



Certificate of Analysis

Product Name	Royal Jelly Extract	Batch Number	4537110
Specification	5%	Expiry Date	March 2027
Plant Part Used	Royal jelly	Active Ingredient Markers	10-HAD

Analysis Items	Specifications	Results	Test Methods
Organoleptic			
Appearance & Color	Fine off-white or light yellow powder	Conforms	Visual
Odor & Taste	Characteristic	Conforms	Organoleptic
Solubility	Partially soluble in water	Conforms	Visual
Marker Compounds			
Assay	NLT 5% 10-HDA	5.03%	HPLC
Physical Characteristics			
Mesh Size	NLT 95% through 100 mesh	Conforms	100 Mesh Screen
Bulk Density	0.45-0.65g/ml	Conforms	CP2015
Other			
Chloramphenicol	NMT 0.3ppb	Conforms	USP
5-Nitofuran	NMT 0.5ppb	Conforms	USP
Heavy metals			
Total Heavy Metals	NMT 10ppm	Conforms	CP2015
Microbiological Tests			
Total Plate Count	NMT 10,000cfu/g	Conforms	GB.4789.2
Total Yeast & Mold	NMT 1000cfu/g	Conforms	GB.4789.15
E. Coli	Negative	Conforms	GB.4789.38
Salmonella	Negative	Conforms	GB.4789.4
Staphylococcus	Negative	Conforms	GB.4789.10
GMO	Non-GMO		
Vegan Suitability	Yes		
Storage	Store in a well-closed container away from moisture.		



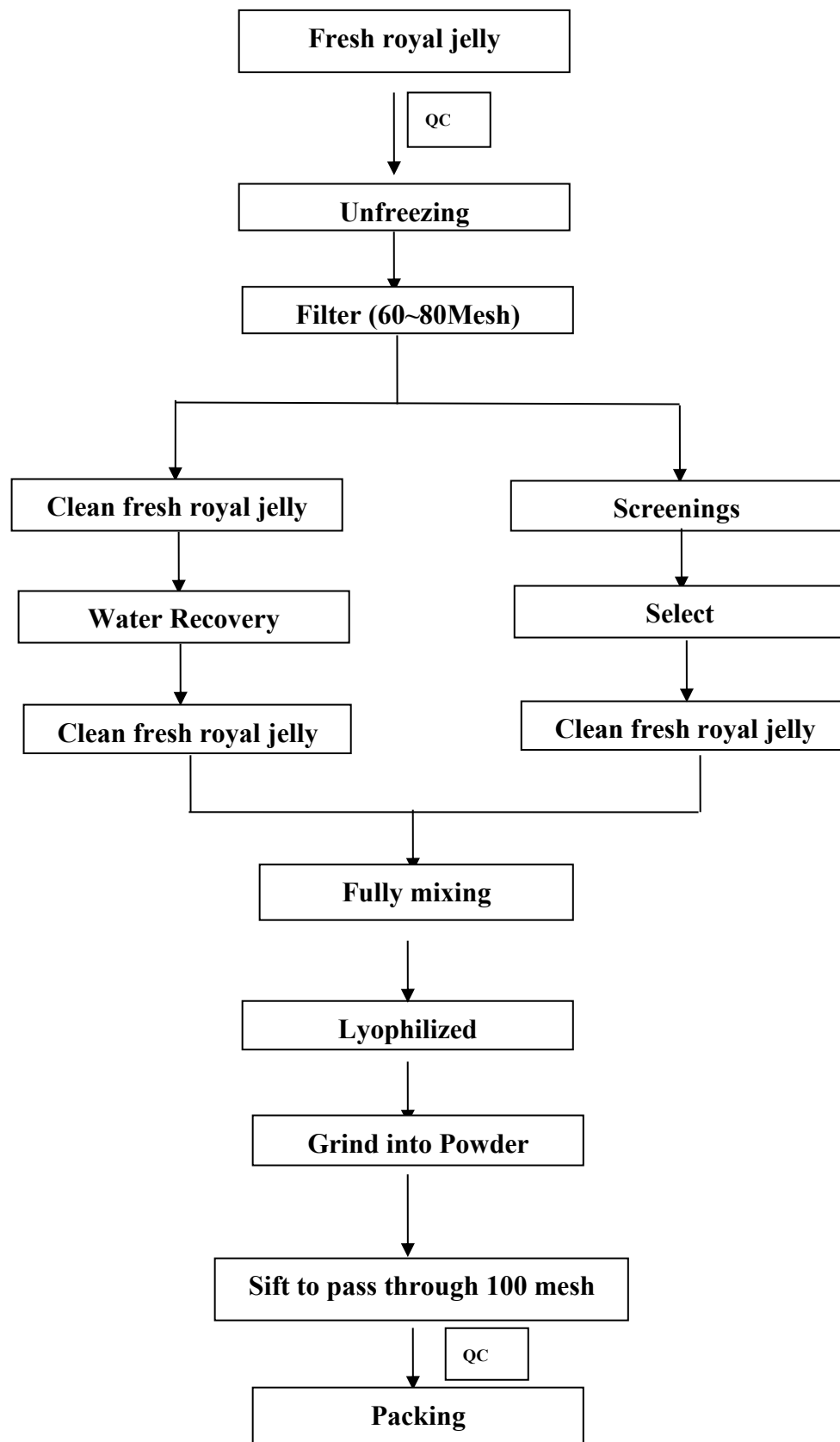
Allergen Statement

Product: Royal Jelly Extract 5%

Reference:

Category of food allergen	Presence (Yes / No)	Comment
Celery (deleriac) and derivatives	No	
Egg's and derivatives	No	
Milk and derivates	No	
Peanut and derivates	No	
Soybean / Soya bean and derivatives	No	
Sulfites (concentration > 10 mg/kg)	No	
Wheat (gluten)	No	
Dairy(lactose) and derivatives	No	
Seafood and derivatives	No	
Sesame and derivatives	No	
Treenuts and derivatives	No	
Crustaceans and derivatives	No	
fish and derivatives	No	
Molluscs and derivatives	No	
Lupin and derivatives	No	
Mango and derivatives	No	
Mustard and derivatives	No	
Kiwi and derivatives	No	

Manufacturing Process Sketch Of Royal Jelly Powder





NON-GMO & VEGAN STATEMENT

WE, MADAR CORPORATION, CERTIFY THAT THE
PRODUCT:

ROYAL JELLY EXTRACT 5% 10-HDA

- IS 100% NATURAL EXTRACT POWDER AND GMO FREE PRODUCTS.
- IS NOT SUITABLE FOR VEGANS.

21-10-22



Material Safety Data Sheet

Company: Madar Corporation Limited	
Product Name: Royal Jelly Powder 5% 10-HDA	
1 Identification	
1.1 Properties: with typical properties of royal jelly	
1.2 Form: Fine powder	
1.3 Color: Off-white or light yellow	
1.4 Odor: Characteristic	
2 Physical Properties	
PH value	N/A
Melting point	N/A
Boiling point	N/A
Igniting point	N/A
Flash point	N/A
Explosion point	N/A
Bulk density	0.3-0.8g/ml
Solubility	Partially soluble in water
3 Transport Information	
Far from away humidity, sunshine, high-temp., and acidic, alkaline substance.	
4 Stability and Reactivity	
4.1 Condition to be avoided	
Humidity, sunshine, high-temp.	
4.2 Substances to be avoided	
Acidic, alkaline substance	
4.3 Hazardous decomposition	
No hazardous decomposition.	
5 Protection, Handling and Storage	
5.1 Safety technical measure:	
Far away from fire, humidity and other hazardous chemicals	
5.2 Personal equipment	
Respiratory Protection: to use respirator when mesh the powder.	
Eye Protection: to use special glasses when mesh the powder.	
Hand Protection: no need special protection measure, when contact hands, use water to wash.	
Other Information: no more available	

5.3 Industrial hygiene

To avoid the powder contact eye and respiratory system.

5.4 Explosion and fire fighting measures

Use quantity water

5.5 Disposal condition

Disposal properly

6 Accidental Release Measures/Fire Fighting Measures**6.1 Accidental release measures**

Washing up the attached area with water

6.2 Suitable extinguishing media**6.3 First aid measures**

In case of eye and skin contacted: rinse out with water

6.4 Other information

No more information available.

7 Toxicological Information

Royal Jelly Powder 5% 10-HDA has high safety coefficient. It belongs to actual nontoxicity determined by acute toxicity experiment.

8 Ecological Information

No ecological problems are to be expected when the product is handled and used with care and attention.

9 Other Information

No more information available.

17/02/2023



Specification Sheet

Product Name	Royal Jelly Extract	Plant Part Used	Royal Jelly
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Analysis Items	Specifications	Test Methods
Organoleptic		
Appearance & Color	Fine off-white or light yellow powder	Visual
Odor & Taste	Characteristic	Organoleptic
Solubility	Partially soluble in water	Visual
Marker Compounds		
Assay	NLT 5% 10-HDA	HPLC
Physical Characteristics		
Mesh Size	NLT 95% through 100 mesh	100 Mesh Screen
Bulk Density	0.45-0.65g/ml	CP2020
Heavy metals		
Total Heavy Metals	NMT 10ppm	CP2020
Microbiological Tests		
Total Plate Count	NMT 10,000cfu/g	GB.4789.2
Total Yeast & Mold	NMT 1000cfu/g	GB.4789.15
E. Coli	Negative	GB.4789.38
Salmonella	Negative	GB.4789.4
Staphylococcus	Negative	GB.4789.10
Packing and Storage	Packed in sealed aluminum foil bags lined with plastic seal or sealed double plastic bags. Store in a well-closed container away from moisture.	
Shelf Life		

