factory & office phone: 0477-2258184 kalavoor - 688 522 alappuzha, india

Email: ksdpltd@gmail.com | fax : 0477 - 2258162

0477-2258828

Website: www.ksdp.co.in

Notice Inviting Tender

KSDP/PS/F-EPRO/EHG-03/2024-25/174

a government of kerala enterprise

01.02.2025

The Managing Director, Kerala State Drugs & Pharmaceuticals Ltd, Kalavoor - PO, Alappuzha, Kerala 688 522 invites online bids in TWO cover system for **Supply of Empty Hard Gelatin** Capsule Shell IP Size '0' and Size '2' from Suppliers / Organizations who have successfully completed similar works / supplies as given elsewhere in the condition of contract.

1	Name of work	Supply of Empty Hard Gelatin Capsule Shell IP Size '0' (Blue/Pink) - 1 Crores, Empty Hard Gelatin Capsule Shell IP Size '0' (Green/Green) - 6 Lakhs, Empty Hard Gelatin Capsule Shell IP Size'0' (Pink/Pink) - 5 Lakhs Empty Hard Gelatin Capsule Shell IP Size'0' (Pink/White) - 5 Lakhs Empty Hard Gelatin Capsule Shell IP Size'0' (White/White) - 1 Lakhs Empty Hard Gelatin Capsule Shell IP Size'2' (White/White) - 5 Lakhs Empty Hard Gelatin Capsule Shell IP Size'2' (White/White) - 5 Lakhs Empty Hard Gelatin Capsule Shell IP Size'2' (Red/White) - 5 Lakhs (As per Specification attached.)
2	Earnest Money Deposit (EMD)	₹11712(by online; Refundable)
3	Tender Submission Fee	₹2124(by online; Non-refundable)
4	Period of completion	15 days
5	Classification of Bidder	From reputed suppliers/organisations with at least 3 years consistent standing in the field.
6	Tender documents	Can be downloaded from the site www.etenders.kerala.gov.in.
7	Last date & time of Receipt of Tender/ Bids	11.02.2025, 1.00 PM
8	Date and Time of Opening of Tender (Technical Bid). Tender documents and tender schedule may be downloaded from the website www.etenders.kerala.gov.in.	12.02.2025, 1.00 PM

NOTE: The Tenderer reserves the right to apportion the tendered quantity among bidders participated

The bid submission fee shall be remitted online during the time of bid submission.

Those bidders possessing valid "Udyog Aadhar" can avail EMD & Tender Cost exception by uploading relevant document. All bid/tender documents are to be submitted online only and in the designated cover(s)/envelope(s) on the e-Tenders website. Technical bid and financial bid shall be submitted in online covers. Tenders/ bids will be accepted only through online mode on the website and no manual submission of the same will be entertained. Late tenders will not be accepted. The scanned conies of registration certificate and FMD exemption certificate (if any) and other documents opened online on specified date and time. If the tender opening date happens to be on a holiday or nonworking day due to any other valid reason, the tender opening process will be done on the next working day at same time and place. Tenders/ bids received online without the fee will not be considered and shall be summarily rejected. Further details on e-tender process can be had from the NIC, Thiruvananthapuram or Office of the Managing Director, KSDP Ltd, Kalavoor, Alappuzha during working hours. The KSDP Ltd will not be responsible for any error like missing of schedule data while downloading by the Bidder.

Sd/-Managing Director



Raw Material Specification

SOP No:	WORDS THE HARD GE	LATIN CAPSULE SH	ELL IP SIZE "2" White / White
	TESDITISOTTSI ECUI	Spec. No:	KSDP/R/SPEC01/88
Effective date:	01/12/2022	Revision No:	02

