material for each specimen. Record the time required to obtain a homogeneous mixture for each specimen. Calculate the mean of the results for the three specimens.

Specimen	1	2	3
Mixing time (s)	235	224	216
Average (s)	225		
Standard requirement (s)	120-300		
Result	Complied		

【Working time】

1. Clear the ring mould, the base plate, and the loading shaft foot of the apparatus of contaminants and coat them with a thin film of the mould release agent.
2. Centre the ring mould on the base plate and use clay or wax to fix the two components in this relationship so as to form the specimen forming mould cavity assembly.
3. Load the required weights on the weight support or collar of the loading shaft.
4. Proportion the hand mixed material preparatory to mixing.
5. Position the specimen forming assembly beneath the foot of the loading shaft such that the following steps can be completed preparatory to testing.
 - position the shaft foot such that it comes to rest on the top surface of the ring mould;
 - let the dial indicator spindle descend in to contact with the top surface of the loading shaft;
 - record the dial gauge reading resulting from the dial indicator spindle contact as Reading a;
 - lift the loading shaft and lock it in place so that the foot is exactly 1mm or more above the top of the ring mould in the specimen forming assembly.
6. Complete the following steps in quick succession:
 - use the modified fork for initial mixing of the putty components;
 - use the gloved hands to knead the putty mixture until it is streak-free;
 - slightly overfill the specimen forming mould cavity with the mixed material and strike off the excess level with the top of the specimen forming ring mould;
 - centre the filed assembly beneath the centre of the loading shaft foot;
 - unlock the loading shaft and carefully let it descend until the foot is barely in contact with the test material and lock the shaft in this position.
7. At 1s before the working time stated in the instructions, unlock the loading shaft and allow the foot to descend into the material in the ring mould cavity over a period of 3 s. Lock the shaft in the lowest position the foot has reached and record the dial indicator reading as Reading b.
8. Subtract dial indicator reading a from reading b to determine the depth to which the loading shaft foot has descended into the test material.
9. If the load shaft foot has descended to at least 4 mm into the test material, the specimen complies with the requirement stated in specimen instructions for use, otherwise, it fails.

Specimen	1	2	3	4	5
a	23	16	21	22	19
b	65	58	70	68	62
b-a	42	42	49	46	43
Average (mm)	4.444				
Standard requirement (mm)	>4.0				
Result	Complied				

【Consistency】

1. Accomplish the following steps within 25 s after the completion of mixing:
 - slightly overfill the cavity in the dispensing tube with the mixed material and strike off the excess to form the test increment;
 - push the increment-extruding end of the plunger against the elastomeric plug to expel the test increment, along with one or both of the polyethylene discs, onto the centre of the base plate. Do not attempt to separate the discs from the test increment;
 - centre the increment on the base of the test apparatus directly under the elevated loading-shaft foot;
 - place and hold the glass loading plate centred and in contact with the shaft foot;
 - allow the (14.71 ± 0.01) N load to descend slowly onto the increment.
2. Allow the total load to rest on the specimen-forming assembly for 5 s. Lift the foot of the loading shaft from contact with the loading plate and allow the assembly to remain at room temperature for at least 15 min. Separate the loading plate from the assembly so as to leave the specimen on the base plate.
3. Use the measuring instrument to make two diametral measurements of the specimen. One across the major diameter of the disc and one across the minor diameter.
4. Report the average of the two measurements as the diameter to be considered when determining whether the specimen complies with the diameter requirement specified in the standard requirement.

Specimen	Max	Min	(Max+Min) /2
1	43	37	40
2	42	39	41
3	44	37	41
Average (mm)	41		
Standard requirement (mm)	>36		
Result	Complied		

【Linear dimensional change】

1. Prepare and position the test block as follows:
 - clean the test block ultrasonically before beginning the procedure;
 - position the test block on the microscope stage with line d_1 to the right and with the line c appearing as the lower line;
 - relate the X axis of the microscope cross hair parallel to, and approximately 0.03mm below line c . This will place the Y axis of the cross hair parallel to line d_1 and d_2 ;
 - move the microscope slide or stage to bring the Y axis of the cross hair at least 0.1mm outside and to the right of line d_1 on the test block.
2. Proceed with the following steps taking into account that after position the test block, the direction of travel of the microscope slide or stage should not be reversed at any point during subsequent travels until after the final measurements between lines d_1 and d_2 have been recorded:
 - move the left edge of Y axis of the cross hair into alignment with the inner edge of line d_1 , stop the travel motion, and record the reading for this position as the initial measurement;
 - move the left edge of Y axis of the cross hair into alignment with the inner edge of line d_2 , stop the travel motion, and record the reading for this position as the final measurement;
 - calculate and record the difference between the initial and final readings. Make two additional measurements for the distance between lines d_1 and d_2 . Average the three values and record the result as L_1 .
3. Dust the underside of each detail reproduction test specimen and the top surface of the

glass plate with talcum powder. Then seat the dusted specimen to rest on the dusted plate and store this assembly in the laboratory environment until the time specified for its measurement.