21/10/2022



**TECHNICAL DATA SHEET OF ROYAL JELLY EXTRACT 5%
(TDS)**

TDS Format for Herbal Active	Documentation required
3.2.S.1. General Information 3.2.S.1.1. Nomenclature	Royal Jelly Extract
Royal Jelly Extract	Source of leaves Royal Jelly Extract from Royal jelly
3.2.S.1.2. Structure Physical form	Powder
Description of the constituents with known therapeutic activity or markers	C ₁₀ H ₁₈ O ₃ 10-HDA
3.2.S.1.3. General properties	<p>Substance: [source] from royal Jelly [Chemical composition] 10-HDA. Herbal preparations properties: 1、 Physical Properties</p> <p>Boiling Point / Igniting point / Flash Point / Explosion Point / Bulk Density 0.3-0.8g/ml Solubility Partially soluble in water</p> <p>2、 Chemical Properties: Typical properties of royal Jelly Extract Form :Fine Powder Color : off white or light yellow powder Odor : Characteristic</p>

3.2.S.2. Manufacturer (s) 3.2.S.2.1. Manufacturer of raw material	Name and address of manufacturer Confidential
3.2. S.2.2. Description of critical steps and Intermediates	OPEN PART: Only flow chart and schematic Information: Detailed information included in restricted part of the EDMF
3.2.S.2.3. Control of materials	Detailed information included in restricted part of the EDMF
3.2.S.2.4. Control of critical steps and Intermediates	OPEN PART: Only flow chart and schematic Information: See appendix 1 Detailed information included in restricted part of the EDMF
3.2.S.2.5. Process validation and/or Evaluation	Detailed information included in restricted part of the EDMF
3.2.S.2.6. Manufacturing process Development	Detailed information included in restricted part of the EDMF

3.2.S.3. Characterization 3.2.S.3.1. Elucidation of structure and other characteristics	<p>The royal jelly is a kind of special milk - like substance secreted by the head nutrition gland (tongue gland and jaw) of 5 - 15 days old worker bee used for feeding queen bee and larva , also known as bee milk , royal jelly and the like .[1]</p> <p>royal jelly contains rich nucleic acid .If the content of nucleic acid in the human body is insufficient, it will affect the division of cells, cause cell defects, slow protein synthesis, and lead to body damage, pathological changes, aging.Taking royal jelly is one of the best ways to get ribonucleic acid. It can make the nucleic acid in the human body be replenished, thus delaying the aging process and prolonging the life span of human beings. The theory of free radical senescence holds that human aging is due to the excessive production and accumulation of free radicals in human body. Only by eliminating these excessive free radicals can health be guaranteed.[2]</p>
3.2.S.3.2. Impurities	<p>Potential impurities arising during the production and purification</p> <p>Analytical test procedures and their limits if detection</p> <p>Conclusions</p>
3.2.S.4. Control of drug substance	Specification for extraction substance and according the specification that we sent previously Specification sheet
3.2.S.4.1. Specification	
3.2.S.4.2. Analytical procedure	Description of the methods used to obtain the specification (when possible according to European Pharmacopoeia) HPLC
3.2.S.4.3. Batch analysis	Three COA for Herbal drug, for the production intermediates and for the herbal preparations taking into account the traceability between them. COA
3.2.S.4.4. Justification of specification	5% 10-HDA
3.2.S.5. Reference standards of material	Certificates for the standards used in the analytical determinations CHP2020
3.2.S.6. Container closure system	Certificate of analysis for the material used as Container pharmaceutical grade
3.2.S.7. Stability	

3.2.S.7.1. Stability summary and conclusion	<p>Stability conditions and parameters (ICH) Normal Evaluation of the result and proposed period of validity. Parameters measured: -Physical appearance Fine off white or light yellow powder -Assay HPLC NLT 5% 10-HDA -Microbiology Total Plate Count NMT 10,000cfu/g Total Yeast & Mold NMT 1000cfu/g E. Coli Negative Salmonella Negative Staphylococcus Negative</p>
3.2.S.7.2. Post-approval stability protocol and stability commitment	<p>Do you have a test program on-going for a longer period? At least for one batch Stability data of one batch See appendix</p>

Appendix

Stability data of one batch(Aug 04, 2020~Aug 04,2022)

Analysis Items/ Test Date	Aug 04, 2020	Nov 07, 2020	Feb15, 2021	May 13, 2021	Aug 09, 2021	Feb 07, 2022	Aug 05, 2022
Appearance & Color	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder	Fine off-white or light yellow powder
Odor & Taste (Characteristic)	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Heavy Metals (NMT 100ppm)	NMT10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm
Assay (NLT 5% 10-HDA)	5.04%	5.01%	5.03%	5.02%	5.03%	5.01%	5.03%
Total Plate Count (NMT 10,000cfu/g)	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g	NMT 10,000cfu/g
Total Yeast & Mold (NMT 1000cfu/g)	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g	N,MT 1000cfu/g
E. Coli (Negative)	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Salmonella (Negative)	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Staphylococcus (Negative)	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Packing and Storage	Packed in sealed aluminum foil bags lined with plastic seal or sealed double plastic bags. Store in a well-closed container away from moisture						
Shelf Life	2 years if sealed and store away from direct sun light.						