Sl.No.	TESTS .	SPECIFICATION *
1	-	
. 1	Description	Empty hard gelatin capsule shell consists of two cylindrical,
		telescoping pieces (cap and body), one end of which is
		rounded and closed and the other, open. The cap overlaps
		the body and maintains a tight fairting to the
		the body and maintains a tight friction closure. The shells
	* *	are smooth and uniform in size, shape and colour. The
	**	pieces are of White and White coloured with size "2"
2	I.I. disc	unprinted on it.
2	Identification	Boil one capsule shell with 20mL of water, allow to cool
	4	and centifuge. To 5mL of the supernatant liquid add 1ml
		of pictic acid solution and to another 5ml add 1ml of
3	Odour	railine acid solution; a precipitate is produced in each case
ر	Odour	The shell do not develop any foreign odour
. 4	Average weight	Within ± 10%
5		
	Disintegration	15 minutes.
6	Microbial contamination	Total microbial count, not more than 103 covy
		Total microbial count, not more than 10 ³ CFU per g; 1g is
		free from Escherichia coli; 10 g is free from Salmonella and Shigella
7	Loss on drying	
	2000 on drying	12.5 to 16 %, determined on 1.0g by drying in an oven at
The Deal	ing Specification for English	105° for 4 hours or to constant weight.

The Packing Specification for Empty Hard Gelatin Capsule Shell:

The shell should be primarily packed with two layers of bubble polythene bag, followed with black polythene bag. This should be enclosed in tightly closed thermocol box, which again packed in 5 Ply Corrugated carton box.

Consignment should be sent in AC Vehicle with Data Logger from concerned manufacturing site to KSDP Store.

Prepared by	Checked by	Reviewed By	Approved By	
Officer QA	QC Head	Production Head	QA Head	MASTER COPY
21/12/2022	01/12/2022	01/12/2022	Thing	UNCONTROLLED COP



Raw Material Specification

COD Man	Webbis and Ti HARD GE	LATIN CAPSULE SH	IELL I.P. SIZE "2" Red/White
501 Tto.	KSDP/SOP/SPEC01	Spec. No:	KSDP/R/SPEC01/87
Effective date:	01/12/2022		RSDI/NSFECUI/8/
	<u> </u>	Revision No:	02

Sl.No.	TESTS .	SPECIFICATION *
1	Description	
•	Description	Empty hard gelatin capsule shell consists of two cylindrical,
		telescoping pieces (cap and body), one end of which is
	****	rounded and closed and the other, open. The cap overlaps
		the body and maintains a tight friction closure. The shells
		are smooth and uniform in size, shape and colour. The
	**	pieces are of Red and White coloured with size "2"
		unprinted on it.
2	Identification	Boil one capsule shell with 20mL of water, allow to cool
	1	and centrifuge. To 5mL of the supernatant liquid add 1ml
		of pictic acid solution and to another 5ml, add 1ml of
3	0.1	tannic acid solution; a precipitate is produced in each case
3	Odour	The shell do not develop any foreign odour
, 4	Average weight	Within ± 10%
5	Disintegration	15
		15 minutes.
6	Microbial contamination	Total microbial count, not more than 10 ³ CFU per g; 1g is
		free from Escherichia coli; 10 g is free from Salmonella and
	•	Shigella.
7	Loss on drying	12.5 to 16 %, determined on 1.0g by drying in an oven at
		105° for 4 hours or to constant weight.

The Packing Specification for Empty Hard Gelatin Capsule Shell:

The shell should be primarily packed with two layers of bubble polythene bag, followed with black polythene bag. This should be enclosed in tightly closed thermocol box, which again packed in 5 Ply Corrugated carton box.

Consignment should be sent in AC Vehicle with Data Logger from concerned manufacturing site to KSDP Store..

