



Solistaa Pharmaceuticals Private Limited

PRODUCT SPECIFICATION

NAME OF THE PRODUCT: WOMEN HEALTH GUMMY

Specification No.	SPC-144	Reference	In-House	Page No.	1 of 9
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Jmg 12/09/23	
STP No.	STP-144†	Review Date	Aug-2026		
Product Code	144	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

Prepared By:

Sign:

Date:

R. Dey
Quality Control

07/09/2023

Reviewed By:

Sign:

Date:

[Signature]
Quality Control

07/09/2023

Reviewed By:

Sign:

Date:

[Signature]
Regulatory Affairs

11/09/2023

Approved By:

Sign:

Date:

N. Dey
Quality Assurance

12/09/2023

† Follow the current version of the STP

F3QC062D22 – WEF – 05/02/2022

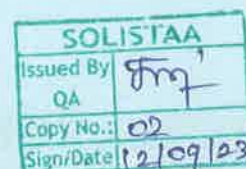
SOLISTAA	
Issued By	Jmg
QA	
Copy No.:	02
Sign/Date	12/09/23

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

Specification No.	SPC-144	Reference	In-House	Page No.	2 of 9
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Jmg 12/09/23	
STP No.	STP-144†	Review Date	Active 2026		
Product Code	144	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: WOMEN HEALTH GUMMY**

Specification No.	SPC-144	Reference	In-House	Page No.	3 of 9
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Tong 12/09/23	
STP No.	STP-144†	Review Date	AUG. 2026		
Product Code	144	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

B. In-Process Specification: (Bulk)

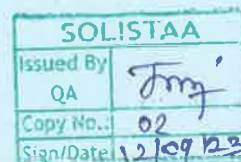
S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Reddish brown colour, hemispherical shaped with cranberry flavoured gummy	In-House
2.	Identification: By Titration: Vitamin C Calcium (as calcium phosphate) By HPLC: Vitamin D ₃ Cranberry extract	A deep blue violet colour observed at termination of 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: WOMEN HEALTH GUMMY**

Specification No.	SPC-144	Reference	In-House	Page No.	4 of 9
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Jmg 12/09/23	
STP No.	STP-144†	Review Date	Aug-2026		
Product Code	144	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 Calcium (as calcium phosphate) 200 mg By HPLC: Vitamin D ₃ 200 IU Cranberry extract 50 mg Soy Isoflavones* 50 mg Green tea powder* 50 mg Black Cohosh extract* 10 mg American ginseng extract* 25 mg Beta vulgaris (Beetroot Extract)* 25 mg Hibiscus extract* 25 mg Pomegranate extract* 10 mg	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%	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 25g Absent in 25g	In-House

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



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

Specification No.	SPC-144	Reference	In-House	Page No.	5 of 9
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Tomy 12/09/23	
STP No.	STP-144†	Review Date	Aug - 2024		
Product Code	144	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

D. Finished Product – Release Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Reddish brown colour, hemispherical shaped with cranberry flavoured gummy	In-House
2.	Identification: By Titration: Vitamin C Calcium (as calcium phosphate) By HPLC: Vitamin D ₃ Cranberry extract	A deep blue-violet colour observed at termination of 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 ± 10 % (4.230 g to 5.170 g)	In-House
4.	Uniformity of Weight	Individual weight of Gummy does not deviate by more than ± 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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**Solistaa Pharmaceuticals Private Limited****PRODUCT SPECIFICATION****NAME OF THE PRODUCT: WOMEN HEALTH GUMMY**

Specification No.	SPC-144	Reference	In-House	Page No.	6 of 9
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Jmg 12/09/23	
STP No.	STP-144†	Review Date	AUG-2026		
Product Code	144	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 Calcium (as calcium phosphate) 200 mg By HPLC: Vitamin D ₃ 200 IU Cranberry extract 50 mg Soy Isoflavones* 50 mg Green tea powder* 50 mg Black Cohosh extract* 10 mg American ginseng extract* 25 mg Beta vulgaris (Beetroot Extract)* 25 mg Hibiscus extract* 25 mg Pomegranate extract* 10 mg	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%	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 25g Absent in 25g	In-House

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STP No.	STP-144†	Review Date	Aug. 2026		
Product Code	144	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:

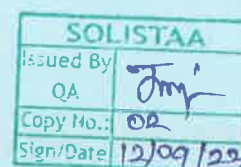
cfu – colony forming unit,

*- 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.

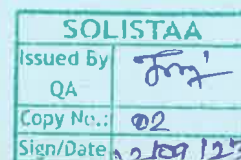


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Specification No.	SPC-144	Reference	In-House	Page No.	8 of 9
Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Jmj 12/09/23	
STP No.	STP-144†	Review Date	Aug. 2026		
Product Code	144	Customer	Cureka, Wedjat Health Solutions Pvt, Ltd. India		

E. Finished Product – Stability Specification:

S. No.	Tests Parameters	Specification Limit	Reference for Test
1.	Description	Reddish brown colour, hemispherical shaped with cranberry flavoured gummy	In-House
2.	Average weight	4.700 g $\pm$ 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 Calcium (as calcium phosphate) 200 mg By HPLC: Vitamin D ₃ 200 IU Cranberry extract 50 mg Soy Isoflavones* 50 mg Green tea powder* 50 mg Black Cohosh extract* 10 mg American ginseng extract* 25 mg Beta vulgaris (Beetroot Extract)* 25 mg Hibiscus extract* 25 mg Pomegranate extract* 10 mg	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%	In-House



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Revision No.	01	Effective Date	12/09/2023	Assigned by/Date: Jony 12/09/23	
STP No.	STP-144†	Review Date	10/07/2022		
Product Code	144	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 25g Absent in 25g	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	19/05/2023	CCRD22080
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.	12/09/2023	CCMB23005

