

List of Additional Products Applied to be Manufactured by **M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61 Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India**, Under Manufacturing Licence No. **Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145** W.E.F. 19.06.2019
Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

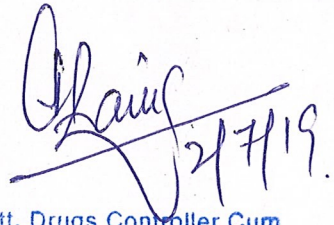
Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.	Approved/Rejected
1	Gemcitabine For Injection USP 200 mg/Vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		Gemcitabine Hydrochloride	BP			
		eq. to Gemcitabine		200	mg	
		Excipients		q.s.		
2	Gemcitabine For Injection USP 1000 mg/Vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		Gemcitabine Hydrochloride	BP			
		eq. to Gemcitabine		1000	mg	
		Excipients		q.s.		
3	Doxorubicin Hydrochloride For Injection BP 50 mg / vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		Doxorubicin Hydrochloride	BP	50	mg	
		Excipients		q.s.		
4	Doxorubicin Hydrochloride For Injection BP 10 mg / vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		Doxorubicin Hydrochloride	BP	10	mg	
		Excipients		q.s.		
5	Bendamustine For Injection 100 mg/vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		Bendamustine Hydrochloride		100	mg	
		Mannitol	BP	170	mg	
6	L-Asparaginase For Injection 5000 IU/ vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		L-Asparaginase		5000	IU	
		Excipients		q.s.		
7	L-Asparaginase For Injection 10,000 IU/ vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		L-Asparaginase		10,000	IU	
		Excipients		q.s.		
8	Bortezomib For Injection 2.0 mg/vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		Bortezomib		2.0	mg	
		Mannitol	BP	20	mg	
9	Paclitaxel (protein bound particles) For Injectable Suspension 100 mg / vial (For Export)	Each ml contains :				APPROVED
		Paclitaxel	USP	100	mg	
		Human Albumin	BP	q.s.		

Ashish Raina
19/6/2019
Asstt. Drugs Controller Cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt. Kangra at Dharamshala (H.P.)
E-mail: ashishraina25@gmail.com
Tel. No. 01892-224874

List of Additional Products Approved to be Manufactured by M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61 Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India, Under Manufacturing Licence No. Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145 W.E.F. 02.07.2019

Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

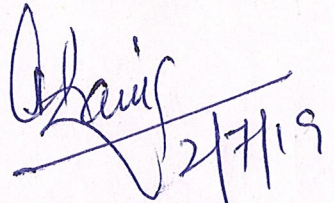
Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.	Approved/Rejected
12	Fluorouracil Injection BP 250 mg/10 ml (For Export)	Each ml contains :				APPROVED
		Fluorouracil	BP	25	mg	
		Water for Injections	BP	q.s.		
13	Fluorouracil Injection BP 250 mg /5.0 ml (For Export)	Each ml contains :				APPROVED
		Fluorouracil	BP	50	mg	
		Water for Injections	BP	q.s.		
14	Irinotecan Hydrochloride Injection USP 40 mg /2.0 ml (For Export)	Each ml contains :				APPROVED
		Irinotecan Hydrochloride Trihydrate	USP	20	mg	
		Water for Injections	BP	q.s.		
15	Irinotecan Hydrochloride Injection USP 100 mg/ 5 ml (For Export)	Each ml Contains:				APPROVED
		Irinotecan Hydrochloride	USP	20	mg	
		Water for Injections	BP	q.s.		
16	Mitoxantrone Injection USP 20 mg / 10 ml (For Export)	Each ml Contains:				APPROVED
		Mitoxantrone Hydrochloride	USP			
		Eq. to Mitoxantrone		2.0	mg	
		Water For Injection	BP	q.s.		
17	Fulvestrant Injection 250 mg/ 5 ml (For Export)	Each ml Contains :				APPROVED
		Fulvestrant		50	mg	
		Water for Injections	BP	q.s.		
18	Methotrexate Injection BP 50 mg/ 2 ml (For Export)	Each ml contains:				APPROVED
		Methotrexate	BP	25	mg	
		Sodium Hydroxide	BP	q.s.		
		Water for Injections	BP	q.s.		
19	Cytarabine Injection BP 100 mg/5 ml (For Export)	Each ml contains :				APPROVED
		Cytarabine	BP	20	mg	
		Water for Injections	BP	q.s.		