Prepared by	' Checked by	Reviewed By	Approved By	BAROTER GORV
Officer QA	QC Head	Production Head	QA Head	MASTER COPY
01/12/2022	01/2/2022	01/12/12/22	- C/12/2022	UNCONTROLLED CO



Raw Material Specification

Name of the Ma	terial: EMPTY HARD GE	LATIN CAPSULE SH	ELL IP SIZE "0" Blue/Pink
SOP No:	KSDP/SOP/SPEC01	Spec. No:	KSDP/R/SPEC01/54
Effective date:	01/12/2022	Revision No:	→ 02

Sl.No.	TESTS	SPECIFICATION
1	Description	Empty hard gelatin capsule shell consists of two cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed and the other, open. The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size, shape and colour. The pieces are of blue and pink coloured with size "0" unprinted on it.
2	Identification	Boil one capsule shell with 20 mL of water, allow to cool and centrifuge. To 5 mL of the supernatant liquid add 1 mL of picric acid solution and to another 5 mL add 1 mL of tannic acid solution; a precipitate is produced in each case.
3	Odour	The shell do not develop any foreign odour.
4 .	Average weight	Within ± 10%
5	Disintegration	15 minutes.
6	Microbial contamination	Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.
7	Loss on drying	12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant weight.

The Packing Specification for Empty Hard Gelatin Capsule Shell:

The shell should be primarily packed with two layers of bubble polythene bag, followed with black polythene bag. This should be enclosed in tightly closed thermocol box, which again packed in 5 Ply Corrugated carton box.

Consignment should be sent in AC Vehicle with Data Logger from concerned manufacturing site to KSDP Store.

Prepared by	Checked by	Reviewed By	Approved By	MASTER COPY
Officer QA	QC Head	Production Head	QA Head	UNCONTROLLED COPY
di	Amt	6.3	- Ophip	
01/12/2022	01/2/2022	01 2 2022	01 12 2022	



Raw Material Specification

COD Mos	VODD/GOD/GOD	LATIN CAPSULE SE	IELL IP SIZE "0" Green/Green	
OU 110.	MODE/SOP/SPECUI	Spec. No:	KSDP/R/SPEC01/56	
Effective date:	: 01/12/2022	Revision No:	01	

Sl.No.	TESTS	SPECIFICATION
1	Description	Empty hard gelatin capsule shell consists of two cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed and the other, open. The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size, shape and colour. The pieces are of green and
2	Identification	green coloured with size "0" unprinted on it. Boil one capsule shell with 20 mL of water, allow to cool and centrifuge. To 5 mL of the supernatant liquid add 1mL of picric acid solution and to another 5 mL add 1 mL of tannic acid solution; a precipitate is produced in each case.
3	Odour	The shell do not develop any foreign odour.
4	Average weight	Within ± 10%.
5	Disintegration	15 minutes.
6	Microbial contamination	Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.
7	Loss on drying	12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant weight.

The Packing Specification for Empty Hard Gelatin Capsule Shell:

The shell should be primarily packed with two layers of bubble polythene bag, followed with black polythene bag. This should be enclosed in tightly closed thermocol box, which again packed in 5 Ply Corrugated carton box.

Consignment should be sent in AC Vehicle with Data Logger from concerned manufacturing site to KSDP Store.

Prepared by	Checked by	Reviewed By	Approved By	
Officer QA	QC Head	Production Head	QA Head	MASTER COPY
di	Ant	£2	- Spaker	UNCONTROLLED COPY
12 2022	01/12/2022	01/12/2022	04/12/2022	



Raw Material Specification

Name of the Ma	terial: EMPTY HARD GE	LATIN CAPSULE SH	ELL IP SIZE "0" Pink/Pink
SOP No:	KSDP/SOP/SPEC01	Spec. No:	KSDP/R/SPEC01/57
Effective date:	01/12/2022	Revision No:	02

Sl.No.	TESTS	SPECIFICATION		
1	Description	Empty hard gelatin capsule shell consists of two cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed and the other, open.		
•		The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size, shape and colour. The pieces are of Pink and Pink coloured with size "0" unprinted on it.		
2	Identification	Boil one capsule shell with 20 mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case.		
3	Odour	The shell do not develop any foreign odour.		
4	Average weight	Within ± 10%.		
5	Disintegration	15 minutes.		
, 6	Microbial contamination	Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.		
7	Loss on drying	12.5 to 16 %, determined on 1.0 g by drying in an oven at 105° for 4 hours or to constant weight.		

