



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	D(+)-Biotin (USP) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	143977		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	58-85-5		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/143977/01

Sr. No.	Test	Pharmacoepial Specifications			
		Manufacturer COA <i>Complies USP</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	Practically white, crystalline powder.	White or almost white, crystalline powder or colourless crystals.	White crystals or a white crystalline powder, melting point about 231°C
2	Solubility	Slightly soluble in water	Very slightly soluble in water and in alcohol; insoluble in other common organic solvents.	Very slightly soluble in water and in ethanol (96 per cent), practically insoluble in acetone. It dissolves in dilute solutions of alkali hydroxides.	Very slightly soluble in water and in ethanol (99.5). It dissolves in dilute sodium hydroxide TS
3	Identification 1	Passes The Test	Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Biotin reference/working standard	Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Biotin reference/working standard	Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Biotin reference/working standard
4	Identification 2	Passes The Test	Should comply by optical rotation test	By TLC: the principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution	Not mentioned
5	Identification 3	Passes The Test	In the assay test the retention time of the major peak of the Sample solution corresponds to that of the Standard solution,	Not mentioned	Not mentioned
6	Optical Rotation	Between +89.0° and +93.0° (dried sample)	Between +89.0° and +93.0° (dried sample)	Between +89.0° and +93.0° (dried sample)	Between +89.0° and +93.0° (dried sample)
7	Clarity and colour of solution	Not mentioned	Not mentioned	Sample solution should be clear and colourless	Sample solution should be clear and colourless
8	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
9	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2.8 ppm
10	Related substances	Individual impurity: NMT 1.0% Total impurities: NMT 2.0%	Individual impurity: NMT 1.0% Total impurities: NMT 2.0%	Impurity A: NMT 0.5% Impurity E: NMT 0.5% Impurity C: NMY 0.2% Maximum unknown impurity: 0.1% Total impurities: NMT 2.0%	NMT 0.2%
11	Loss on drying	Not mentioned	Not mentioned	NMT 1.0%	NMY 0.5%
12	Residue on ignition/Total Ash	Not mentioned	Not mentioned	NMT 0.1%	NMT 0.1%
13	Assay	Between 98.5% and 101.0%	Between 97.5% and 102.0%	Between 98.5% and 101.0%	Between 98.5% and 101.0%
14	Residual solvents	Passes The Test			
	Storage	Storage between 2 and 8°C	Store in tight containers.	Protected from light.	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.

Disclaimer - The information above is solely for your consideration. We do not recommend or affirm the suitability for any specific end use. We suggest the users should research & verify the specifications in accordance with their intended usage.