 21/7/19
 Asstt. Drugs Controller Cum
 Drug Licensing Authority
 O/o Chief Medical Officer
 Distt. Kangra at Dharamshala (H.P.)
 E-mail: ashishraina25gmail.com
 Tel. No. 01892-224874

List of Additional Products Approved to be Manufactured by M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61 Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India, Under Manufacturing Licence No. Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145 W.E.F. 02.07.2019

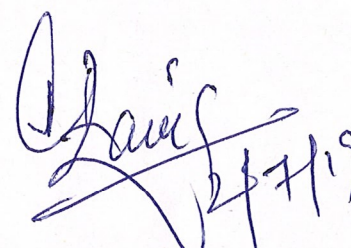
Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.	Approved/Rejected
11	Sorafenib Tablets 250 mg (For Export)	Each film coated tablet contains: Sorafenib Tosylate eq. to Sorafenib Excipients Colour: Approved Colour Used		250	mg	REJECTED
12	Tamoxifen Tablets BP 20 mg (For Export)	Each uncoated Tablets Contains : Tamoxifen Citrate Eq. to Tamoxifen Excipients	BP	20	mg	APPROVED
13	Tamoxifen Tablets BP 40 mg (For Export)	Each uncoated Tablets Contains : Tamoxifen Citrate Eq. to Tamoxifen Excipients	BP	40	mg	REJECTED
14	Mercaptopurine Tablets BP 50 mg (For Export)	Each uncoated tablet contains: Mercaptopurine Excipients	BP	50	mg	APPROVED
15	Dasatinib Tablets 50 mg (For Export)	Each film coated tablet contains: Dasatinib Excipients Approved Colours Used		50	mg	APPROVED
16	Dasatinib Tablets 70 mg (For Export)	Each film coated tablet contains: Dasatinib Excipients Approved Colours Used		70	mg	APPROVED
17	Dasatinib Tablets 100 mg (For Export)	Each film coated tablet contains: Dasatinib Excipients Approved Colours Used		100	mg	APPROVED
18	Chlorambucil Tablets BP 2.0 mg (For Export)	Each film coated tablet contains: Chlorambucil Excipients Approved Colours Used	BP	2.0	mg	APPROVED
19	Chlorambucil Tablets BP 5.0 mg (For Export)	Each film coated tablet contains: Chlorambucil Excipients Approved Colours Used	BP	5.0	mg	APPROVED
20	Bicalutamide Tablet BP 50 mg (For Export)	Each film coated tablet contains: Bicalutamide Excipients Approved Colours Used	BP	50	mg	APPROVED


2/7/19.
Asstt. Drugs Controller Cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt. Kangra at Dharamshala (H.P.)
E-mail: ashishraina25@gmail.com
Tel. No. 01892-224874

List of Additional Products Approved to be Manufactured by M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61 Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India, Under Manufacturing Licence No. Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145 W.E.F. 02.07.2019
Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

