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	**Bendamustin For Injection 100 mg/vial (As Lyophilized) (For Export)**	Each vial contains :				APPROVED
		Bendamustin 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.		

19/6/2019

Assit. Drugs Controller Cum
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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.		

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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:				REJECTED
		Sorafenib Tosylate				
		eq. to Sorafenib		250	mg	
		Excipients		q.s.		
		Colour: Approved Colour Used				
12	**Tamoxifen Tablets BP 20 mg (For Export)**	Each uncoated Tablets Contains :				APPROVED
		Tamoxifen Citrate	BP			
		Eq. to Tamoxifen		20	mg	
		Excipients		q.s.		
13	**Tamoxifen Tablets BP 40 mg (For Export)**	Each uncoated Tablets Contains :				REJECTED
		Tamoxifen Citrate	BP			
		Eq. to Tamoxifen		40	mg	
		Excipients		q.s.		
14	**Mercaptopurine Tablets BP 50 mg (For Export)**	Each uncoated tablet contains:				APPROVED
		Mercaptopurine	BP	50	mg	
		Excipients		q.s.		
15	**Dasatinib Tablets 50 mg (For Export)**	Each film coated tablet contains:				APPROVED
		Dasatinib		50	mg	
		Excipients		q.s.		
		Approved Colours Used				
16	**Dasatinib Tablets 70 mg (For Export)**	Each film coated tablet contains:				APPROVED
		Dasatinib		70	mg	
		Excipients		q.s.		
		Approved Colours Used				
17	**Dasatinib Tablets 100 mg (For Export)**	Each film coated tablet contains:				APPROVED
		Dasatinib		100	mg	
		Excipients		q.s.		
		Approved Colours Used				
18	**Chlorambucil Tablets BP 2.0 mg (For Export)**	Each film coated tablet contains:				APPROVED
		Chlorambucil	BP	2.0	mg	
		Excipients		q.s.		
		Approved Colours Used				
19	**Chlorambucil Tablets BP 5.0 mg (For Export)**	Each film coated tablet contains:		5.0		APPROVED
		Chlorambucil	BP	~~2.0~~	mg	
		Excipients		q.s.		
		Approved Colours Used				
20	**Bicalutamide Tablet BP 50 mg (For Export)**	Each film coated tablet contains				APPROVED
		Bicalutamide	BP	50	mg	
		Excipients		q.s.		
		Approved Colours Used				

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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.		

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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:				APPROVED
		Daunorubicin Citrate	BP	50	mg	
2	**PEG L-Asparaginase For Injection 750 IU/ ml (As Liposomal) For Export**	Each vial contains:				APPROVED
		PEG L-Asparaginase		750	IU	
3	**Epirubicin Hydrochloride For Injection 50 mg / vial (As Lyophilized)**	Each vial contains :				APPROVED
		Epirubicin Hydrochloride	BP	50	mg	
		Excipients		q.s.		
4	**Epirubicin Hydrochloride For Injection 10 mg / vial (As Lyophilized) (For Export)**	Each vial contains :				APPROVED
		Epirubicin Hydrochloride	BP	10	mg	
		Excipients		q.s.		

2/7/19

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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				

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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 [illegible] COMPLIANCE OF ALL KINDS OF DIRECTIVES/GUIDELINES BY [illegible] MANUFACTURER WHICH ARE ISSUED BY DCGI/CDSCO OFFICE [illegible] TIME TO TIME & COMPLIANCE OF DRUGS & COSMETICS ACT 19[illegible] RULES 1945 MADE THERE UNDER, INCLUDING AMENDMENTS MAD[illegible] FROM TIME TO TIME

19/5/2020

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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	

23/7/20.

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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				

25/9/20.

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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	
		Water For Injection	BP	q.s		
38	**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	2.0	gm	
		Each ml contains				
		Mesna	USP	100	mg	
		Water For Injection	BP	q.s		
39	**Dactinomycin For Injection USP 0.5 mg/vial (as lyophilized) (For Export)**	Each vial contains				USP 40 Page No. 3627
		Dactinomycin	USP	0.5	mg	
		Mannitol	USP	20	mg	
40	**Goserlin Acetate Injection 3.6 mg (For Export)**	Each vial contains				**Product Name:** Zoladex3.6 **Mfg By:** Astra Zeneca
		Goserlin Acetate				
		Eq. to Goserlin		3.6	mg	
41	**Goserlin Acetate Injection 10.8 mg (For Export)**	Each vial contains				**Product Name:** Zoladex 10.8 **Mfg By:** Astra Zeneca
		Goserlin Acetate				
		Eq. to Goserlin		10.8	mg	
42	**Dacarbazine For Injection BP 100 mg/vial (As Lyophilized) (For Export)**	Each vial contains				BP 2017 Vol.3 Pg No. 440
		Dacarbazine	BP	100	mg	
		Excipients		q.s.		
43	**Vinblastine Sulfate For Injection BP 10 mg/vial (As Lyophilized) (For Export)**	Each vial contains				BP 2017 Vol 3, Pg No. 1289
		Vinblastine Sulfate	BP	10	mg	
		Excipients		q.s		

ASSTT. DRUGS CONTROLLER CUM DRUGS LICENSING AUTHORITY DHARAMSHALA (HP) H.P. (INDIA)

8/1/24

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