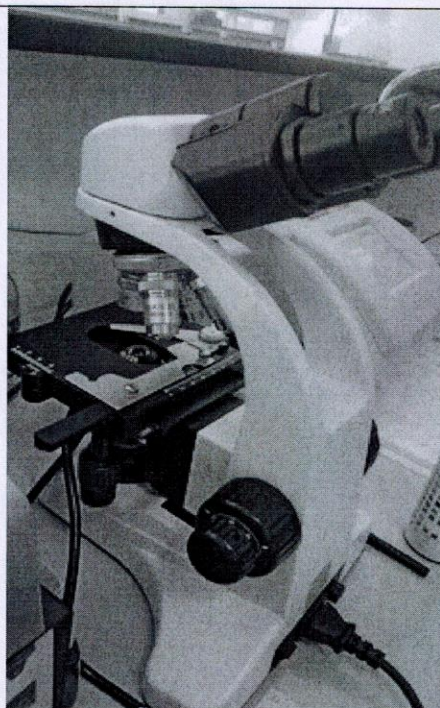
4. The time at which the specimens are to be measured shall be related as follows to the permissible time lapse, recommended in the manufacture's instructions, between removal of the impression from the mould and pouring of the gypsum product:

- when a manufacture's instructions state that pouring of the impression can be delayed for 24h or more, the specimens shall be measured at 24h after separation from the forming assembly;
- when the manufacturer states a maximum permissible time delay of less than 24h before pouring the impression, the specimen shall be measured at the end of the maximum permissible time delay stated.

5. Follow the procedure for measuring the distance between lines d_1 and d_2 , along line c , on the specimen, with the following exception: place the specimen on the microscope stage with line d_2 positioned to the right for the initial measurement, thus ensuring that line c will appear as the lower line. Record this measurement as L_2 .

6. Calculate the percentage of dimensional change, ΔL , for each specimen to the nearest 0.05%, using the formula: $\Delta L = \frac{L_1 - L_2}{L_1} * 100\%$.

- L_1 is the distance measured between lines d_1 and d_2 on the test block;
- L_2 is the distance measured between lines d_1 and d_2 on the impression material specimen.



Specimen	1	2	3	4	5
L_1 (mm)	26.33	24.69	25.87	25.53	24.71
L_2 (mm)	26.15	24.5	25.69	25.34	24.54
ΔL (%)	0.68	0.77	0.58	0.74	0.69
Average (mm)	0.69				
Standard requirement (mm)	<1.5				
Result	Complied				

【Compatibility with gypsum】

1. Accomplish the following steps before carrying out the test for compatibility with gypsum:

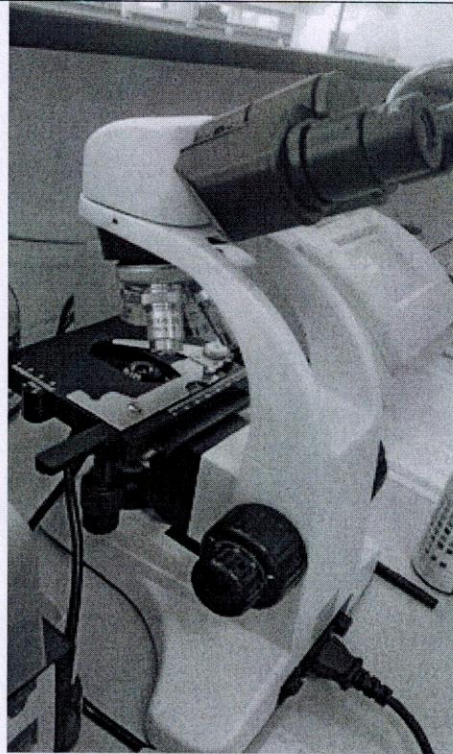
- treat the inner surface of the slit mould, including the slit surface, with a thin of the mould release agent and use the clamping mechanism to close the slit;
- position the specimen in the ring mould and press the riser against the underside of the specimen so as to push the lined surface of the specimen to a position level with the top flat surface of the ring mould. Seat this assembly, with the riser in place, and the lined surface down, into the recess of the slit mould. Cover this part of the assembly with the plate and invert the entire assembly.

2. After the earliest time special for pouring impressions after their removal from the mouth, introduce the first increments of a gypsum mixture, through mechanical vibration, so

that they flow down along an internal surface of the mould cavity to first cover the ends of the raised lines,a,b,and c,on one side of the specimen surface and to be directed to flow gradually over the lines to their opposite ends.add enough of the gypsum mixture to slightly underfill the mould cavity.

