

RAW MATERIAL SPECIFICATION

Title : Benzyl Alcohol BP
(Item No. 41020280)

Spec. No : SP-AK30-B16

Reference(s) : BP 2010 p.245-246

Rev. No : 03

Other Requirements : -

Page : 1/2

BP 2010

Description	: Clear, colourless, oily liquid.
Solubility	: Soluble in water, miscible with ethanol (96%) and with fatty and essential oils.
Relative density	: 1.043 to 1.049.
Identification	: Infrared spectrum is concordant with the spectrum of standard.
Appearance of solution	: Shake 2.0 ml with 60 ml of purified water. It dissolves completely. The solution is clear and colourless.
Acidity	: Not more than 1 ml of 0.1 M sodium hydroxide is required to change the colour of phenolphthalein solution to pink. [Test solution : 10 ml in 10 ml ethanol(96%).]
Refractive index	: 1.538 to 1.541.
Peroxide value	: Maximum 5.
Related substances	
- impurity A	: not more than the difference between the area of the peak due to impurity A in the chromatogram obtained with reference solution (a) and the area of the peak due to impurity A in the chromatogram obtained with the test solution (0.15%);
- impurities B	: not more than the difference between the area of the peak due to impurity B in the chromatogram obtained with reference solution (a) and the area of the peak due to impurity B in the chromatogram obtained with the test solution (0.10%);
- sum of other peaks with a relative retention less than that of benzyl alcohol	: not more than 4 times the area of the peak due to ethylbenzene in the chromatogram obtained with reference solution (a) corrected if necessary as described above (0.04%);
- sum of other peaks with a relative retention greater than that of benzyl alcohol	: not more than the area of the peak due to dicyclohexyl in the chromatogram obtained with reference solution (a) corrected if necessary as described above (0.3%);
Residue on evaporation	: Maximum 0.05 %.
Assay	: 98.0 % to 100.5 % of C_7H_8O .

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : S. Moppradech / 12/11/10 Head of Raw Material Standard Section 2	Reviewed by : [Signature] / 18/11/10 Director of Raw Material Standard Division	Approved by : D. Tangchaisri / 18/11/10 Director of Regulatory Compliance and Documentation Division	Eff. Date 29/11/10
---	--	---	-----------------------



COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Benzyl Alcohol BP (Item No. 41020280)	Spec. No : SP-AK30-B16
Reference(s) : BP 2010 p.245-246	Rev. No : 03
Other Requirements : -	Page : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Benzyl Alcohol BP (Item No. 41020280).
Sampling plan	$\sqrt{N} + 1$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-B16.
Storage condition	To be stored in an airtight container, under nitrogen, protected from light and at a temperature between 2°C and 8°C.
Retest period	2 years after first testing date.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : S. Noppadech / 18/11/10 Head of Raw Material Standard Section 2	Reviewed by : Yinip / 18/11/10 Director of Raw Material Standard Division	Approved by : N. Timgelchint / 18/11/10 Director of Quality Assurance Department	Eff. Date 29/11/10
--	--	---	-----------------------