



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Benzoyl Peroxide humidified with ~ 25% of H2O (USP, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	142357		Prepared by	Sr. Tech Lead
CAS NO.	94-36-0		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/142357/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	White crystals	White, granular powder, having a characteristic odor	White or almost white, amorphous or granular powder. It loses water rapidly on exposure to air with a risk of explosion.	Product Not Official in Japanese Pharmacopoeia
2	Solubility	Very slightly soluble in water	Soluble in acetone, in chloroform, and in ether; sparingly soluble in water and in alcohol.	Practically insoluble in water, soluble in acetone, soluble in methylene chloride with the separation of water, slightly soluble in ethanol (96 per cent).	
3	Identification 1	Passes The Test	By TLC, the RF value of the principal spot of the Sample solution corresponds to that of the Standard solution	UV bsorption spectrum of sample in the range 200 to 400 nm shows maxima at 235 nm and 274 n,, the aborption ratio at 235 nm to 274 nm is between 1.17 and 1.21	
4	Identification 2	Passes The Test	In organic impurity test, the Sample solution exhibits a major peak for benzoyl peroxide, the retention time of which corresponds to that exhibited by the Standard solution	The infrard absorption spectrum obtained with sample should be concordant with spectrum obtained with reference/working standard, the transmittatnce at 2000 cm-1 should be NLT 40% without compensation	
5	Identification 3	Passes The Test	Not mentioned	Should comply by red color development which should quickly darken and become violet within 5 minutes	
6	Identification 4	Passes The Test	Not mentioned	Precipitate should melt between 120 °C to 124 °C	
7	Melting range	Between 102 and 105°C	Not mentioned	Not mentioned	
8	Acidity	Passes The Test	Not mentioned	NMT 1.25 mL of 0.1 M NaOH is required to change the colour of the indicator	
9	Chloride	NMT 0.4%	Not mentioned	NMT 0.4%	
10	Related substances	Impurity B: NMT 1.5% Impurity A: NMT 0.25% Impurity C: NMT 0.25% Maximum individual impurity: NMT 0.1% By USP Maximum unknown impurity: NMT 1.5% Total impurities: NMT 2.0%	Maximum unknown impurity: NMT 1.5% Total impurities: NMT 2.0%	Impurity B: NMT 1.5% Impurity A: NMT 0.25% Impurity C: NMT 0.25% Maximum individual impurity: NMT 0.1%	
11	Water	NLT 20.0%	NLT 20.0%	NLT 20.0%	
12	Assay	Between 70.0% and 77.0% By Iodometry: NLT 98.0%	Between 90.0% and 110.0% (labelled amount)	Between 70.0% and 77.0%	
	Storage	Storage between +2 and +8°C.	Store in the original container, at room temperature. [Note—Do not transfer to metal or glass containers fitted with friction tops. Do not return unused material to its original container, but destroy it by treatment with 10% NaOH until addition of a crystal of KI results in no release of free iodine.]	In a container that has been treated to reduce static discharge and that has a device for release of excess pressure, at a temperature of 2 °C to 8 °C, protected from light.	

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