3. Unless otherwise specified in manufacture's instructions for the gypsum or impression material,store the gypsum/impression material assembly in the laboratory environment until 45min later the initial setting time previously determined for the gypsum product,separate the gypsum specimen from the assembly.

4. Use the microscope to examine the lined surface of the gypsum specimen for compliance with the standard requirements.



【Elastic recovery】

1. Carry out the following steps within 60s after completing the mixing:

- fill the fixation ring slightly more than full;

- press the split mould halves down through the impression material in the fixation ring until their bottom surfaces are in near contact with the polyethylene-covered base plate so as to force the impression material above the top of the split mould halves;

- press the second polyethylene-covered plate onto the material so as to expel almost all the excess and use the C-clamp to force the plates into contact with the top and bottom surfaces of the split mould.

NOTE If glass plates are used instead of metal plates,metal back-up plates can be used between the glass plates and the C-clamp parts to minimize scratching and breakage of the glass plates.

At 60s after completion of mixing,place this specimen-forming assembly in the water bath for the time specified in the manufacture's instructions for leaving impressions in the mouth;

Within 40s after completion of the water bath storage,separate the specimen from the split mould,place the glass or metal test plate to rest on the top surface of the specimen,and seat this assembly on the test apparatus base centred in axial alignment with the dial indicator spindle.

2. Conduct the test in accordance with the following time schedule,where t is the time the specimen is removed from the water bath:

- t+45 s : gently lower the dial indicator spindle contact point to rest on the test plate on the top of the specimen;

-t+55 s :read the dial indicator and record the reading as h_1 ;

-t+60 s:deform the specimen (6.0 ± 0.1) mm,as limited by the stop on the test apparatus,within 1s,release the deforming force slowly over a period of 5s and then lift and hold the contact point from contact with the test plate remaining at rest on the specimen;

-t+170 s :gently return the contact point to rest on the specimen;

-t+180s :record this dial indicator reading as h_2 .

NOTE Possibility for lateral displacement of the specimen during application of the deforming force can be reduced by cementing an abrasive paper covering,about 600 grit,over the surfaces of the apparatus base and the test plate that will be in contact with the top and bottom surfaces of the specimen during the test.

3. Calculate the percentage of elastic recovery, K ,for each specimen,using the formula:

$$K=100-[100 \times (h_1-h_2) / h_0]$$

Where

h_0 is the height of the split mould;

h_1 is the dial indicator reading at t+55s (immediately before the specimen is deformed);

h_2 is the dial indicator reading at t+180s (115s after the deforming force has been removed from the specimen).

Discard values for defective specimens. Defective specimens can be identified by sectioning each specimen axially into eight approximately equal-sized segments and examining each segment for defects such as air inclusions.

Specimen	1	2	3
h_0	39.0	45.2	42.9
h_1	36.1	43.7	40.12
h_2	35.6	42.51	38.87
K	98.72	97.37	97.09
Average	97.73		
Standard requirement	>96.5		
Result	Complied		

【Strain-in-compression】

1. Prepare five specimen according to the procedure described in elastic recovery's 1,with the exception that the test plate is not placed on the specimen;

2. Immediately after separation of the specimen from the forming assembly,position it on the base of the test apparatus centred below the foot of the loading shaft.Conduct the test in accordance with the following time schedule,where it is the time the specimen is removed from the water bath:

-t+60 s:lower the foot of the loading shaft into direct contact with the top of the specimen,thus applying an initial load of (1.22 ± 0.01) N exerted by the loading shaft/weight support assembly only;

-t+90 s:lock the loading shaft in place,lower the dial indicator contact point to rest on the top of the loading shaft,and record the dial indicator reading as h_1 ;

-t+95 s:remove the dial indicator contact point from contact with the loading shaft,unlock the loading shaft,and increase the load to a total force of (12.26 ± 0.01) N gradually over a period of 10 s;

-t+135 s:lock the lading shaft in place,return the dial indicator contact point to rest on the loading shaft,and record the dial indicator reading as h_2 ;

3. Calculate the percentage of strain-in-compression, E ,for each specimen,using Formula:

$$E=100 \times (h_1-h_2) / h_0$$

where

h_0 is the height of the split mould;

h_1 is the dial indicator reading,30s after application of the initial load;

h_2 is the dial indicator reading,30s after complete application of the increase load.

Specimen	1	2	3	4	5
h_0	48.98	45.97	46.24	47.58	45.74
h_1	48.73	45.65	46.21	47.12	45.65
h_2	46.26	42.88	44.79	45.09	43.73
E	5.04	6.03	3.07	4.27	4.20
Average	4.52				
Standard requirement	0.8-20				
Result	Complied				