



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Ampicillin Sodium Salt (Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	A6352		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	69-52-3		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/A6352/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White to off-white, odorless or practically odorless, crystalline powder	white or almost white powder, hygroscopic.	White to light yellow-white, crystals or crystalline powder
2	Solubility	passes test	Very soluble in water and in isotonic sodium chloride and dextrose solutions.	freely soluble in water, sparingly soluble in acetone, practically insoluble in fatty oils and in liquid paraffin	Very soluble in water, and sparingly soluble in ethanol (99.5)
3	Identification 1	passes test	The infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with ampicillin trihydrate RS/WS	The infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with ampicillin trihydrate RS/WS	The infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with ampicillin trihydrate RS/WS
4	Identification 2	passes test	Should comply by a dense precipitate formation	By TLC: The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution	Should impart a yellow colored flame
5	Identification 3	passes test	Not mentioned	Should comply by a dark yellow colour development with sulfuric acid-formaldehyde	Not mentioned
6	Identification 4	passes test	Not mentioned	Should comply by a dense white precipitate formation	Not mentioned
7	Appearance of solution	passes test	Not mentioned	Solutions A and B are not more opalescent than reference suspension II and the absorbance of solution B at 430 nm should be NMT 0.15	Sample solution is clear, and its absorbance at 400 nm should be NMT 0.40.
8	pH	Between 8.0 and 10.0	Between 8.0 and 10.0	Between 8.0 and 10.0	Between 8.0 and 10.0
9	Specific optical rotation test	Between +258° and +287°	Not mentioned	Between + 258 <sup>0</sup> to + 287 <sup>0</sup>	Between + 246 <sup>0</sup> and + 272 <sup>0</sup>
10	Water	NMT 2.0 %	NMT 2.0 %	NMT 2.0 %	NMT 2.0 %
11	2-Ethylhexanoic acid	NMT 0.8 %	Not mentioned	NMT 0.8 %	Not mentioned
12	Organic impurities	Methylene Chloride: NMT 0.2% Dimethylene aniline: NMT 0.002%	Methylene Chloride: NMT 0.2% Dimethylene aniline: NMT 0.002%	Methylene Chloride: NMT 0.2% Dimethylene aniline: NMT 20 ppm	Not mentioned
13	Related substances	passes test	Not mentioned	Ampicillin dimer: NMT 4.5% other impurity: NMT 2.0%	Any NMT 1.0%
14	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 20 ppm
15	Crystallinity	Not mentioned	Should comply the test	Not mentioned	Not mentioned
16	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
17	Assay (anhydrous subst.)	Between 91.0 % and 102.0 %	Between 845 and 988 µg/mg	Between 91.0 % and 102.0 %	Between 850 mg and 950 mg /mg
	Storage	Store at room temperature	Preserve in Tight containers.	Air tight containers	Tight containers

Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.