



Solistaa Pharmaceuticals Private Limited

PRODUCT SPECIFICATION

NAME OF THE PRODUCT: HAIR HEALTH GUMMY

Specification No.	SPC-141	Reference	In-House	Page No.	1 of 9
Revision No.	01	Effective Date	13/09/2023	Assigned by/Date: Tomy 13/09/23	
STP No.	STP-141†	Review Date	AUG-2026		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

Prepared By:

Sign:

Date:

R. Dey
Quality Control

11/09/2023

Reviewed By:

Sign:

Date:

[Signature]
Quality Control

11/09/2023

Reviewed By:

Sign:

Date:

[Signature]
Regulatory Affairs

12/09/2023

Approved By:

Sign:

Date:

[Signature]
Quality Assurance

13/09/2023

† Follow the current version of the STP

F3QC062D22 – WEF – 05/02/2022

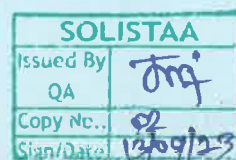
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QA	
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Sign/Date	13/09/23

**Solistaa Pharmaceuticals Private Limited****PRODUCT SPECIFICATION****NAME OF THE PRODUCT: HAIR HEALTH GUMMY**

Specification No.	SPC-141	Reference	In-House	Page No.	2 of 9
Revision No.	01	Effective Date	13/09/2023	Assigned by/Date: Jog 13/09/23	
STP No.	STP-141†	Review Date	Aug. 2022		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

A. In-Process Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Water content by KF A. Before Drying B. After Drying	For information only Not More Than 12.0% (%w/w)	In-House



**Solistaa Pharmaceuticals Private Limited****PRODUCT SPECIFICATION****NAME OF THE PRODUCT: HAIR HEALTH GUMMY**

Specification No.	SPC-141	Reference	In-House	Page No.	3 of 9
Revision No.	01	Effective Date	13/09/2023	Assigned by/Date: Tmg 13/09/23	
STP No.	STP-141†	Review Date	Aug. 2026		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

B. In-Process Specification: (After drying and oil coated stage)

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Red to dark red colored, hemispherical shaped, mixed berry flavored gummy	In-House
2.	Identification By Titration: Vitamin C Iron (as sodium ferredate) By UV: Zinc (as zinc citrate) By HPLC: Vitamin A Vitamin B ₃ Vitamin D ₃ Vitamin E Vitamin B ₆	A deep blue-violet colour observed at termination of the assay. A deep blue-violet colour disappeared at the termination of the assay. The absorbance of sample preparation correspondence to absorbance of standard preparation as obtained in the assay. The Retention time of the major peak in the chromatogram of the sample preparation correspondence to that in the chromatogram of the standard preparation, as obtained in the assay.	In-House
3.	Average weight	4.700 g $\pm$ 10 % (4.230 g to 5.170 g)	In-House
4.	Uniformity of Weight	Individual weight of Gummy does not deviate by more than $\pm$ 20 % from the average weight.	In-House
5.	Water content by KF	Not More Than 12.0% (% w/w)	In-House

**Solistaa Pharmaceuticals Private Limited****PRODUCT SPECIFICATION****NAME OF THE PRODUCT: HAIR HEALTH GUMMY**

Specification No.	SPC-141	Reference	In-House	Page No.	4 of 9
Revision No.	01	Effective Date	13/09/2023	Assigned by/Date: Jm 13/09/23	
STP No.	STP-141†	Review Date	AUG. 2026		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

S. No.	Tests Parameters	Specification Limit	Reference for Test
6.	Assay: Each Gummy contains: By Titration: Vitamin C 20 mg Iron (as Sodium ferredate) 1 mg By UV: Zinc (as zinc citrate) 3 mg By HPLC: Vitamin A 300 mcg Vitamin B ₃ 7 mg Vitamin D ₃ 200 IU Vitamin E 5 mg Vitamin B ₆ 1.6 mg Folic acid* 150 mcg Biotin* 30 mcg Glycine* 10 mg L- Arginine hydrochloride* 15 mg L-Lysine Hydrochloride* 50 mg L-Tryptophan* 10 mg Grapeseed extract* 10 mg Soy Isoflavones* 50 mg	Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100%	In-House
7.	Microbiological Test: a) Total Aerobic Microbial count b) Total Yeasts and Molds count c) <i>Enterobacteriaceae</i> d) <i>Listeria monocytogenes</i> e) <i>Salmonella species</i>	Not More Than 10000 cfu/g Not More Than 100 cfu/g Not More Than 100 cfu/g Absent in 25 g Absent in 25 g	In-House

Note: cfu – Colony forming unit, *- Calculation based on initial input

F3QC062D22 – WEF – 05/02/2022

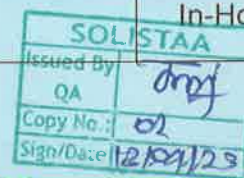
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Sign/Date	13/09/23

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Specification No.	SPC-141	Reference	In-House	Page No.	5 of 9
Revision No.	01	Effective Date	13/09/2023	Assigned by/Date: Tmf. 13/09/23	
STP No.	STP-141†	Review Date	AUG 2026		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

