



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Magnesium Sulfate 7-hydrate (Ph. Eur, BP) GMP - IPEC grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	631404		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	10034-99-8		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/631404/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies Ph. Eur, BP	USP 2022	EP Version 11.0	JP 18
1	Description	Small White Crystals	Small, colorless crystals, usually needle-like, with a cooling, saline, bitter taste. It effloresces in warm, dry air.	White or almost white, crystalline powder or brilliant, colourless crystals	Color less or white crystals. It has a cooling, saline, bitter taste.
2	Solubility	Soluble in water	Very soluble in boiling water; freely soluble in water; freely (and slowly) soluble in glycerin; sparingly soluble in alcohol.	Freely soluble in water, very soluble in boiling water, practically insoluble in ethanol (96 %).	It is very soluble in water, and practically insoluble in ethanol(95%).It dissolves in dilute HCl
3	Identification 1	Passes The Test	1. After addition of NH4Cl yield NMT a slightly hazy precipitate should be formed when neutralized with ammonium carbonate TS, but on the subsequent addition of dibasic sodium phosphate TS, a white, crystalline precipitate, which is insoluble in 6 N ammonium hydroxide, is formed	After addition of 1 mL of dilute NH3, a white precipitate should be formed that dissolves on addition of 1 mL of ammonium chloride solution. Add 1 mL of disodium hydrogen phosphate solution.A white crystalline precipitate is formed.	After addition of ammonium carbonate TS a white precipitate should be produced, which dissolves in ammonium chloride TS. A white, crystalline precipitate is reproduced by subsequent addition of disodium hydrogenphosphate TS. 2) After addition of sodium hydroxide TS a white, gelatinous precipitate should be formed When excess sodium hydroxide TS is added to another portion, the precipitate does not dissolve.
4	Identification 2	Passes The Test	1. After addition of barium chloride TS, a white precipitate that is insoluble in HCl and in HNO3 should be formed. 2. After addition of lead acetate TS, a white precipitate that is soluble in ammonium acetate TS should be formed. 3. After addition of HCl no precipitate should be formed	1. Should comply by white precipitate formation 2. No coloured precipitate should be formed	1) After addition of barium chloride TS a white precipitate, which does not dissolve upon addition of dilute nitric acid should be formed 2) After addition of lead(II) acetate TS a white precipitate, which dissolves upon subsequent addition of ammonium acetate TS should be formed. 3) After addition of equal volume of dilute dilute HCl no white turbidity should be produced (discrimination from sulfides).
5	Clarity and color of solution	Passes The Test	Not mentioned	Sample solution should be clear and colourless	Sample solution should be clear and colourless
6	Acidity or alkalinity	Passes The Test	Not mentioned	NMT 0.2 mL of 0.01 M HCl or 0.01 M NaOH is required to change the colour of the indicator.	Not mentioned
7	pH		Between 5.0 and 9.2	Not mentioned	Between 5.0 and 8.2
8	Loss on ignition (450 ± 25°)		Between 40.0% and 52.0%	Not mentioned	Between 45.0% and 52.0%
9	Loss on drying (105° for 2 hrs)	Between 48.0 % - 52.0 %	NMT 2.0%	Between 48.0% and 52.0%	Not mentioned
10	Chlorides	NMT 0.0300 %	NMT 0.014%	NMT 300 ppm	NMT 0.014%
11	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
12	Zinc	Not mentioned	Not mentioned	Not mentioned	No turbidity should be produced
13	Calcium	Not mentioned	Not mentioned	Not mentioned	NMT 0.02%

14	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
15	Iron	NMT 0.0020 %	NMT 20 ppm	NMT 20 ppm	Not mentioned
16	Selenium	Not mentioned	NMT 30 ppm	Not mentioned	Not mentioned
17	Assay (Dried/ignited basis)	Between 99.0% and 100.5%	Between 99.0% and 100.5%	Between 99.0% and 100.5%	NLT 99.0%
18	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 5 ppm			
	Pb	NMT 50 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 10 ppm			
	Au	NMT 10 ppm			
	Pd	NMT 10 ppm			
	Ir	NMT 10 ppm			
	Os	NMT 10 ppm			
	Rh	NMT 10 ppm			
	Ru	NMT 10 ppm			
	Se	NMT 15 ppm			
	Ag	NMT 15 ppm			
	Pt	NMT 10 ppm			
	Li	NMT 55 ppm			
	Sb	NMT 120 ppm			
Ba	NMT 140 ppm				
Mo	NMT 25 ppm				
Cu	NMT 250 ppm				
Sn	NMT 600 ppm				
Cr	NMT 25 ppm				
19	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Keep container tightly closed in a dry and well-ventilated place.	Preserve in well-closed containers.	Not mentioned	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.