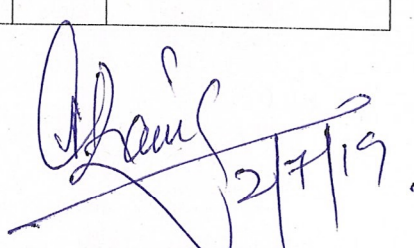
Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.	Approved/Rejected
20	Daunorubicin Hydrochloride For Injection USP 20 mg/vial (as Lyophilized) (For Export)	Each vial contains				APPROVED
		Daunorubicin Hydrochloride	BP	20	mg	
		Mannitol	USP	100	mg	
21	Ifosfamide For injection USP 1.0gm/vial (as lyophilized) For Export	Each vial contains				APPROVED
		Ifosfamide	BP	1.0	gm	
22	Ifosfamide For injection USP 2.0gm/vial (as lyophilized) (For Export)	Each vial contains				APPROVED
		Ifosfamide	BP	2.0	gm	
23	Carmustine For Injection USP 100 mg/vial (as lyophilized) (For Export)	Each vial contains:				APPROVED
		Carmustine	USP	100	mg	
24	Mitomycin For Injection USP 2.0 mg/vial (as lyophilized) (For Export)	Each vial contains:				APPROVED
		Mitomycin	USP	2.0	mg	
25	Mitomycin For Injection USP 5.0 mg/vial (as lyophilized) (For Export)	Each vial contains:				APPROVED
		Mitomycin	USP	5.0	mg	
26	Mitomycin For Injection USP 10 mg/vial (as lyophilized) For Export	Each vial contains:				APPROVED
		Mitomycin	USP	10	mg	
27	Mitomycin For Injection USP 20 mg/vial (as lyophilized) (For Export)	Each vial contains:				APPROVED
		Mitomycin	USP	20	mg	
28	Methotrexate For Injection USP 50 mg/vial (As Lyophilized) For Export	Each vial contains:				APPROVED
		Methotrexate	BP	50	mg	
29	Methotrexate For Injection USP 250 mg/vial (As Lyophilized) For Export	Each vial contains:				APPROVED
		Methotrexate	BP	250	mg	
30	Methotrexate For Injection USP 500 mg/vial (As Lyophilized) For Export	Each vial contains:				APPROVED
		Methotrexate	BP	500	mg	
31	Pemetrexed For Injection USP 100 mg/Vial (As Lyophilized) (For Export)	Each vial contains :				APPROVED
		Pemetrexed Disodium	USP			
		eq. to Pemetrexed		100	mg	
		Excipients		q.s.		


Asstt. Drugs Controller Cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt. Kangra at Dharamshala (H.P.)
E-mail: ashishraina25@gmail.com
Tel. No. 01892-224874

List of Additional Products Approved to be Manufactured by M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61 Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India, Under Manufacturing Licence No. Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145 W.E.F. 02.07.2019

Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

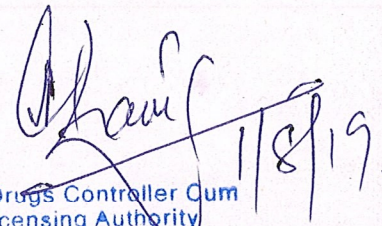
Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.	Approved/Rejected
1	Daunorubicin Citrate Liposome Injection 50 mg/25 ml For Export	Each vial contains: Daunorubicin Citrate	BP	50	mg	APPROVED
2	PEG L-Asparaginase For Injection 750 IU/ ml (As Liposomal) For Export	Each vial contains: PEG L-Asparaginase		750	IU	
3	Epirubicin Hydrochloride For Injection 50 mg / vial (As Lyophilized)	Each vial contains : Epirubicin Hydrochloride Excipients	BP	50	mg	APPROVED
4	Epirubicin Hydrochloride For Injection 10 mg / vial (As Lyophilized) (For Export)	Each vial contains : Epirubicin Hydrochloride Excipients	BP	10	mg	
				q.s.		APPROVED


 Asstt. Drugs Controller Cum
 Drug Licensing Authority
 O/o Chief Medical Officer
 Distt. Kangra at Dharamshala (H.P.)
 E-mail: ashishraina25@gmail.com
 Tel. No. 01892-224874

List of Additional Products Approved to be Manufactured by M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61, Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India, Under Manufacturing Licenses Nos. Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145 valid up to 18.06.2024

Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

Sr. No.	Brand Name & Generic Name	Composition	Spec	Qty.	Unit.	Approved/Rejected
1	Exemestane Tablets 25 mg (For Export)	Each film coated tablet contains				APPROVED
		Exemestane		25	mg	
		Excipients		q.s.		
		Colour: Approved colour used				
2	Nilutamide Tablets 150 mg (For Export)	Each uncoated tablet contains				APPROVED
		Nilutamide		150	mg	
		Excipients		q.s.		
		Colour: Approved colour used				
3	Letrozole Tablets USP 2.5 mg (For Export)	Each film coated tablet contains				APPROVED
		Letrozole	USP	2.5	mg	
		Excipients		q.s.		
		Colour: Approved Colour used				
4	Flutamide Tablets 250 mg (For Export)	Each uncoated tablet contains				APPROVED
		Flutamide	USP	250	mg	
		Excipients		q.s.		
		Colour: Approved colour used				
5	Sorafenib Tablets 200 mg (For Export)	Each film coated tablet contains				APPROVED
		Sorafenib Tosylate Eq. to Sorafenib		200	mg	
		Excipients		q.s.		
		Colour: Approved colour used				