The Packing Specification for Empty Hard Gelatin Capsule Shell:

The shell should be primarily packed with two layers of bubble polythene bag, followed with black polythene bag. This should be enclosed in tightly closed thermocol box, which again packed in 5 Ply Corrugated carton box.

Consignment should be sent in AC Vehicle with Data Logger from concerned manufacturing site to KSDP Store.

Prepared by	Checked by	Reviewed By	Approved By	MASTER COP
Officer QA	QC Head	Production Head	QA Head	UNCONTROLLED COPY
di	fil	42	- Ophip	
01 12 2022	01/12/2022	01/12/2022	01/12/2022	



Raw Material Specification

SOP No:	WORDS THE HARD GE	LATIN CAPSULE SH	IELL I.P. SIZE "0" white/white
	KSDP/SOP/SPEC01	Spec. No:	KSDP/R/SPEC01/123
Effective date:	01/12/2022		
	01/12/2022	Revision No:	02

Description Empty hard gelatin capsule shell consists of two cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed and the other, open. The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size	Sl.No.	TESTS	CDECUTYC
Empty hard gelatin capsule shell consists of two cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed and the other, open. The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size, shape and colour. The pieces are of white and white coloured with size "0" unprinted on it. Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of pieric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. The shell do not develop any foreign odour. Within ± 10% Disintegration 15 minutes, using discs. Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.	1		SPECIFICATION
cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed and the other, open. The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size, shape and colour. The pieces are of white and white coloured with size "0" unprinted on it. Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. Codour The shell do not develop any foreign odour. Within ± 10% Disintegration Is minutes, using discs. Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and of the other, open. The shell do not develop any foreign odour.	1 1	Description	Empty hard gelatin capsule shell consists of two
The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size, shape and colour. The pieces are of white and white coloured with size "0" unprinted on it. Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. Odour The shell do not develop any foreign odour. Within ± 10% Disintegration Is minutes, using discs. Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and other streets.			cylindrical, telescoping pieces (can and body) one and
Identification		*	of which is rounded and closed and the other orem
Identification Identification Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. Odour Average weight Disintegration Is minutes, using discs. Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and white and white colours, had white and white and white coloured with size "0" unprinted on it. Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.			The cap overlaps the body and maintains a tight friction
Identification Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. Odour Average weight Disintegration Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and white colours. Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of picric acid solution and to another 5mL add 1mL of picric acid solution; a precipitate is produced in each case. The shell do not develop any foreign odour. Within ± 10% Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.	*		closure. The shells are smooth and uniform in single
Identification Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. Odour Average weight Disintegration Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant to the color of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.			shape and colour. The pieces are of white and white
Boil one capsule shell with 20mL of water, allow to cool and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. 3 Odour 4 Average weight 5 Disintegration 15 minutes, using discs. 6 Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. 7 Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant at 105° for 4 hours or to constant at 105° for 4 hours or to constant.	-		coloured with size "0" unprinted on it
Coor and centrifuge. To 5mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. 3 Odour 4 Average weight 5 Disintegration 15 minutes, using discs. 6 Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. 7 Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and the supernatant liquid add 1mL of the supernatant liquid add 1mL of picric acid solution and to another 5mL add 1mL of picric acid solution; a precipitate is produced in each case. 7 Loss on drying	2	Identification	Boil one cansule shell with 20ml of with
Add TmL of picric acid solution and to another 5mL add 1mL of tannic acid solution; a precipitate is produced in each case. 3			cool and centrifuge. To 5ml of the severe allow to
3 Odour 4 Average weight 5 Disintegration 6 Microbial contamination 7 Loss on drying 1 Odour The shell do not develop any foreign odour. Within ± 10% 15 minutes, using discs. Total microbial count, not more than 10³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and the same of the sam			add ImI. of picric acid solution and the supernatant liquid
Odour The shell do not develop any foreign odour. Within ± 10% Disintegration Is minutes, using discs. Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16%, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant with the shell do not develop any foreign odour. Within ± 10% Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.			ImI of tennie acid solution and to another 5mL add
Average weight Within ± 10% Disintegration Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant with the shell do not develop any foreign odour. Within ± 10% Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella.			in each acid solution; a precipitate is produced
Disintegration 15 minutes, using discs. Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant with the same con	3	Odour	
5 Disintegration 15 minutes, using discs. 6 Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. 7 Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant with the same of the same	4	Average weight	the shell do not develop any foreign odour.
Microbial contamination Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant with the same of the	5		
Total microbial count, not more than 10 ³ CFU per g; 1g is free from Escherichia coli; 10 g is free from Salmonella and Shigella. Total microbial count, not more than 10 ³ CFU per g; 1g is free from Salmonella and Shigella. Total microbial count, not more than 10 ³ CFU per g; 1g is free from Salmonella and Shigella.	6		15 minutes, using discs.
7 Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant with the second states.	,	wiferobial contamination	Total microbial count, not more than 10 ³ CFU per g: 1g
7 Loss on drying 12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and shigella.	1		is free from Escherichia coli: 10 g is free from
12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant and it.	7		Salmonella and Shigella.
at 103 10r 4 nours or to constant	'	Loss on drying	12.5 to 16 %, determined on 1.0g by drying in an over
	TI D I		at 103 10r 4 nours or to constant