C. Finished Product – Release Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Red to dark red colored, hemispherical shaped, mixed berry flavored gummy	In-House
2.	Identification By Titration: Vitamin C Iron (as sodium ferredate) By UV: Zinc (as zinc citrate) By HPLC: Vitamin A Vitamin B ₃ Vitamin D ₃ Vitamin E Vitamin B ₆	A deep blue violet colour observed at termination of the assay. A deep blue violet colour disappeared at the termination of the assay. The absorbance of sample preparation correspondence to absorbance of standard preparation as obtained in the assay. The Retention time of the major peak in the chromatogram of the sample preparation correspondence to that in the chromatogram of the standard preparation, as obtained in the assay.	In-House
3.	Average weight	4.700 g $\pm$ 10 % (4.230 g to 5.170 g)	In-House
4.	Uniformity of Weight	Individual weight of Gummy does not deviate by more than $\pm$ 20 % from the average weight.	In-House
5.	Water content by KF	Not More Than 12.0% (% w/w)	In-House





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STP No.	STP-141†	Review Date	Aug-2026		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

S. No.	Tests Parameters	Specification Limit	Reference for Test
6.	Assay: Each Gummy contains: By Titration: Vitamin C 20 mg Iron (as Sodium ferredate) 1 mg By UV: Zinc (as zinc citrate) 3 mg By HPLC: Vitamin A 300 mcg Vitamin B ₃ 7 mg Vitamin D ₃ 200 IU Vitamin E 5 mg Vitamin B ₆ 1.6 mg Folic acid* 150 mcg Biotin* 30 mcg Glycine* 10 mg L- Arginine hydrochloride* 15 mg L-Lysine Hydrochloride* 50 mg L-Tryptophan* 10 mg Grapeseed extract* 10 mg Soy Isoflavones* 50 mg	Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100%	In-House
7.	Microbiological Test: a) Total Aerobic Microbial count b) Total Yeasts and Molds count c) <i>Enterobacteriaceae</i> d) <i>Listeria monocytogenes</i> e) <i>Salmonella species</i>	Not More Than 10000 cfu/g Not More Than 100 cfu/g Not More Than 100 cfu/g Absent in 25 g Absent in 25 g	In-House

**Solistaa Pharmaceuticals Private Limited****PRODUCT SPECIFICATION****NAME OF THE PRODUCT: HAIR HEALTH GUMMY**

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STP No.	STP-141†	Review Date	Aug. 2026		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

S. No.	Tests Parameters	Specification Limit	Reference for Test
8.	Heavy Metals ^{+\$} a) Lead b) Copper c) Arsenic d) Tin e) Cadmium f) Mercury g) Methyl Mercury	Not More Than 2.5 ppm Not More Than 30.0 ppm Not More Than 1.1 ppm Not More Than 250.0 ppm Not More Than 1.5 ppm Not More Than 1.0 ppm Not More Than 0.25 ppm	FSSAI
9.	Total Aflatoxins ^{+\$} Aflatoxin B1 ^{+\$}	Maximum 20mcg/kg Maximum 10mcg/kg	FSSAI
10.	Pesticides ^{+\$}	Should Comply	FSSAI

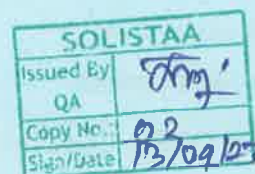
Note:

cfu – colony forming unit,

*- Calculation based on initial input

\$ -These tests will be performed for first commercial batch and will be repeated every 6 months. The requirements for these tests are as per the regulatory framework laid by FSSAI and Test performed at NABL accredited / FSSAI recognized laboratory.

+-This Test is not a part of Product Release.

Shelf life: 18 Months from the date of manufacturing.



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Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

D. Finished Product – Stability Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Red to dark red colored, hemispherical shaped, mixed berry flavored gummy	In-House
2.	Average weight	4.700 g ± 10 % (4.230 g to 5.170 g)	In-House
3.	Water content by KF	Not More Than 12.0% (% w/w)	In-House
4.	Assay: Each Gummy contains: By Titration: Vitamin C 20 mg Iron (as Sodium ferredate) 1 mg By UV: Zinc (as zinc citrate) 3 mg By HPLC: Vitamin A 300 mcg Vitamin B ₃ 7 mg Vitamin D ₃ 200 IU Vitamin E 5 mg Vitamin B ₆ 1.6 mg Folic acid* 150 mcg Biotin* 30 mcg Glycine* 10 mg L- Arginine hydrochloride* 15 mg L-Lysine Hydrochloride* 50 mg L-Tryptophan* 10 mg Grapeseed extract* 10 mg Soy Isoflavones* 50 mg	Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 90.0% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100% Not Less Than 100%	In-House

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STP No.	STP-141†	Review Date	AUG-2026		
Product Code	141	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

S. No.	Tests Parameters	Specification Limit	Reference for Test
5.	Microbiological Test: a) Total Aerobic Microbial count b) Total Yeasts and Molds count c) <i>Enterobacteriaceae</i> d) <i>Listeria monocytogenes</i> e) <i>Salmonella species</i>	Not More Than 10000 cfu/g Not More Than 100 cfu/g Not More Than 100 cfu/g Absent in 25 Absent in 25 g	In-House

Note:

cfu – colony forming unit.

*- Calculation based on initial input

REVISION HISTORY:

Rev No.	Nature of revision in brief	Effective Date	DCR Reference
00	New Document	24/05/2023	CCRD22081
01	1. Microbiological Test parameters are modified as per current FSSAI (Food Products Standards and Food Additives) Amendment Regulation 2023. 2. In C. Finished Product Release Specification Aflatoxins is changed into Total Aflatoxins and Aflatoxin B1.	13/09/23	CCMB23005