 11/8/19.
 Asstt. Drugs Controller Cum
 Drug Licensing Authority
 O/o Chief Medical Officer
 Distt. Kangra at Dharamshala (H.P.)
 E-mail: ashishraina25@gmail.com
 Tel. No. 01892-224874

List of Additional Products to be Approved for manufacture by **M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61, Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India**, Under Manufacturing Licence No. **Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145** valid upto 18.06.2024

Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.
1.	Vincristine Sulfate Injection USP 1.0 mg/ml (For Export)	Each ml contains			
		Vincristine Sulfate	USP	1.0	mg
		Water For Injection	BP	q.s	
2	Methotrexate Injection BP 5.0 gm/50 ml (For Export)	Each ml contains:			
		Methotrexate	BP	100	mg
		Water for Injections	BP	q.s.	
3	Octreotide Acetate Injection 1000 mcg/5ml (0.2 mg/ml) (For Export)	Each ml Contains			
		Octreotide Acetate	USP		
		Eq. to Octreotide base		0.2	mg
4	Docetaxel Injection USP 20 mg/ 2.0ml (For Export)	Each ml contains :			
		Docetaxel Anhydrous	USP	10	mg
		Polysorbate 80	BP	260	mg
		Citric Acid Anhydrous	BP	4.0	mg
		Dehydrated Alcohol	BP	23 %	v/v
		Polyethylene glycol 300	USNF	q.s	
5	Docetaxel Injection USP 80 mg/ 8.0ml (For Export)	Each ml contains :			
		Docetaxel Anhydrous	USP	10	mg
		Polysorbate 80	BP	260	mg
		Citric Acid Anhydrous	BP	4.0	mg
		Dehydrated Alcohol	BP	23 %	v/v
		Polyethylene glycol 300	USNF	q.s	

ALL PRODUCT APPROVALS AS ABOVE ARE VALID SUBJECT TO THE COMPLIANCE OF ALL KINDS OF DIRECTIVES/GUIDELINES BY THE MANUFACTURER WHICH ARE ISSUED BY DCGI/CDSO OFFICE FROM TIME TO TIME & COMPLIANCE OF DRUGS & COSMETICS ACT 1940, RULES 1945 MADE THERE UNDER, INCLUDING AMENDMENTS MADE FROM TIME TO TIME

Ashish Raina
19/5/2020
Asstt. Drugs Controller Cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt. Kangra at Dharamshala (H.P.)
E-mail: ashishraina25@gmail.com
Tel. No. 01892-224874

List of additional Products Approved to be Manufactured by **M/s. Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61 Bela Bathri, Tehsil Haroli, Distt. Una, Himachal Pradesh-174301 India**, Under Manufacturing Licence No. Form 25: NNZ/2019/144 & Form 28: BNZ/2019/145 valid upto 18.06.2024

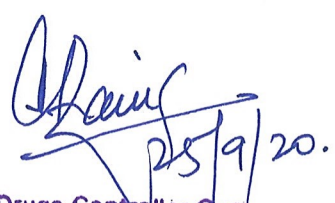
Pack size as per Schedule – P-1 of the Drugs and Cosmetics Rules, 1945

Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.
1	Methotrexate Injection BP 500 mg/20 ml (For Export)	Each ml contains			
		Methotrexate	BP	25	mg
		Sodium Hydroxide	BP	q.s.	
		Water for Injections	BP	q.s.	
2	Methotrexate Injection BP 1000 mg/40 ml (For Export)	Each ml contains			
		Methotrexate	BP	25	mg
		Sodium Hydroxide	BP	q.s.	
		Water for Injections	BP	q.s.	
3	Vinblastine Injection BP 10 mg/10 ml (For Export)	Each ml contains			
		Vinblastine Sulfate	BP	1.0	mg
		Sodium Chloride	BP	9.0	mg
		Benzyl Alcohol	BP	0.9 %	v/v
		Water For Injection	BP	q.s	

Ashish Raina
23/7/20.
Asstt. Drugs Controller Cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt. Kangra at Dharamshala (H.P.)
E-mail: ashishraina25gmail.com
Tel. No. 01892-224874