The Packing Specification for Empty Hard Gelatin Capsule Shell:

The shell should be primarily packed with two layers of bubble polythene bag, followed with black polythene bag. This should be enclosed in tightly closed thermocol box, which again packed in 5 Ply Corrugated carton box.

Consignment should be sent in AC Vehicle with Data Logger from concerned manufacturing site to KSDP Store.

Prepared by	Checked by	Reviewed By	Approved By	
Officer QA	QC Head	Production Head	QA Head	MASTER COPY
Jni -	Jal	(d)	Uhhap	UNCONTROLLED COP
01 12 20 23	01/12/2022	01(12/2022	01/18/8038	



Raw Material Specification

SOP No:	VCDD/COD/CD	LATIN CAPSULE SH	ELL I.P. SIZE "0" Pink/white	
	KSDP/SOP/SPEC01 01/12/2022	Spec. No:	KSDP/R/SPEC01/122	
Effective date:		Revision No:		

Sl.No.	TESTS	SDECIEICATION
. 1	Description	SPECIFICATION
-	Description	Empty hard gelatin capsule shell consists of two
	· ·	'cylindrical, telescoping pieces (cap and body), one end of
		which is rounded and all all and body), one end of
		which is rounded and closed and the other, open. The cap
		overlaps the body and maintains a tight friction alogues
		The shells are smooth and uniform in size, shape and
		colour. The pieces are of Dials and
	*	colour. The pieces are of Pink and white coloured with
2	Identification	size "0" unprinted on it.
	-demined from	Boil one capsule shell with 20mL of water, allow to cool
		and centrifuge. To 5mL of the supernatant liquid add 1mL
		of pictic acid solution and the supernatant inquid add ImL
		of picric acid solution and to another 5mL add 1mL of
. 3	Odour	tarine acid solution; a precipitate is produced in each
4		The shell do not develop any foreign odour
	Average weight	Within ± 10%
5	Disintegration	15 minutes, using discs.
6	Microbial contamination	Text 1 is a large discs.
	ontainmation	Total microbial count, not more than 10 ³ CFU per g; 1g is
		free from Escherichia coli; 10 g is free from Salmonella
		and Shigella.
7		
		12.5 to 16 %, determined on 1.0g by drying in an oven at
	*	105° for 4 hours or to constant weight.

The Packing Specification for Empty Hard Gelatin Capsule Shell:

The shell should be primarily packed with two layers of bubble polythene bag, followed with black polythene bag. This should be enclosed in tightly closed thermocol box, which again packed in 5 Ply

Consignment should be sent in AC Vehicle with Data Logger from concerned manufacturing site to KSDP

Prepared by	Checked by	Reviewed By		
Officer QA	QC Head	Production Head	Approved By QA Head	MASTER COPY
m'	AL	2	Opky	UNCONTROLLED CO
01 18 3033	01/12/2022	01/12/2022	01/12/2022	