

List of the products under development for Europe

Sr. No.	Product Name	Finished product grade	API Name	API Grade	Source of API	CEP certificate availability	status of stability as on 26.12.2023	List of Available Documents
1.	Cefazolin for Injection BP 1 gm	BP	Sterile Cefazolin Sodium	EP	Orchid Pharma Ltd.	CEP available	6 Month Stability Study available	<ul style="list-style-type: none"> • DMF • MFR • BMR-BPR • PVP-PVR • AMV • API Spec-STP-COA • FP Spec-STP-COA • PM Spec-STP-COA • In-use study • Stability protocol • Stability Summary
2.	Ceftriaxone for Injection BP 1 gm	BP	Sterile Ceftriaxone Sodium	EP	Orchid Pharma Ltd.	CEP available	3 Month Stability Study available	
3.	Ceftriaxone for Injection BP 2 gm	BP	Sterile Ceftriaxone Sodium	EP	Orchid Pharma Ltd.	CEP available	3 Month Stability Study available	
4.	Co-Amoxiclav for Injection BP 600 mg	BP	Amoxicillin Sodium and Clavulanate Potassium (5:1) Sterile	Amoxicillin Sodium IH Clavulanate Potassium IH Blend IH	Zhuhai United Laboratories Co., Ltd.	CEP Available for Clavulanate Potassium and Amoxicillin trihydrate (Starting material of Amoxicillin Sodium)	2 Month Stability Study available	
5.	Co-amoxiclav for Injection BP 1.2 gm	BP	Amoxicillin Sodium and Clavulanate Potassium (5:1) Sterile	Amoxicillin Sodium IH Clavulanate Potassium IH Blend IH	Zhuhai United Laboratories Co., Ltd.	CEP Available for Clavulanate Potassium and Amoxicillin trihydrate (Starting material of Amoxicillin Sodium)	2 Month Stability Study available	

6.	Piperacillin and Tazobactam for Injection USP 2.25 gm	USP	Sterile Piperacillin Sodium and Tazobactam Sodium (8:1)	Piperacillin Sodium IH Tazobactam Sodium IH Blend IH	Shandong Anxin Pharmaceutical Co., Ltd.	CEP Available for Piperacillin Monohydrate (Starting material of Piperacillin Sodium)	1 Month Stability Study available	<ul style="list-style-type: none"> • DMF • MFR • BMR-BPR • PVP-PVR • AMV • API Spec-STP-COA • FP Spec-STP-COA • PM Spec-STP-COA • In-use study – running • Stability protocol • Stability Summary
7.	Piperacillin and Tazobactam for Injection USP 4.5 gm	USP	Sterile Piperacillin Sodium and Tazobactam Sodium (8:1)	Piperacillin Sodium IH Tazobactam Sodium IH Blend IH	Shandong Anxin Pharmaceutical Co., Ltd.	CEP Available for Piperacillin Monohydrate (Starting material of Piperacillin Sodium)	1 Month Stability Study available	

Proposed products development for Europe

8.	Ampicillin and Sulbactam for Injection USP 375 mg	USP	Sterile ampicillin sulbactam 2:1		Apitoria (Aurobindo) or Zhuhai united lab.			<p>Following documents will arrange</p> <ul style="list-style-type: none"> • DMF • MFR • BMR-BPR • PVP-PVR • AMV • API Spec-STP-COA • FP Spec-STP-COA
9.	Ampicillin and Sulbactam for Injection USP 750 mg	USP	Sterile ampicillin sulbactam 2:1		Apitoria (Aurobindo) or Zhuhai united lab.			
10.	Ampicillin and Sulbactam for Injection USP 1.5 gm	USP	Sterile ampicillin sulbactam 2:1		Apitoria (Aurobindo) or Zhuhai united lab.			

11.	Cefuroxime for Injection BP 750 mg	BP	Sterile Cefuroxime Sodium		Qilu Antibiotics pharmaceuticals Co., Ltd.			<ul style="list-style-type: none"> • PM Spec-STP-COA • In-use study • Stability protocol • Stability Summary
12.	Cefuroxime for Injection BP 1.5 gm	BP	Sterile Cefuroxime Sodium		Qilu Antibiotics pharmaceuticals Co., Ltd.			
13.	Ampicillin Sodium for Injection BP 250 mg	BP	Sterile Ampicillin Sodium	EP	Apitoria Pharma Private Limited			
14.	Ampicillin Sodium for Injection BP 500 mg	BP	Sterile Ampicillin Sodium	EP	Apitoria Pharma Private Limited			
15.	Ampicillin Sodium for Injection BP 1 gm	BP	Sterile Ampicillin Sodium	EP	Apitoria Pharma Private Limited			
16.	Amoxicillin Sodium for Injection BP 500 mg	BP	Amoxicillin Sodium		Zhuhai United Laboratories Co., Ltd.			
17.	Amoxicillin Sodium for Injection BP 1 gm	BP	Amoxicillin Sodium		Zhuhai United Laboratories Co., Ltd.			
18.	Benzyl penicillin for Injection BP 1 mega	BP	Benzyl Penicillin Sodium (Sodium Citrate + Citric acid as a excipients)		CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.			
19.	Benzyl penicillin for Injection BP 5 mega	BP	Benzyl Penicillin Sodium (Sodium Citrate +		CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.			

			Citric acid as a excipients)					
20.	Benzyl penicillin for Injection BP 10 mega	BP	Benzyl Penicillin Sodium (Sodium Citrate + Citric acid as a excipients)		CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.			