List of Additional Products Approved to be manufacture by **M/s Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61, Bela Bathri, Haroli, Una, Himachal Pradesh 174301 India** Under manufacturing License No. **Form 25: NNZ/2019/144 and Form 28: BNZ/2019/145 W.E.F 19.06.2019**
Pack size as per schedule-P-1 of the Drugs and Cosmetic Rules 1945

Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.	Reference
25.	Procarbazine Hydrochloride Capsules USP 50 mg (For Export)	Each hard gelatin Capsule Contains				USP 40, Page No. 5845
		Procarbazine Hydrochloride	USP			
		Eq. to Procarbazine		50	mg	
		Excipients		q.s		
		Approved colour used in empty capsule shell				
26.	Enzalutamide Capsules 40 mg (For Export)	Each hard gelatin capsule contains				CDSCO Approved Date: 18.12.2015
		Enzalutamide		40	mg	
		Excipients		q.s		
		Approved colour used in empty capsule shell				


 Asstt. Drugs Controller Cum
 Drug Licensing Authority
 O/e Chief Medical Officer
 Distt. Kangra at Dharamshala (H.P.)
 E-mail: ashishraina25@gmail.com
 Tel. No. 01892-224874

List of Additional Products Approved to be manufacture by M/s Biozenta Lifescience Pvt. Ltd., Khasra No. 59, 60 & 61, Bela Bathri, Haroli, Una, Himachal Pradesh 174301 India Under manufacturing License No. Form 25: NNZ/2019/144 and Form 28: BNZ/2019/145 W.E.F 19.06.2019
Pack size as per schedule-P-1 of the Drugs and Cosmetic Rules 1945

Sr. No.	Brand Name & Generic Name	Composition	Spec.	Qty.	Unit.	Reference
36	Epirubicin Hydrochloride For Injection 100 mg/vial (as lyophilized) (For Export)	Each vial contains				Product Name: Epithra 100 Mfg By: Onkos
		Epirubicin Hydrochloride	BP	100	mg	
		Excipients		q.s		
37	Ifosfamide For Injection USP with Mesna Injection (For Export)	Each combi pack contains				Product Name: Ifosfamide For Injection USP with Mesna Injection Mfg By: Bextar
		Each vial contains				
		Ifosfamide	USP	1.0	gm	
		Each ml contains				
		Mesna	USP	100	mg	
38	Ifosfamide For Injection USP with Mesna Injection (For Export)	Water For Injection	BP	q.s		Product Name: Ifosfamide For Injection USP with Mesna Injection Mfg By: Bextar
		Each combi pack contains				
		Each vial contains				
		Ifosfamide	USP	2.0	gm	
		Each ml contains				
39	Dactinomycin For Injection USP 0.5 mg/vial (as lyophilized) (For Export)	Mesna	USP	100	mg	USP 40 Page No. 3627
		Water For Injection	BP	q.s		
		Each combi pack contains				
		Each vial contains				
		Dactinomycin	USP	0.5	mg	
40	Goserlin Acetate Injection 3.6 mg (For Export)	Mannitol	USP	20	mg	Product Name: Zoladex 3.6 Mfg By: Astra Zeneca
		Each vial contains				
		Goserlin Acetate				
41	Goserlin Acetate Injection 10.8 mg (For Export)	Eq. to Goserlin		3.6	mg	Product Name: Zoladex 10.8 Mfg By: Astra Zeneca
		Each vial contains				
		Goserlin Acetate				
42	Dacarbazine For Injection BP 100 mg/vial (As Lyophilized) (For Export)	Eq. to Goserlin		10.8	mg	BP 2017 Vol.3 Pg No. 440
		Each vial contains				
		Dacarbazine	BP	100	mg	
43	Vinblastine Sulfate For Injection BP 10 mg/vial (As Lyophilized) (For Export)	Excipients		q.s.		BP 2017 Vol 3, Pg No. 1289
		Each vial contains				
		Vinblastine Sulfate	BP	10	mg	
		Excipients		q.s		



Ashish Raina
8/1/21
Asstt. Drugs Controller cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt. Kangra at Dharamshala (H.P.)
E-mail: ashishraina25@gmail.com
Tel. No. 01892-224874